IRB Charter and Standard Operating Procedures (SOP)

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Section 6: IRB Procedures:

Section 1: Introduction:

1.1 Mission:

The primary mission of the UMass Dartmouth Institutional Review Board (IRB) is to provide a comprehensive and systematic review process designed to protect the rights, dignity, and welfare of individuals who are the subjects of research conducted by university faculty, staff, or students. The UMass Dartmouth IRB is registered with the US Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) (**IRB00000820**) and UMass Dartmouth holds a Federalwide Assurance (FWA) which documents the University's commitment to comply with federal regulations for the protection of human subjects in research (**FWA00000180**).

UMass Dartmouth IRB subscribes to the ethical standards delineated in the Belmont Report and the Declaration of Helsinki, all applicable federal, state, and local regulations related to the conduct of human subject research, and University policies and procedures. The University also understands the necessity to take into consideration various cultural contexts and to comply with local laws and customs when conducting transnational research.
To achieve this mission, the IRB and Human Research Protection Program (HRPP) strive to:

1. **Ensure Ethical Conduct and Safeguard Participants:** Promote and uphold the ethical principles of respect for persons, beneficence, and justice as outlined in the Belmont Report, and protect the rights, safety, and well-being of research participants by thoroughly reviewing and monitoring research protocols.
2. **Foster Compliance and Promote Quality Research:** Ensure all research involving human subjects complies with relevant laws, regulations, and institutional policies, and facilitate the conduct of high-quality, ethically sound research that advances knowledge and benefits society.
3. **Educate, Support, and Engage Researchers:** Provide education, training, and guidance to researchers on ethical standards and regulatory requirements for human subjects research, and foster open communication and collaboration with the research community, ensuring transparency in IRB processes and decisions.
4. **Commit to Continuous Improvement:** Regularly assess and enhance IRB practices and procedures to ensure they meet evolving ethical and regulatory standards.

The IRB is dedicated to maintaining a culture of respect, integrity, and accountability, ensuring that all research participants are treated with dignity and respect, and that their rights and welfare are a central focus of the research enterprise at UMass Dartmouth.

1.2 Definitions:

Affiliated Member: An employee or nonemployee with a formal or informal relationship with UMassD is considered affiliated. An unaffiliated member has no close association with UMassD beyond serving as an IRB member.

Ancillary Review: Ancillary reviews allow individuals, departments, offices, and other additional reviewers to give feedback, approval, and/or provide documentation on the submission in parallel with the IRB review. During IRB review, staff of the IRB office will manually select the reviewer or reviewing organization/department each time a review is needed or required. IRB staff can add ancillary reviewers to a study, modification, or continuing review.

Anonymity: Refers to the condition in which the identities of research participants are not known to the researchers and cannot be linked to individual responses or data. In an anonymous study, no personal identifiers (such as names, addresses, or any other data that can directly link responses to an individual) are collected. This ensures that it is impossible for anyone, including the researchers, to trace the data back to a specific participant. Anonymity provides a high level of privacy and is crucial in protecting the confidentiality of participants, particularly in studies involving sensitive topics.

Appeal: a request for reconsideration of an IRB determination related to research involving human subjects. This includes decisions on approval status, conditions for approval, or issues of noncompliance. Appeals are reviewed by the convened IRB that made the original decision or, for expedited reviews, the corresponding convened IRB may review the appeal.

Assurance of Compliance (Human Subjects) or Federalwide Assurance: A legally binding written document that commits an institution to complying with the Federal Policy (Common Rule) and other applicable Federal and VA standards for the protection of human subjects.

Authorization Agreement: Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review. For more information please see: IRB Guidance on Reliance Agreements.

Certification: The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In the United States, the general age of consent is 18 years. However, in Massachusetts, the age of consent for medical treatments and procedures may vary depending on specific circumstances such as the nature of the treatment or procedure and the minor's status (e.g., emancipated minors, married minors, or those seeking certain medical services like reproductive health care). Therefore, researchers must determine the applicable age of consent based on the specific context and legal requirements of the jurisdiction where the research is conducted.

Classified Research: Research involving any information or material, regardless of its physical form or characteristics, that is owned by the United States Government, and determined pursuant to Executive Order 12356, April 2, 1982, or prior orders to require protection against unauthorized disclosure and is so designated.

Classroom Project: Educational inquiry activities conducted solely to fulfill a course requirement that lack the intent to develop or contribute to generalizable knowledge and do not involve the public dissemination of findings. Generally, projects are designed to provide students with training in and experience with research methods, for more information see: IRB Guidance on Class Projects.

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Collaborative Study: A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.

Community–based participatory research (CBPR): A collaborative approach to research that combines methods of inquiry with community capacity building strategies to bridge the gap between knowledge produced through research and what is practices in communities to improve their health and well-being.

Condition: The IRB interprets condition as referring to a specific (or a set of specific) physical, psychological, neurodevelopmental, or social characteristics that an established body of scientific evidence or clinical knowledge has shown to negatively affect person's health and well-being, or to increase their risk of developing a health problem in the future.

Conflicting Interest: Any situation in which an individual (or the individual's spouse, domestic partner, children, and/or dependents) is involved in research has a personal, professional, financial, or other interest that could potentially influence their objectivity, judgment, or decision-making regarding the review, approval, or oversight of research protocols. Conflicts related to research may involve the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family, including:

- Involvement in the design, conduct, or reporting of the research.

- Financial interests related to equity holdings, exclusive of interests through mutual funds, compensation related to the research in the preceding 12 months, or proprietary interests (patent, trademark, copyright or licensing agreement).
- Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly traded, diversified mutual funds.
- Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.
- Board or executive relationship, regardless of compensation.
- Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.
- Affiliation with organizations, companies, or ventures related to the research that could result in a direct financial benefit.
- Personal or professional relationships with the researchers or sponsors or investigators of the research which could create bias or the appearance of bias.
- Any other circumstance that could reasonably be perceived as affecting the impartiality or integrity of the review process.

Disclosure of conflicts deemed related to research is essential for maintaining transparency, integrity, and public trust in the review and oversight of research. Conflicts must be identified and managed appropriately to ensure that decisions are made in the best interests of safety, compliance, and ethical conduct. Conflict of interest must be disclosed at the beginning of review of any documents and meeting attendance.

Confidentiality: Refers to the ethical and legal duty of researchers to protect participants' personal information from unauthorized access, use, disclosure, or loss. It involves ensuring that any data collected from or about participants is kept secure and is only accessible to authorized individuals who need the information for legitimate research purposes. Maintaining confidentiality is crucial for fostering trust, protecting participants' privacy, and ensuring the integrity of the research process.

Coercion: When an overt or implicit threat of harm is intentionally presented by one person to another to obtain compliance. See also undue influence.

Decisional Impairment: Persons who have impaired ability to make decisions as a result of intellectual or mental health challenges as well as adults who have lost capacity to make decisions because of clinical status or situations such as unconsciousness.

Designated Reviewer: The IRB Chair or an Experienced IRB Member designated by the IRB chair to conduct Non-convened Reviews. For non-convened reviews, IRB staff who meet the definition of an Experienced IRB Member conduct the review.

Experienced IRB Member: An IRB member is considered experienced if the IRB chair deems the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.

Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.

General Wellness Device: refers to a product or technology designed to support, enhance, or monitor general health and well-being, but not intended for medical or diagnostic purposes. These devices typically focus on promoting healthy behaviors, improving quality of life, or providing general wellness information rather than diagnosing, treating, or preventing diseases.

Characteristics of General Wellness Devices:

1. **Non-Medical Purpose:** These devices are not intended to diagnose, treat, cure, or prevent any specific medical condition. They focus on general health and wellness rather than medical interventions.
2. **Wellness Monitoring:** They may track various aspects of an individual's daily activities, such as physical activity, sleep patterns, heart rate, or stress levels, to help users manage their overall well-being.

3. **Health Promotion:** They aim to encourage healthy lifestyle choices and behaviors, such as regular exercise, balanced nutrition, and stress management.
4. **Examples:** Common examples include fitness trackers, smartwatches with wellness features, general health apps, and wellness scales. These devices provide feedback and data that can help individuals make informed decisions about their lifestyle but are not classified as medical devices.
5. **Regulatory Classification:** In many jurisdictions, general wellness devices are not subject to the same regulatory requirements as medical devices, provided they do not make specific medical claims or serve medical purposes.

Human Research: Any activity that either:

- Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; **or**
- Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains data (information or biospecimens) through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

For the purpose of this definition:

- **Intervention** includes any procedure, treatment, or action taken as part of a research study that is intended to modify the health, well-being, or behavior of the participants. This can include physical procedures such as surgeries or medical treatments, as well as behavioral or educational strategies, and any other activities designed to alter the participants' experiences or outcomes. Interventions are undertaken to evaluate their effects on the participants and may involve direct interactions with participants or the use of devices, drugs, or other therapeutic modalities.
- **Interaction** refers to communication or interpersonal contact between the investigator and the subject.
- **Private Information** is information about behavior occurring in a context where an individual can reasonably expect no observation or recording, and information provided for specific purposes that an individual can reasonably expect will not be made public (e.g., medical records).
- **Identifiable Information** is information where the identity of the subject is or may be readily ascertained by the investigator or associated with the information.
- **De-identified data** is any data collected from a study participant for which their identifiable private information has been permanently unlinked.

Human Subject as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used. If the activity involves a new drug or medical device, a new use for an approved drug or device, or if data will be submitted to the FDA or held for their inspection, IRB approval is required to proceed.

Immediate Family: Spouse, domestic partner; and dependent children.

Institutional Official: The University Chief Research Compliance Officer.

Institutional Profile: A record of information an institution keeps about another collaborating institution/organization for one or more Collaborate Studies or Multi-Site Studies.

IRB of Record: The IRB of Record is the IRB responsible for the ethical review and oversight of a research study, particularly in multi-site studies where multiple institutions are involved. This IRB has the authority to approve, require modifications in, or disapprove research activities. The IRB of Record assumes primary responsibility for ensuring that the study complies with all applicable ethical guidelines, regulatory requirements, and institutional policies. This designation is usually formalized through agreements such as reliance agreements or IRB authorization agreements (IAA), which outline the specific responsibilities and expectations for the IRB of Record and any relying institutions.

Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research. If there is no applicable law addressing this issue, then this individual is recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- **For research involving prisoners:** Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
- **When following Department of Defense regulations:** the definition of minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests" shall not be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

Medical Device: Per the FDA, a medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, software, material, or other similar or related article, including any component, part, or accessory, which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- Intended for use in the diagnosis, monitoring, or alleviation of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or
- Intended to affect the structure or any function of the body of humans or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

Note: this definition covers a broad range of products, from simple tools like tongue depressors and bandages to complex technologies like pacemakers and MRI machines. See also software as a medical device.

Multi-Site Study: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.

Neonate: A newborn child under 28 days of age.

Nonviable Neonate: A neonate that, although alive following delivery, is not viable.

Viable Neonate: A neonate following delivery, of surviving (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. If a neonate is viable, it may be included in research only to the extent permitted by, and in accordance with, the requirements of Subparts A and D of 45 CFR 46.

Non-Convened Review: Any of the following:

- Determination of whether an activity is Human Research (Including Determinations: 118 and nonengaged).
- Determination of whether Human Research is exempt from regulation.
- Reviews of non-exempt research using the expedited procedure.
- Determinations of which subjects can continue in expired research.

Noncompliance: Failure to follow the regulations, or the requirements or determinations of the IRB.

- **Allegation of Noncompliance:** An unproven assertion of Noncompliance.
- **Finding of Noncompliance:** Noncompliance in fact.

- **Corrective Action Plan (CAP):** an outline of specific steps to be taken to remedy the cause of Noncompliance.
- **General Noncompliance:** Deviation from the approved research protocol or practices commonly accepted by the scientific community.
- **Continuing Noncompliance:** A pattern of noncompliance that is likely to continue without intervention or failure to work with the IRB to resolve noncompliance.
- **Serious Noncompliance:** Noncompliance violations which deviate from the approved research protocol and practices commonly accepted by the scientific community; adversely affect the integrity of the study, the rights, safety, and welfare of researchers, the general public, subjects and the environment; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data; or require revision to the approved protocol;. The actions of the investigator pose a substantive harm to the health and/or safety of personnel, students, the institution, and/or the public environment.
- **Need to Know Individuals**: For Research Noncompliance: PI, IRB Chair, Chair of the Respondent's department, applicable IO, DIEC, Office of the General Counsel, and Provost (if externally funded). For IRB Noncompliance: DIEC and applicable IO.

Agency-Specific Definitions of Noncompliance:

- **Department of Defense (DOD)**: Noncompliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.
- **National Institutes of Health (NIH)**: The NIH defines noncompliance as failure to adhere to HHS regulations, NIH policies, and guidelines, including those related to the Responsible Conduct of Research (RCR), which covers a broad range of research misconduct and noncompliance issues.
- **Office for Human Research Protections (OHRP)**: Noncompliance is defined as failure to follow the regulations or the requirements of the institutional review board (IRB). This can include both intentional and unintentional actions that violate the regulatory requirements or IRB determinations.
- **Food and Drug Administration (FDA)**: Noncompliance is defined as the failure to adhere to federal regulations governing the conduct of clinical trials, including FDA's regulations on good clinical practice (GCP) and human subject protection. This includes violations of protocols, informed consent requirements, and other GCP standards.
- **Department of Education (ED)**: The ED defines noncompliance as failing to follow the Common Rule or ED-specific regulations for human subjects research. This includes failure to adhere to informed consent requirements, IRB approval, and other protections for human research participants.
- **Environmental Protection Agency (EPA)**: The EPA defines noncompliance in human subjects research as failure to comply with the EPA's regulations and guidelines on human subjects protection. This includes deviations from the Common Rule as well as additional EPA-specific requirements aimed at protecting human subjects in environmental research.

Nonscientist Members: Members whose training and professional experience incline them to view scientific matters from a layperson's perspective.

Participating Site (pSite): An institution that participates in a Single IRB (sIRB) Study.

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced or sanctioned to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

- For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody.

Prisoner Representative: An IRB member with a deep understanding of conditions from the perspective of prisoners, who is not an employee of a correctional facility.

Privacy: Refers to the protection of an individual's personal information and their right to control the access and use of that information. It encompasses ensuring that participants can make informed decisions about what personal information they share, how it is collected, who has access to it, and how it is used.

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Protected Health Information (PHI): PHI refers to any information about health status, provision of health care, or payment for health care that is created or collected by a Covered Entity (or its Business Associate) and can be linked to a specific individual. This information is protected under the Health Insurance Portability and Accountability Act (HIPAA).

Personally Identifiable Information (PII): PII refers to any information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. This information is protected under various privacy laws and regulations, depending on the context (e.g., the Privacy Act, GDPR, etc.).

Program/Service Evaluation/Assessment/Reporting: Refers to a systematic method for collecting, analyzing, and using information to answer specific questions about the effectiveness and efficiency of projects, policies, programs, or services. The primary purpose is to assess whether the program/service is achieving its intended goals and to measure the current situation regarding a specific phenomenon or set of factors. These evaluations are typically used for internal decision-making or informational purposes and data may be shared only with the sponsor/client/requesting party and, where appropriate, the faculty advisor. These activities typically do not require IRB approval provided specific conditions are met. *See Non-Engaged in Research section for more information.*

Quality Improvement (QI): Refers to a systematic pattern of actions aimed at constantly optimizing productivity, communication, and value within an organization to measure the attributes, properties, and characteristics of a product or service in the context of the expectations and needs of customers and users. QI projects are designed to improve the quality of a service, program, or process within a specific institution. These activities typically do not require IRB approval provided specific conditions are met. *See Non-Engaged in Research section for more information.*

Regulatory Review: Review of administrative and regulatory issues unrelated to the regulatory criteria for approval that under the regulations must be determined by a convened IRB or reviewer using the expedited procedure.

Related to the Research: A financial interest is Related to the Research when the interest is in:

- A sponsor of the research;
- A competitor of the sponsor of the research;
- A product or service being tested; or
- A competitor of the product or service being tested.

Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- **Systematic Investigation**: An activity involving a prospective study plan that incorporates data collection and analysis, either quantitative or qualitative, to answer a study question. Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population or situation).
- **Generalizable Knowledge**: Knowledge gained from the study intended to draw general conclusions or to be applicable beyond the specific study population or situation. This includes developing or testing scientific theories or hypotheses and drawing conclusions intended to be shared beyond the studied

populations or situations (e.g., presenting data at meetings, conferences, or seminars; publishing results in academic or scientific journals; writing books or book chapters; submitting grant proposals which include research findings; creating educational materials based on research findings; sharing data via repositories or databases; etc.).

Research as Defined by FDA: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:

- Requires prior submission to the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act, which involves any use of a drug other than the use of an approved drug in medical practice.
- Requires prior submission to the FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act, which evaluates the safety or effectiveness of a device; or
- Intends to submit results to, or hold results for inspection by, the FDA as part of an application for a research or marketing permit.

Research Key Characteristics include:

- **Intent**: The primary goal is to develop or contribute to generalizable knowledge, such as testing hypotheses.
- **Professional Benefit**: The project occurs in large part because of individual professional goals and requirements, such as seeking tenure or obtaining grants.
- **Design**: Research projects may involve randomization of individuals to different treatments, regimens, or processes.
- **Institutional Mandate**: Research activities are not typically mandated by an institution or program.
- **Impact**: Findings are not expected to directly affect institutional or programmatic practice.
- **Inclusivity**: Research usually involves a subset of individuals, with statistical justification for sample size used to ensure endpoints can be met. Universal participation of an entire clinic, program, or department is not expected.
- **Direct Benefit**: Participants may or may not benefit directly from the research. Any benefit to individuals is typically incidental or delayed.
- **Dissemination**: The intent to publish or present findings is generally presumed at the outset of the project as part of professional expectations and obligations. Dissemination of information usually occurs in research/scientific publications or other research/scientific forums, with results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies.

Research Data: Human subjects data, documentation of subject eligibility and related information, original signed and dated consent forms (or record of such for verbal and waivers of signed consent), master keys/coding dictionary, review logs, as well as ancillary materials including administrative and financial records.

Research Engagement: **Engaged in Research** refers to the involvement of an institution in non-exempt human subjects research. An institution is considered engaged in a research project when its employees or agents perform specific actions related to the research. This engagement necessitates holding or obtaining OHRP-approved Federalwide Assurances (FWAs) and certifying IRB review and approval to HHS. The determination of engagement depends on the specific facts of the research study and can be complex. See Research Engagement section for more information.

Research Non-Engagement: **Non-Engaged in Research** refers to scenarios where an institution's involvement in a non-exempt human subjects research project does not meet the criteria for being considered engaged in research. Consequently, these institutions would not need to hold an OHRP-approved Federalwide Assurance (FWA) or certify IRB review and approval to HHS. See Research Non-Engagement section for more information.

Research Proposals Lacking Definite Plans for Involvement of Human Subjects: Under federal regulations (§46.118), certain grant applications are submitted without specific plans for human subjects' involvement detailed in the proposal. These situations typically fall into three categories:

- Institutional grants where specific projects are determined by the institution.
- Research training grants where activities involving human subjects are yet to be selected.

- Projects where human subjects' participation depends on the development of instruments, completion of prior animal studies, or purification of compounds.

Applications falling under §46.118 may request a determination to satisfy federal sponsor requirements, such as Just-In-Time submissions, allowing access to funding for aspects of the project not involving human subjects. However, initiation of human subject research activities is contingent upon the completion and approval of a full application, including all required materials (e.g., consents, surveys, tools), and obtaining IRB approval (§46.111).

Responsible Conduct: The adherence to ethical principles, professional standards, and regulatory requirements in the planning, conduct, and reporting of human subject research. Responsible conduct encompasses integrity, honesty, transparency, and accountability in all aspects of research activities, including experimental design, data collection and analysis, interpretation of results, authorship and publication practices, and adherence to relevant laws, regulations, and institutional policies. Researchers and institutional officials are expected to demonstrate responsible conduct to ensure the integrity and credibility of scientific research, protect the welfare of human subjects and animals, safeguard the environment, and maintain public trust in the research enterprise.

Reportable New Information: Actions that pose substantive harm to the health or safety of personnel, students, the public, or the environment, or a serious deviation from either the established research protocol or those practices that are commonly accepted by the scientific community in human subjects research. A violation may also occur when a researcher demonstrates other serious or continued noncompliance with federal, state, or local laws, regulations, or policies.

Restricted: Applies to investigators who are delinquent in meeting IRB requirements.

Secondary Data Analysis: The re-analysis of existing data that were originally collected for a purpose other than the current research project. This may include data from publicly available datasets, de-identified datasets, or previously gathered data. Secondary data analysis can involve human subjects research if the data contains identifiable private information, requiring IRB review. However, if the data is fully de-identified or publicly available, it may be exempt from IRB oversight. Researchers must confirm the nature of the data and the original consent terms to determine the appropriate level of review.

Scientific Members: Members whose training and professional experience primarily involve scientific activities and research, leading them to view scientific matters from a researcher's perspective.

Single IRB (sIRB) Study: A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution’s/organization’s IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the pSites.

SMARTIRB: An online reliance system to request, track, and document reliance agreements between institutions.

Software as a Medical Device (SaMD): SaMD refers to software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. This definition includes any standalone software that is used to diagnose, monitor, or treat medical conditions.

Key aspects of SaMD:

- **Medical Purpose:** SaMD is intended to be used for medical purposes such as diagnosing, preventing, monitoring, treating, or alleviating disease.
- **Standalone Software:** SaMD operates independently of a hardware medical device, though it can interface with other devices and software.
- **Regulatory Framework:** SaMD must comply with the same regulatory requirements as other medical devices, including performance, safety, and efficacy standards set by the FDA.

Examples of SaMD include:

- Mobile applications that monitor patient health conditions.
- Software that uses algorithms to diagnose conditions from medical images.

- Programs that provide recommendations for patient treatment based on data analysis.

Suspension of IRB Approval: An action of the IRB, IRB designee, Institutional Official, or designee of the Institutional Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

Termination of IRB Approval: An action of the IRB, IRB designee, Instituedu cationtional Official, or designee of the Institutional Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

Unanticipated Problem Involving Risks to Subjects or Others: An unanticipated problem involving risks to subjects or others is defined as any information that is:

1. **Unanticipated**: Unexpected in terms of nature, severity, or frequency given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.
2. **Related or Possibly Related**: Related or possibly related to participation in the research, where "possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.
3. **Indicates Increased Risk**: Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

Federal Agencies Definitions:

- **Office for Human Research Protections (OHRP)**: Unanticipated problems are incidents, experiences, or outcomes that are unexpected, related or possibly related to the research, and suggest that the research places participants or others at greater risk of harm. Institutions are required to have procedures for reporting these problems to the IRB and, where appropriate, to the institution's officials and regulatory authorities.
- **Food and Drug Administration (FDA)**: The FDA defines unanticipated problems as "unanticipated adverse device effects" (for medical devices) or "unexpected adverse drug reactions" (for drugs). These include serious adverse events not identified in the study protocol or investigator brochure and not expected based on prior information. Such events must be reported to the IRB, the sponsor, and regulatory authorities within specified time frames.
- **National Institutes of Health (NIH)**: NIH follows the general OHRP and FDA definitions for unanticipated problems. These problems are typically unexpected, related to the research, and increase the risk to participants. NIH requires that these problems be reported to the IRB and NIH grant or contract officials in accordance with institutional policies and federal regulations.
- **Department of Veterans Affairs (VA)**: The VA defines unanticipated problems as incidents, experiences, or outcomes not previously described in the research protocol or informed consent documents that indicate an increased risk of harm to participants. These problems must be reported to the VA's IRB and the local VA research office in accordance with VA-specific regulations.
- **Department of Defense (DOD)**: For DOD research, the term "Unanticipated Problem Involving Risks to Subjects or Others" includes any incident, experience, or outcome that is unexpected in terms of nature, severity, or frequency, given the procedures described in the research protocol documents and the characteristics of the human subject population being studied. It must be related or possibly related to participation in the research, where "possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research. Additionally, it must suggest that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

Undue Influence: Occurs through an offer of an excessive or inappropriate reward or other overture to obtain compliance.

Wards: Children who are cared for and the responsibility of the state or any other agency, institution, or entity. Any child for whom a state agency (in Massachusetts this is the Department of Children and Family (DCF)) has obtained temporary or permanent legal custody of a child. Please note that this definition and policy does not apply to children who are in the physical custody of the Massachusetts Department of Youth Services (DYS). Parents retain legal custody of children in DYS custody. However, DYS regulations also legally allow for a parent to delegate authority for medical decision making to the clinical staff at the DYS facility.

1.3 Abbreviations:

AID: United States Agency for International Development
CGSB: Canadian General Standards Board
CIA: United States Central Intelligence Agency
Commerce: United States Department of Commerce
CGIRB: Copernicus Group IRB
CRO: Chief Research Officer
CPSC: United States Consumer Products Safety Commission
DHS: United States Department of Homeland Security
DOD: United States Department of Defense
DOE: United States Department of Energy
DOJ: United States Department of Justice
DOT: United States Department of Transportation
ED: United States Department of Education
EPA: United States Environmental Protection Agency
FDA: United States Food and Drug Administration
FDR: Canadian Food and Drug Regulations
FERPA: Family Educational Rights and Privacy Act
FWA: Federalwide Assurance
HDE: Humanitarian Device Exemption
HHS: United States Department of Health and Human Services
HIPAA: Health Insurance Portability and Accountability Act
HRPP: Human Research Protection Program
HUD: Humanitarian Use Device
ICH-GCP: International Council on Harmonisation – Good Clinical Practice
IDE: Investigational Device Exemption
IND: Investigational New Drug
IRB: Institutional Review Board
LAR: Legally Authorized Representative
NASA: National Aeronautics and Space Administration
NSF: United States National Science Foundation
NSR: Non-significant Risk Device
OHRP: Office of Human Research Protections
OSTP: United States Office of Science Technology and Policy
PIPEDA: Personal Information Protection and Electronic Documents Act
PPRA: Protection of Pupil Rights Amendment
REB: Research Ethics Board
REC: Research Ethics Committee
SOP: Standard Operating Procedure
SR: Significant Risk Device
SSA: United States Social Security Administration
TCPS: Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
US: United States
USDA: Department of Agriculture
WIRB: Western IRB
VA: Veterans Affairs

Section 2: IRB Roles and Responsibilities:

2.1 Institutional Official (IO):

The IO is the legally authorized individual who acts on behalf of the institution to obligate the institution to the Terms of the Assurance. The IO is responsible for ensuring the Human Research Protection Program (HRPP) IRB functions effectively and that necessary resources and support are provided to comply with all requirements for research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA).

Responsibilities:

- **Designate IRBs:** Designate one or more Institutional Review Boards (IRBs) to review research covered by the institution's FWA.
- **Resource Allocation:** Provide sufficient resources, space, and staff to support the IRB's review and record-keeping duties.
- **Training and Education:** Ensure training and educational opportunities for IRB members and investigators.
- **Promote Ethical Culture:** "Set the tone" by promoting an institutional culture of respect and conscience, supporting the ethical conduct of human subjects research at the highest levels of the organization.
- **Effective Communication:** Ensure effective institution-wide communication and guidance on human subjects research.
- **Investigator Responsibilities:** Ensure that investigators fulfill their responsibilities.
- **Encourage Participation in Education:** Encourage all staff engaged in the conduct or oversight of human subject research to participate in educational activities.
- **Point of Contact:** Serve as a knowledgeable point of contact for the Office for Human Research Protections (OHRP) and other federal agencies, or delegate this responsibility to an appropriate individual.

Limitations: The IO cannot approve research that has been disapproved or has not yet been approved by the IRB.

2.2 Director of Institutional Ethics & Compliance (DIEC):

The DIEC serves as the Director of the IRB is responsible for the leadership and direction of day-to-day management and oversight of the institution's IRB, ensuring alignment with the institution's mission and compliance with regulatory requirements. This role ensures that all human research conducted under the institution's auspices complies with federal, state, and institutional regulations and policies.

Responsibilities:
Leadership and Management:

- **Program Oversight:** Oversee the daily operations of the HRPP and IRB to ensure compliance with regulatory requirements and institutional policies.
- **IRB Membership:** Appoint IRB members and suspend or terminate the membership of any individual who is not fulfilling their responsibilities and obligations.
- **Evaluation:** Perform periodic evaluations of the performance of IRB chairs, members, and administrative staff and provide this evaluation to the Chief Research Officer (CRO) and/or Provost. Evaluations will consider the following:
    - Knowledge and application of regulations, ethical principles, and IRB policies/procedures.
    - Completion of member training.
    - Meeting attendance and participation.

    - The quantity, quality, and timeliness of reviews completed.
- **Recruitment:** Recruit qualified members to include expert, non-scientific, and unaffiliated representation on the IRB.
- **Strategic Planning:** Engage in strategic planning for the IRB, including identifying goals, objectives, and metrics for program improvement and growth.

Administrative Duties:

- **Review Process:** Oversee the IRB's review process to ensure all submissions meet ethical and regulatory standards. Guide the IRB in making informed decisions regarding the approval, modification, or disapproval of research protocols based on ethical and regulatory criteria.
- **IRB Meeting Development:** Oversee the development of agendas and minutes for IRB meetings. Coordination of IRB meetings, distribution of materials, and documentation of meeting minutes.
- **Meeting Facilitation:** Preside over IRB meetings, ensuring they are conducted efficiently, fairly, and in accordance with institutional policies and regulatory requirements.
- **Policy Development:** Develop, implement, and update IRB policies and procedures to ensure compliance with applicable laws, regulations, and ethical standards.
- **Memoranda and Agreements:** Review and sign memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements).
- **Training Resource:** Provide training resources for IRB members, investigators, and research staff to promote understanding and adherence to regulatory and ethical requirements. Ensure ongoing training opportunities are available for researchers to remain current on regulatory changes and best practices.

Compliance and Monitoring:

- **Regulatory Compliance:** Ensure the institution's compliance with federal regulations, state laws, and institutional policies regarding human subjects research.
- **Quality Assurance:** Develop and oversee quality assurance and quality improvement programs to monitor and improve HRPP operations and outcomes.
- **Audits and Inspections:** Prepare for and respond to audits and inspections by regulatory agencies, ensuring that any findings are addressed promptly and effectively.

Communication and Collaboration:

- **Point of Contact:** Serve as the primary point of contact for correspondence addressing human subjects research with the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), and other agencies as applicable. Serve as the primary liaison with external regulatory agencies, sponsors, and other relevant organizations regarding human research protections.
- **Internal Communication:** Facilitate communication between the IRB, investigators, and other institutional offices to ensure coordinated and compliant research activities.
- **Stakeholder Engagement:** Engage with stakeholders across the institution to address and resolve issues related to noncompliance, unanticipated problems, and other challenges that arise in the conduct of human research and to promote a culture of ethical research and continuous improvement in human research protections.

Limitations: The DIEC cannot approve research that has been disapproved of by the IRB.

2.3 IRB Chairs:

The IRB Chair and Vice Chairs are appointed by the DIEC after consultation with the IO. The Chairs are selected from tenured faculty who have prior service on the IRB and have demonstrated sufficient experience and expertise to be suitable for the position. The IRB Chair is responsible for leading the IRB in its mission to protect the rights and welfare of human research subjects. The Chair oversees the IRB's review process, ensuring all research protocols meet ethical and regulatory standards.

Responsibilities:
Leadership and Oversight:

- **Agenda Setting:** Collaborate with the DIEC to set meeting agendas, prioritizing protocol reviews and other IRB business.
- **Meeting Facilitation:** Preside over IRB meetings, ensuring they are conducted efficiently, fairly, and in accordance with institutional policies and regulatory requirements.
- **Decision-Making:** Guide the IRB in making informed decisions regarding the approval, modification, or disapproval of research protocols based on ethical and regulatory criteria.
- **Problem-Solving:** Address and resolve issues related to noncompliance, unanticipated problems, and other challenges that arise during the conduct of research.
- **Suspension or Termination of Research:** Suspend or terminate the approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
- **Policy Development:** Contribute to the development and revision of IRB policies and procedures, incorporating feedback from IRB members and other stakeholders. Ensure that IRB policies and procedures are consistently applied and updated as needed to reflect regulatory changes and best practices.

Protocol Review:

- **Regulatory Review:** Conduct regulatory review for all research protocols, conduct or delegate the review of research that qualifies for expedited or exempted review, and ensure a timely and thorough evaluation.
- **Non-Engaged in Research Review:** Assess research activities to determine if they qualify as non-engaged in research, and ensure appropriate categorization and compliance with regulatory guidelines.
- **Conflict of Interest Management:** Identify and manage potential conflicts of interest within the IRB, ensuring unbiased review and decision-making.
- **Initial Review:** Lead the review of new research proposals, ensuring they meet all ethical and regulatory standards before approval.
- **Continuing Review:** Oversee the ongoing review of approved research to ensure continued compliance with IRB requirements and human subjects protections.
- **Documentation:** Ensure IRB review decisions, meeting minutes, and other documentation are accurate, complete, and maintained in accordance with institutional policies and regulatory requirements.

Education and Training:

- **Regulatory Knowledge:** Maintain current knowledge of federal, state, and institutional regulations governing human subjects research.
- **IRB Member Training:** Provide orientation and ongoing training for IRB members to ensure they are knowledgeable about their roles and responsibilities.
- **Investigator Guidance:** Offer guidance to researchers on ethical and regulatory issues related to their protocols, fostering a culture of compliance and ethical conduct.

Communication and Collaboration:

- **Institutional Liaison:** Serve as a liaison between the IRB, researchers, and institutional leadership, facilitating communication and addressing any concerns or issues.
- **External Engagement:** Represent the IRB in interactions with external regulatory agencies, sponsors, and other stakeholders as needed.
- **Reporting:** Report IRB activities and findings to the IO and other relevant institutional leaders.

2.4 IRB Members:

The IRB Members are appointed by the DIEC after consultation with the IO. IRB members are responsible for evaluating research study proposals and informed consent documents to ensure they meet regulatory criteria, ethical standards, and institutional policies. They attend IRB meetings, actively participate in discussions, and vote on protocol approvals, modifications, or disapprovals. IRB members also contribute to policy improvements, report compliance issues, participate in ongoing education, manage conflicts of interest, and maintain diversity within the IRB to support comprehensive review perspectives.

IRB Membership Composition, Qualifications, and Diversity:

- The IRB must consist of at least five members with diverse backgrounds to review research activities effectively with at least one member with a scientific focus and one with a nonscientific focus, plus at least one member unaffiliated with UMassD and not a family member of an UMassD affiliate.
- The IRB is composed of 9 members: 4 selected by the Faculty Senate and 5 selected by the DIEC (as designated by the IO), one which must not be affiliated with the UMass
- Members should have knowledge of institutional commitments, regulations, applicable laws, and professional standards, and may include representatives from administration.
- The IRB's composition must reflect diversity in race, gender, cultural backgrounds, and sensitivity to community attitudes to uphold the rights and welfare of human subjects.
- For research involving vulnerable subjects, the IRB may include members or consultants with relevant experience.
- The IRB adheres to equal opportunity principles and does not discriminate based on race, color, religion, sex, pregnancy, disability, national origin, citizenship status, ancestry, age, genetic information, marital status, sexual orientation, gender identity, gender expression, arrest record, military status, or military discharge status.
- Each member is to have a 3-year term which may be renewable. The terms are to be staggered so that no more than three (3) terms terminate concurrently.

Responsibilities:

- Disclose and manage conflicts of interest appropriately, including recusal from discussions and voting when conflicts arise.
- Evaluate research study proposals and informed consent documents for compliance with regulatory criteria, ethical standards, and institutional policies. Assess the level of risk involved in proposed research activities (minimal or greater than minimal). Participate in decisions regarding the frequency of continuing reviews for greater than minimal risk studies.
- Complete at least 70% of assigned protocol reviews, including initial reviews, continuing reviews, modifications, reports of unanticipated problems, and closure requests.
- Attend at least 70% of IRB meetings, actively participating in discussions and voting on protocol approvals, modifications, or disapprovals.
- Participate in initial and ongoing education sessions to stay informed about institutional policies, regulatory updates, and ethical standards pertinent to human subjects research.
- Recommend improvements to IRB policies and procedures to enhance human subject protections and streamline the research review process.
- Promptly report instances of noncompliance or ethical concerns related to human subject research to the IRB Chair and DIEC.
- Maintain confidentiality and adhere to legal and ethical principles during all IRB activities and deliberations.

2.5 IRB Meeting Chair:

The Meeting Chair role is held by the IRB Chair, Vice Chair, or any member assigned the role of Meeting Chair by the IRB Chair to serve in the absence of the IRB Chairs. At an IRB meeting, the Meeting Chair is responsible for oversight of meeting conduct at the IRB meeting and is expected to:

- Lead the IRB meeting.
- Facilitate IRB review.
- Ensure this SOP is followed.
- Monitor the IRB's decisions for consistency.
- Vote as an IRB member.
- Help IRB members meet their member expectations and responsibility.
- Encourage IRB members to:
  - Ask questions.
  - Speak their minds at every protocol review
  - Share information that has not been discussed.
  - Listen and learn from the group.
  - Respect dissenting opinions.

- Think, participate, and vote independently.

- Mentor and guide IRB members to use the criteria for approval by:
  - Facilitating members' understanding of the research to apply the criteria for approval.
  - Having members base concerns and recommended changes on the criteria for approval.
  - Framing difficult or controverted issues in terms of the criterion that is the basis of the controversy.
  - Taking votes on the criterion for approval that is the basis for a controversy, if after sufficient discussion a controverted issue remains unresolved. Reminding members who believe that one or more criteria for approval voted are not met that they should not vote for approval.
  - Removing issues from consideration when members determine they do not affect the criteria for approval.
  - Supporting and rewarding dissent based on the criteria for approval.
  - Obtaining assistance from DIEC when members are uncertain whether an issue affects the criteria for approval.
- Ensure that IRB members can actively and equally participate in all discussions. Encourage member engagement by:
  - Reinforcing member expectations.
  - Encouraging members to use their unique perspective to contribute to deliberations.
  - Providing recognition and praise to members.
  - Encouraging members to develop their review skills.
  - Ensuring opinions of members count.
- Ensure members know the definition of and self-identify their Conflicting Interests. If there are individuals (either members or consultants) with a Conflicting Interest related to an agenda item, neither should not participate in the review (including discussion or voting), except to provide information requested by the IRB. Conflicted members may be present for discussion and to answer questions will be asked to recuse themselves from the vote. If a committee member is unaware of any conflict of interest or potential conflict of interest at the time they sit in a meeting, and later discovers the Conflict of Interest, the member should inform the Meeting Chair and DIEC immediately. If a committee member is in any doubt about whether or not they are in a potential conflict situation, they must state this to the committee members at the commencement of the meeting. Faculty members residing in the same Department are allowed to review protocols and registrations coming from the same Department as long as the Committee member does not have a personal interest or stake in the research being proposed.
- If the study is eligible for Non-Convened Review, the Meeting Chair can make a motion for members to vote on taking no action and have the item reviewed via Non-Convened Review.

2.6 Principal Investigator (PI):

PI Eligibility: To be eligible to serve as a principal investigator, an individual must hold one of the following titles: professor, associate professor, assistant professor, or research professor. Other full-time benefited individuals holding titles other than professor, associate professor, assistant professor, and research professor must obtain approval from the Chief Research Officer (CRO) or his/her designee to submit an IRB protocol. Students may serve as a Co-PI if they have a faculty sponsor (described below).

Responsibilities:

- To not commence research until IRB approval letter and all other required approvals have been obtained, such as radiation safety approval, biosafety approval, and approvals of departments or divisions that require approval of the use of their resources. If there are any questions about whether you are conducting research involving human subjects, contact the IRB before commencing the study. Ensure any human subjects work conducted has an IRB approval, where required, and that such approval remains valid while human subjects work is conducted. Note, failure to comply with this condition on funded work can result in suspension and/or termination of any associated award.
- Comply with all requirements and determinations of the IRB. Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

- Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
- Personally conduct or supervise the research.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Submit proposed modifications to the IRB prior to their implementation. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- Submit continuing reviews when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
    - The protocol is permanently closed to enrollment
    - All subjects have completed all protocol related interventions and interactions
    - No additional identifiable private information about the subjects is being obtained.
    - Your analysis of private identifiable information is completed.
- If research approval expires, stop all research activities and immediately contact the IRB.
- Do not accept or provide payments in exchange for referrals of potential subjects ("finder's fees.")
- Do not accept payments designed to accelerate recruitment tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- For studies regulated by a federal department or agency, follow any additional obligations, as applicable.

2.7 Faculty Sponsor:

Faculty Sponsor Eligibility: Generally, only those who have a full-time academic appointment with the titles of professor, associate professor, assistant professor, or research professor may serve as Faculty Sponsors. However, there may be circumstances when individuals who do not have an academic appointment or full-time status may be the best person to oversee a student's research. In such cases, a Faculty Sponsor Approval must be obtained from the CRO and included with the students IRB application. Any studies deemed greater than minimal risk will require a full-time academic appointment at UMassD.

A faculty sponsor is required for all student investigators conducting human subjects research. Faculty sponsors guide student investigators through each phase of the IRB process and therefore, must be familiar with research methods specific to their field and stay informed about the rules and regulations governing research at UMassD. The faculty sponsor should be the primary resource for student investigators with questions or needing assistance with their projects. Faculty sponsors play a crucial role in ensuring the ethical and regulatory compliance of student research projects. The faculty sponsor must approve the student's application prior to IRB submission and serve as the primary contact for any concerns or questions related to human subjects in the research. Their guidance helps maintain the integrity of the research process and safeguards the rights and welfare of research participants. The IRB offers office hours and appointments to both students and faculty sponsors to facilitate this process.

Responsibilities:
Verification:

- Confirm the student investigator has sufficient knowledge and experience to conduct the proposed research.
- Verify the scientific merit and appropriate study design for the relevant field.
- Ensure the project meets criteria for degree satisfaction.
- Confirm adherence to field-specific codes of conduct.
- Ensure completion of required online human subjects protection training (CITI) and any other relevant protocol-specific research-related training.
- Ensure the proposed research is not initiated (including advertisement/recruitment) until final written approval from the IRB has been obtained.

Ongoing Supervision:

- Supervise the submission and conduct of the study, advising the student on clarifications/changes requested by the IRB.
- Monitor the progress of the project to ensure continued adherence to the protocol and regulatory requirements.

- Ensure timely submission of reports on unanticipated problems, issues of noncompliance, and use of approved documents/tools.
- Avoid over-enrollment of subjects.

Staying Informed:

- Keep abreast of the policies and procedures of the IRB.
- Stay updated on the published guidelines for the ethical conduct of research relevant to the field of inquiry, as well as state and federal regulations.
- Provide the student with guidance on the protection of human subjects as necessary.

2.8 Student Investigators:

Student investigators play a crucial role in upholding ethical standards and regulatory compliance throughout the research process, thereby contributing to the integrity and validity of the study outcomes. Student investigators are able to serve as Co-PIs, under the direction of a Faculty Sponsor.

Responsibilities:

- Ensuring that research activities do not commence until receiving final approval from the IRB.
- Taking charge of the overall design and execution of the study, ensuring adherence to the IRB-approved protocol throughout the research period.
- Maintaining regular communication with the Faculty Sponsor and the IRB to address any questions regarding the IRB submission process or the conduct of the research.
- Overseeing the research team to ensure that all members have reviewed and understood the protocol and are adequately trained in the relevant study procedures.
- Safeguarding the rights and welfare of human subjects by obtaining informed consent, ensuring privacy during interactions, and maintaining confidentiality of data as specified in the approved protocol.
- Submitting modifications and awaiting IRB approval before implementing any changes to the study protocol.
- Promptly reporting any unanticipated problems or instances of noncompliance identified by the study team members to the IRB using the designated Report Form.
- Consulting with the Faculty Sponsor to identify and implement protocol modifications necessitated by unexpected events or circumstances.

2.9 Key Personnel:

The IRB holds all study personnel responsible for meeting certain obligations. All study personnel are required to:

- Fulfill the training requirement for the protection of human participants in research (CITI online training modules, www.citiprogram.org), and understand the ethical standards and regulatory requirements governing research activities with human participants,
- Comply with applicable IRB policies and procedures and federal regulations regarding human subjects research,
- Document contact with participants, e.g., obtaining informed consent or informing participants of changes that may affect their willingness to continue participating,
- Ensure a thorough explanation of the study in lay terms to the participant during the consent process.
- Provide the participant with an opportunity to ask questions and have them answered when obtaining informed consent and throughout their participation.
- Understand the appropriate use of an investigational intervention (treatment, drug or device) as described in the protocol, investigator brochures, product information/drug labeling, and various other available sources such as newsletters, safety alerts, or communications from sponsors, if applicable.
- Be familiar with and follow the adverse event and protocol deviation reporting requirements.

Section 3: IRB Oversight:

3.1 Engagement in Research:

The term **Engaged in Research** refers to the involvement of an institution in non-exempt human subjects research. An institution is considered engaged in a research project when its employees or agents perform specific actions related to the research. This engagement necessitates holding or obtaining OHRP-approved Federalwide Assurances (FWAs) and certifying IRB review and approval to HHS. The determination of engagement depends on the specific facts of the research study and can be complex. Below are the criteria and examples of scenarios that indicate whether an institution is engaged in human subjects research.

General Criteria for Engagement include: An institution is engaged in a non-exempt human subjects research project if its employees or agents:

- Obtain data about research subjects through intervention or interaction.
- Obtain identifiable private information about research subjects.
- Obtain the informed consent of human subjects for the research.

Specific Scenarios Indicating Engagement: An institution is considered engaged in human subjects research if its employees or agents:

- **Receive HHS Awards**: Institutions receiving awards through grants, contracts, or cooperative agreements directly from HHS for non-exempt human subjects research are engaged, even if all human subject activities are conducted by another institution's employees or agents.
- **Intervene for Research Purposes**: Employees or agents perform invasive or noninvasive procedures with human subjects. Examples include:
  - Drawing blood.
  - Collecting buccal mucosa cells.
  - Administering counseling or psychotherapy.
  - Administering drugs or other treatments.
  - Surgically implanting medical devices.

    - Utilizing physical sensors or other measurement procedures.
- **Manipulate the Environment for Research Purposes**: Employees or agents control or influence the research environment. Examples include:
    - Controlling environmental light, sound, or temperature.
    - Presenting sensory stimuli.
    - Orchestrating environmental events or social interactions.
- **Interact for Research Purposes**: Employees or agents engage in research-related communication or interpersonal contact. Examples include:
    - Engaging in protocol-dictated communication.
    - Asking subjects to provide specimens.
    - Conducting research interviews or administering questionnaires.
- **Obtain Informed Consent**: Obtain the informed consent of human subjects for the research.
- **Obtain Identifiable Information or Specimens**: Employees or agents acquire identifiable private information or biological specimens for research purposes, regardless of direct interaction or intervention with subjects. This includes:
    - Observing or recording private behavior.
    - Using, studying, or analyzing identifiable information or specimens provided by another institution.
    - Using, studying, or analyzing identifiable information or specimens already possessed by the investigators.

3.2 Levels of Review:

The following are the levels of review for which the IRB can make a determination.

3.2.1 118 Review (Proposals Lacking Definite Plans for Involvement of Human Subjects):

Under federal regulations (§46.118), certain grant applications are submitted without specific plans for human subjects' involvement detailed in the proposal. These situations typically fall into three categories:

- **Institutional Grants**: Specific projects are determined by the institution at a later stage.
- **Research Training Grants**: Activities involving human subjects are yet to be selected.
- **Projects Dependent on Preliminary Work**: Human subjects' participation depends on the development of instruments, completion of prior animal studies, or purification of compounds.

Process for 118 Proposal Review:

- **Submission**: Principal Investigators (PIs) should submit their proposals to the IRB when applying for grants that fall under §46.118. Submissions should occur at the grant application stage, prior to the selection or development of specific human subject activities.
- **Assessment**: The IRB will review the proposal to assess whether the project involves human subjects at its current stage. The review will determine if the application meets the criteria for §46.118 and if it can be approved as lacking definite plans for human subjects' involvement.
- **Outcome**: If the preliminary proposal is acceptable under §46.118, the IRB will issue a determination to satisfy federal sponsor requirements, such as Just-In-Time submissions, allowing access to funding for aspects of the project not involving human subjects.
- **Conditions**: The initiation of any human subject research activities is strictly contingent upon the completion and approval of a full application. This includes submission of all required materials (e.g., recruitment materials, consent forms, surveys, research tools, etc.) and obtaining IRB approval in accordance with §46.111.

When the 118 Determination is Not Acceptable:

If the IRB determines that the proposal does not meet the criteria under §46.118:

- The PI will be notified and must provide additional details or modifications to address the IRB's concerns.
- The project cannot proceed with human subject activities until these requirements are met and full IRB approval is obtained.
- The IRB will provide guidance on what is needed to make the proposal acceptable.

PIs should anticipate this process and submit their proposals as early as possible to ensure timely review and determination. This allows for necessary adjustments and avoids delays in accessing grant funds or commencing human subjects research.

3.2.2 Exempt Review:

The term "exempt" is frequently mistakenly interpreted as not requiring IRB review. However, exempt human subjects research still necessitates an IRB determination of exempt status. Researchers are not authorized to independently determine if their study qualifies for exemption; such exemption determinations are issued by the IRB. Furthermore, it's important to note that exempt status does not exempt research from ethical considerations or regulatory requirements. Studies meeting the exemption criteria must still undergo IRB for review before commencing the research as well as report enrollment status to the IRB annually. *For a full list of exemption categories, see Appendix – Exemption Categories.*

Criteria for Exemption:
To qualify for exempt status, research activities must meet specific criteria as outlined in federal regulations (45 CFR 46):

- **Minimal Risk**: The research presents minimal risk to participants, meaning that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations.
- **Specific Categories**: The research falls into one or more categories specified in the federal regulations as eligible for exemption. These categories typically include research involving existing data, documents, records, or specimens; certain educational practices; anonymous surveys or interviews; and certain types of public observation.
- **Protection of Privacy and Confidentiality**: Adequate measures are in place to protect the privacy and confidentiality of participants and their data.
- **Voluntary Participation**: Participation in the research is voluntary, and participants provide informed consent when required, ensuring they are fully aware of the nature and purpose of the study before deciding to participate.

Process for Exempt Review:

- **Submission**: Researchers seeking an exempt determination must complete and submit an IRB application along with the proposal, consent documents, site letters, subject-facing materials (e.g., recruitment flyers/emails, questionnaires, survey documents), and any other relevant attachments. These materials should be submitted via email to irb.research@umassd.edu for review and approval.
- **Review**: Exempt reviews are conducted by designated IRB members who focus on confirming that the research meets the exemption criteria and ensuring appropriate protections are in place for participants.
- **Outcome**: If the study qualifies for exemption, the IRB will issue an exempt determination. Studies receiving this determination do not receive an expiration date and do not require continuing review. However, PIs are responsible for notifying the IRB annually of the study's enrollment status.

Studies which receive exemption determinations must only submit amendments when:

- Adding procedures that could alter risks to participants; **or**
- Adding procedures outside the approved exemption categories; **or**
- Involving new types of participants, especially vulnerable populations (e.g., adding children, individuals with cognitive impairments, prisoners, pregnant women, etc.) **or**
- Changing the Principal Investigator.

Examples of modifications that would likely require IRB review:

- Changes to the data storage plan which may affect confidentiality.
- Removal of the consent process, or use of deception or incomplete disclosure.
- Significant changes to the recruitment procedures.
- Adding sensitive questions to a survey or interview process (e.g. questions regarding illegal activities; traumatic events such as childhood, sexual, or domestic abuse; suicide; or other probing questions that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation).

- Collection of new or additional identifiable information or sources.

Restrictions on Exemptions:
- Studies which are greater than minimal risk do not qualify for exemption.
- Exemptions do not apply to research with prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners. [45 CFR 46.104(b)(2)].
- Exemption 2(iii) and Exemption 3 do not apply to research with children.
- Only exemption category 6 (for taste and food quality evaluation and consumer acceptance studies) applies to studies that are FDA-regulated. Exemptions, other than Exemption Category 6, do not apply to FDA-regulated research.

3.2.3 Expedited Review:

Expedited review is a streamlined process designed for specific types of non-exempt, minimal-risk research. This type of review is faster than full board review but still requires careful IRB scrutiny to ensure ethical standards are met and participant protections are in place. Research must fall into one of the seven regulated categories to qualify for expedited review. *For a full list of Expedited Review Categories, see Appendix: Expedited Review Categories.*

Key Points for PIs:
- **Eligibility:** Only non-exempt, minimal-risk research qualifies for expedited review.
- **Privacy and Confidentiality:** Risks related to privacy and confidentiality must be minimal.
- **Exemptions:** Not applicable if risks related to privacy breaches or confidentiality are more than minimal.
- **Common Examples:** Moderate exercise studies by healthy volunteers, data analyses, linguistic studies, ethnographic studies, focus groups, non-anonymous sample collection with minimal risk.

Criteria for Expedited Review:
To qualify for expedited status, research activities must meet specific criteria as outlined in federal regulations (45 CFR 46):
1. **Minimal Risk:** The research presents minimal risk to participants, meaning that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations.
2. **Specific Categories:** The research falls into one or more categories specified in the federal regulations as eligible for expedited review. These categories typically include:
    - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
    - Prospective collection of biological specimens for research purposes by noninvasive means.
    - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice.
    - Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes.
    - Collection of data from voice, video, digital, or image recordings made for research purposes.
    - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
    - Continuing review of research previously approved by the convened IRB under specific conditions.

Process for Expedited Review:
1. **Submission:** PIs must complete and submit an IRB application along with the proposal, consent documents, site letters, subject-facing materials (e.g., recruitment flyers/emails, questionnaires, survey documents), and any other relevant attachments. These materials should be submitted via email to irb.research@umassd.edu for review and approval.
2. **Review:** Expedited reviews are conducted by at least one designated IRB member who focuses on confirming that the research meets the expedited criteria and ensuring appropriate protections are in place for participants.

3. **Outcome:** If the study qualifies for expedited review, the IRB will issue an approval. Approved studies are valid for one year and require an annual continuing review. PIs must seek IRB approval for any changes affecting review category, risk, population, study funding, or PI. PIs who wish to continue their research projects beyond the year term should plan to submit a continuing review application before the one-year expiration date.

3.2.4 Full Board Review:

Proposed human subject research which does not fall into either the exempt or expedited review categories must be submitted for full committee review (also referred to as Convened Review). This is the most rigorous level of review and, accordingly, is reserved for research projects that present more than minimal risks to subjects.

Common examples include:

- **Greater than Minimal Risk:** Research projects involving more than minimal risk
- **Clinical Trials:** Research projects involving clinical trials and/or clinical interventions
- **Vulnerable Populations:** Research involving vulnerable populations, such as children, prisoners, pregnant women, or individuals with intellectual or physical impairments/disabilities, is subject to Full Board review due to the additional protections required.
- **Medical Devices:** Research involving medical devices, especially if the device is FDA-regulated, often requires Full Board review.
- **Sensitive Information:** Research that involves the collection of sensitive information (e.g., child abuse, violence, sexual conduct/misconduct, mental health/status information, AIDS, alcohol, compulsive disorders, etc.) may require Full Board review to ensure adequate protections are in place.
- **Potential Coercion:** Projects that involve possible coercion or undue influence that induces or entices consent (e.g., excessive compensation, inequitable relationship, etc.)
- **Deception:** Research involving deception or incomplete disclosure to participants typically requires Full Board review to address ethical concerns (e.g., intentionally misleading subjects about their status, giving false information about the researchers or the research purpose).
- **Significant Changes:** Any notifications or significant changes to an approved greater than minimal risk study that impact risk levels, participant populations, or the study's design must be reviewed and approved by the Full Board before implementation.

Submission Process:

PIs must complete and submit an IRB application along with the proposal, consent documents, site letters, subject-facing materials (e.g., recruitment flyers/emails, questionnaires, survey documents), training, and any other relevant attachments. These materials should be submitted via email to irb.research@umassd.edu for review and approval.

Review Process:

The ability to schedule a study for review is related to the pre-review response time needed to ascertain whether the application is complete, provide IRB members time to review these materials prior to a convened Full Board Meeting, and allow the IRB the opportunity to gather additional expertise that may be required for the review. Full Board committee meetings are held once monthly, and ad-hocs are scheduled on an as-needed basis to review applications, typically within two weeks of submission of all necessary proposal materials. The committee discusses the study and determines whether the Criteria of Approval for Human Subject Research are met and makes a decision. Within one week after the meeting, the IRB will communicate to the PI any changes requested by the committee and will work with the study team to resolve any issues. Typically, this communication will indicate one of the following:

- **Approval:** This letter indicates nothing else is needed and you may proceed using the protocol or other documents uploaded in the submission.
- **Modifications Required:** This determination is made when the IRB or designated reviewer requires specific, clear-cut modifications to the research before approval can be granted. This means that all regulatory review criteria have been met; however, additional modifications or documents must be provided for the protocol to be considered complete (for example, minor modifications to consent forms,

revision of a flyer, or completion of training). Modifications may be reviewed and approved by the IRB without requiring re-review by a convened IRB.
    - **Steps for PIs:** The PI must address concerns identified and submit the revised documents to the IRB. The IRB will review these modifications and, if satisfactory, grant final approval without requiring another full board review.
- **Tabled:** This determination is made when the IRB was unable to reach a determination during the specified meeting time and will discuss the proposal at a later date. This tabling may be needed if additional information is needed from the IRB applicant before review can continue.
- **Returned:** This determination is made when the convened IRB determines that regulatory review criteria either have not been met or that not enough information is provided to determine if these criteria have been met (for example, risks to subjects are unclear or not minimized, subject selection is not equitable, the consent process described is not approvable). When making this motion, the IRB describes its reasons for this decision, offers suggestions for revisions to address these concerns, and provides the investigator an opportunity to respond by providing additional information or justification to the IRB. Responses to a deferred protocol require review by the full committee at a convened IRB meeting.
    - **Steps for PIs:** The PI must address the concerns identified and submit the revised documents to the IRB. The IRB will review these modifications and, if satisfactory, submit for another full board review.
- **Disapproved:** This determination is made when the IRB determines that it is unable to approve research because the protocol does not meet regulatory approval criteria, and the IRB also cannot describe modifications that might make the research approvable in its current state or design. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to re-write and resubmit the protocol. The investigator may request to be allotted time in a convened meeting to discuss the issues with the board. The research may also be disapproved at an institutional level if it involves subject areas or procedures unacceptable to the university's vision or mission. The Institutional Official may not approve a study if the IRB has disapproved it. Protocols that are disapproved require a full re-design and a new submission to be reconsidered by the IRB.
- **Suspended:** This determination is made when the IRB decides to temporarily halt the research due to concerns regarding participant safety, regulatory compliance, or other issues that need resolution.
- **Terminated:** This determination is made when the IRB decides to permanently halt the research due to serious noncompliance, participant safety concerns, or other significant issues.

3.2.5 Reliance/Facilitated Review:

Reliance or Facilitated reviews occur when the UMassD IRB relies upon the review of another IRB (IRB of Record), in accordance with the terms of a reliance agreement. A facilitated review does not require a convened IRB review, rather, a facilitated review accepts and relies on the approval issued by the external IRB (either center or single IRB). A facilitated review is conducted when an IRB agrees to rely on the review of an IRB from an external institution, via an executed IRB Authorization Agreement (IAA) or other reliance agreement. The specific details of the level of review and the criteria for review of protocols process is contingent upon the relevant Agreement. The DIEC may act in liaison with the IRBs of other institutions as necessary to assist in the review of joint and cooperative projects involving multiple sites and/or investigators. Approvals under these categories are reported to members of the IRB that conducted the facilitated review via approved minutes. Studies that qualify for an exempt determination, do not require a reliance agreement, although consultation with the IRB office is recommended to confirm the exemption status and ensure proper documentation.

During a reliance or facilitated review process, the IRB undertakes several key steps to ensure ethical and regulatory compliance for research involving human subjects.

Process for Reliance/Facilitated Review:

1. **Submission:** PIs must complete and submit an IRB application along with the proposal, consent documents, site letters, subject-facing materials (e.g., recruitment flyers/emails, questionnaires, survey documents), and any other relevant attachments. These materials should be submitted via email to irb.research@umassd.edu for review and approval.

2. **Evaluate the Request:** The IRB reviews the request for reliance or facilitated review to ensure appropriateness, including the scope of the study and the institutions involved. This involves assessing whether the research meets the criteria for reliance or if facilitated support is needed.
3. **Coordinate with External Parties:** The IRB coordinates and manages communication with researchers, external reviewers, and/or consultants, as needed, to obtain additional expertise or feedback throughout the review process. Establish a clear communication plan between the relying institution and the IRB of Record to ensure all parties are informed of any updates, changes, or issues.
4. **Facilitate Resolution of Issues:** The IRB works to resolve any ethical or compliance issues that may emerge during the study. This may involve coordinating with other institutions, reviewing additional documentation, or making recommendations for improvements.
5. **Assess and Confirm Compliance:** For facilitated review, the IRB may conduct a preliminary review to identify and address major issues before the full review. For reliance, the IRB reviews documentation from the lead institution's IRB to verify that the study has been reviewed and approved according to applicable regulations.
6. **Execute Agreements:** Once a reliance/facilitated review is completed, if there are no issues, and if the study qualifies for reliance, the IRB executes a reliance agreement that outlines the responsibilities and terms of reliance between institutions and specific instructions related to the review of each different type of event (e.g., new protocols, modifications, unanticipated problems, noncompliance, etc.) explained in the respective sections. Via a reliance agreement, the IRB accepts to rely on the approval issued by the external IRB, which may be a single IRB or a central IRB, in accordance with the terms of a reliance agreement.
7. **Monitor and Ensure Compliance:** The IRB monitors the study's ongoing compliance with ethical standards and institutional policies, whether through direct oversight or by working with the lead IRB and local investigators in reliance scenarios to ensure terms of agreement are followed. This includes submitting amendments, continuing review, reviewing reports, and addressing any issues that arise. Approvals under reliance/facilitated reviews are reported to the IRB members via approved minutes. Maintain thorough documentation of all reliance agreements, reviews, communications, and decisions to ensure transparency and accountability.

For more information see guidance: IRB Guidance on Reliance Agreements.

3.3 Post Approval Processes for Studies Approved via Expedited and Full Board Review:

- **Amendments:** Prior to implementing any changes or modifications that impact the approval category, risk, population, study funding, or PI, the PI must obtain IRB approval for the amendment(s) which:
    - Add procedures that could alter risks to participants.
    - Add procedures which deviate from the approved protocol.
    - Involve new types of participants, especially vulnerable populations (e.g., adding children, individuals with cognitive impairments, prisoners, pregnant women, etc.). **or**
    - Change the Principal Investigator.
- **Continuing Reviews:** Research approved by the IRB via expedited review, or a convened Full Board is approved for one year. The expiration date is included in the approval letters. The PI is notified 60 days prior to the expiration date that they must submit a progress report in sufficient time for the IRB to approve the continuation of human subjects research activities. Any active protocol that previously received a full board review must come back to the Full Board for its yearly renewal. PIs who wish to continue their research projects beyond the year term should plan to submit a continuing review application before the one-year expiration date. In certain cases, a protocol that previously received Full Board review can go through an Expedited review (Category #8), so long as it meets one of the following three requirements:
    - The research is permanently closed to the enrollment of new participants;
    - All participants have completed all research-related interventions; and
    - The research remains active only for long-term follow-up of participants; or where no participants have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.
- **New Information and Unanticipated Problems:** PIs must promptly report any new information or unanticipated problems that may affect the risk to participants or others. This includes any new findings that may impact the participants' willingness to continue in the study. The PI must submit a report to the IRB detailing the nature of the new information or unanticipated problem, the potential impact on the

study, and any proposed changes to the protocol. Any instances of noncompliance with the approved protocol or IRB requirements must be reported to the IRB immediately. Noncompliance includes, but is not limited to, deviations from the approved study procedures, failure to obtain informed consent, or failure to adhere to regulatory requirements. The PI must provide a detailed report outlining the nature of the noncompliance, the circumstances surrounding it, and any corrective actions taken to prevent recurrence.

3.4 Post Approval Required Reporting and IRB Reviews:

Please report the following items to the IRB within 5 business days of discovery. If unsure, contact the IRB.

1. **New Funding and Financial Conflicts of Interest**
    - **Types of Reports:** New financial conflicts of interest or changes in funding affecting the study's integrity.
    - **IRB Review Process:** Expedited or Full Board Review to evaluate potential impacts on research objectivity and participant welfare.
2. **New or Increased Risk/Safety Issue and Protocol Deviations**
    - **Types of Reports:** New information indicating increased or new risks, revised investigator brochures or device labeling, protocol violations or deviations that harm participants or increase their risk, and participant complaints indicating new risks. Any changes significantly increasing the risk to participants and affecting the research conduct, including any deviations from the approved research protocol that affect the study's integrity or increase risk.
    - **IRB Review Process:** Expedited or Full Board Review based on the severity and impact of the risk or deviation on participant safety and study conduct.
3. **Unexpected Harm Related to Research**
    - **Types of Reports:** Harm that is unexpected based on previously reviewed risk information. Harm that is at least possibly related to the research procedures, in the investigator's opinion. Serious adverse effect on health or safety, life-threatening problem, or death associated with a device or procedure not previously identified. Complaints which cannot be resolved by the research team.
    - **IRB Review Process:** Expedited or Full Board Review based on the severity and relevance of the harm.
4. **Compliance and Data Integrity Issues**
    - **Types of Reports:** Noncompliance with federal regulations or IRB requirements, inspection audit reports, written reports from study monitors, unreviewed protocol changes, premature suspension/termination of the study by sponsor or investigator, and issues affecting the integrity or validity of research data, including potential falsification or manipulation.
    - **IRB Review Process:** Expedited or Full Board Review based on the nature, severity, and impact of the compliance and data integrity issues.
5. **Breach of Confidentiality**
    - **Types of Reports:** Security incidents or breaches involving research data.
    - **IRB Review Process:** Expedited or Full Board Review based on the severity and potential impact of the breach.
6. **Informed Consent Issues and Unexpected Benefits**
    - **Types of Reports:** Problems affecting participant understanding or rights in the informed consent process, and if new, unexpected benefits identified during the study that were not anticipated in the original IRB review.
    - **IRB Review Process:** Expedited or Full Board Review based on the impact of the issues on participant rights, understanding, and study conduct.
7. **External Reports**
    - **Types of Reports:** Early suspension or termination of the study by the sponsor, investigator, or institution, findings from additional regulatory bodies, compliance issues not covered by primary IRB oversight, significant participant complaints related to study procedures or safety, and safety monitoring or final study reports.
    - **IRB Review Process:** Full Board Review to evaluate the circumstances, address additional regulatory findings, assess the impact on participants, and ensure proper follow-up and final reports.

3.5 Noncompliance with IRB Policies, Procedures, or Decisions:

The IRB cannot retrospectively approve research. Please do not begin research without IRB approval. Approved IRB protocols which deviate from the policies, procedures, stipulations, or decisions of the IRB are subject to further inquiry by the IRB. Initially, DIEC may send the investigator(s) in question a notice requesting the suspension of all research activities while the issue of noncompliance is reviewed, consistent with Federal Mandate 45 CRF Part 46.113. This initial notice will also include a statement detailing the rationale for the IRB's action. Finally, DIEC will investigate allegations of noncompliance.

Areas of Noncompliance IRB Inquiry Review:

- **Category of Review**: Determine if the study was reviewed as Exempt, Expedited, or Full Board.
- **Type and Nature**: Identify whether the noncompliance is general, serious, or continuing. Assess the impact on participants, research integrity, and the informed consent process.
- **History of Noncompliance**: Review the noncompliance history of the PI, CO-PI, and/or faculty sponsors.
- **Deviation and Implications**: Assess specific deviations observed and evaluate how investigators deviated from the approved protocol or failed to adhere to IRB procedures. Consider the context of these deviations, including their impact on research integrity, participants' rights and welfare, and study outcomes. Ensure there is adequate documentation supporting the described noncompliance issues.
- **Reporting**: Evaluate how and when the event was reported to the IRB, including the submission of the final report and Corrective Action Plan (CAP). Confirm that outcomes of corrective and preventive actions are communicated to relevant stakeholders, including participants and research staff.
- **Corrective Actions**: Assess the actions taken to address and mitigate the noncompliance, including necessary revisions to the protocol, study design, or other relevant aspects. Evaluate the plans for training or re-training research staff on procedures and practices to prevent recurrence of the issue. Review the monitoring measures established to ensure ongoing compliance, including how these measures will be tracked and reported.
- **Preventive Actions**: Examine changes made to processes or systems designed to prevent similar issues in the future. Ensure mechanisms are in place for ongoing feedback to identify potential issues early, including how feedback will be collected and addressed. Confirm that clear deadlines are provided for implementing corrective and preventive actions and identify who is responsible for overseeing these actions. Outline how the effectiveness of the corrective and preventive actions will be assessed, including any follow-up reviews or audits.

Noncompliance Process

Allegation:

1. Concerns about possible Noncompliance can be raised by DIEC, IRB Chairs, IRB members, investigators, subjects, or others. Concerns not raised by a DIEC should be forwarded to a DIEC for initial determination.
2. The DIEC may determine if the concern constitutes General Noncompliance or warrants further inquiry. Concerns determined to be greater than General Noncompliance are considered allegations and are forwarded to the Chair for review.

Investigation:

1. DIEC conducts the Investigation, contacting relevant individuals for verification of facts.
2. Once sufficient information is available regarding the allegation, a report is prepared for committee review.
3. The IRB Chair or convened IRB may accept, reject, or modify DIEC’s findings and recommendations report. Corrective actions may include changes to the research protocol, required training, research restrictions, subject notification, data destruction, publication disallowance, oversight monitoring, or protocol suspension/termination.
4. The Convened IRB, IRB Chair, or DIEC can make a final determination, including severity and corrective actions, will be documented in the IRB meeting minutes.
5. A Final Report reflecting the IRB’s final determinations is sent to the IO. If Noncompliance is found, the Report is sent to Need to Know Individuals; if not, it is provided only to the Respondent.

Outcome:

1. If the Respondent disagrees with the Final Report, they may notify the IO, DIEC, and IRB Chair, to request an appeal citing reasons for disagreement within 30 days. The IRB Chair or DIEC can make the final decision, in consultation with the IO, as necessary.
2. If the PI agrees with the Final Report or after the IRB's final decision, the DIEC or IRB Chair ensures the corrective and preventive action plan is implemented. If necessary, a notice of closure is sent to Need to Know Individuals.

Not for Cause Audits:
1. If Noncompliance is identified during a DIEC audit, DIEC determines the type of Noncompliance.
2. If not General Noncompliance, DIEC follows the same steps for investigation, reporting, and corrective actions as detailed above.

Notification to Regulatory Agencies or Sponsors:
The DIEC reports Serious or Continuing Noncompliance to the appropriate regulatory agencies and sponsors as required. This includes OHRP, FDA (for drug and device research), and other relevant parties at the DIEC's discretion.

3.6 Lapse in Approval:

If IRB approval of the Human Research expires, no human subjects activities may occur. This includes recruitment, enrollment, interventions, interactions, and collection of private identifiable information. Continuation of Human Research procedures is a violation of federal regulations. If IRB approval of the Human Research expires, the Principal Investigator (PI) must report the lapse to the IRB and include:
1. An explanation of how the lapse occurred.
2. A strong corrective action plan to avoid a future lapse.
3. The timeline for when the lapse will be resolved, either through a Continuing Review application or Study Closure.
4. Confirmation that no human subjects research activities took place during the lapse.
5. Confirmation that there are no pending issues/modifications, participant complaints/concerns, etc.
6. A statement about whether there have been prior lapses for this project.
7. Verification the lapse has been communicated to the sponsor, local site/IRB, DSMB, etc., if/when applicable.

If it is necessary to continue Human Research activities to eliminate apparent immediate hazards to participants, prior notification is required.

Note: Consult IRB for guidance on appropriate actions for specific circumstances not covered above.

3.7 Transfer of Research when PI is Leaving the University:

If the PI of an IRB-approved study plans to leave the university, please consider the following options:

For Active Research:
1. **Transfer to Another Institution with Ongoing Enrollment:** Submit a modification describing plans for notifying subjects, determining their willingness to continue participation, and safely transferring or ending subject participation.
2. **Transfer to Another Institution with Completed Enrollment:** Submit a modification to describe how confidentiality of identifiable data will be maintained according to subjects' consent agreements.
3. **Change of PI at Current Institution:** Identify a qualified individual to serve as PI and submit a modification to implement this change.
4. **Data or Material Transfer:** Execute an appropriate agreement before transferring any data or materials collected at the university to an external site.

For Research Not Yet Started or Concluded with Pending Publication: Submit a closure submission to the IRB.

3.8 Study Closure:

Regardless of how a study was approved (full review, expedited review, or exempt), closure is required in any of the following situations:

- The study was not initiated and will not be.
- The study was discontinued before completion.
- The IRB-approved time period for the study has ended, and no extension was requested.
- Data collection and study-related interventions are complete, and use of identifiable data has ended.
- The PI will no longer be affiliated with UMassD and does not plan to transfer the protocol.

A study should be closed when all human subject interactions have ended and subjects are not identifiable. Studies are eligible for closure once the following criteria are met:

- Enrollment of subjects is closed.
- All research-related interventions are completed.
- Data collection is finished.
- Data are de-identified.(identifiers are separated from the coding system or stored securely).
- No additional research beyond the original intent is planned for these data.

For IRB closure requests, the study is considered complete if only data analysis using de-identified data remains. If identifiers remain on the data, researchers must request continuing review. It remains the research team's responsibility to maintain the confidentiality of the data.

The IRB may close a study without the principal investigator's permission if:

- The principal investigator is no longer affiliated with UMassD, and no protocol transfer was arranged.
- The protocol has lapsed and no extension or closure request was made.
- An application for continuing review was submitted, but the PI has not addressed the IRB's requests.
- The IRB determines the protocol should be terminated due to issues like misrepresentation or ethical concerns.

Closing Process:

1. **Closure Request:** Submit a closure report upon completion of the study before the study expiration date. The closure report is a brief summary of the research project signed by the PI and, if applicable, the faculty sponsor.
2. **Confidentiality:** If any risk to confidentiality remains (e.g., subjects can still be identified in the data during analysis), do not close the study until this risk is mitigated.

What to Do After Closing a Study

After closing a study, the research team must:

- Cease data collection and analysis of identifiable data.
- De-identify data and destroy identifiable data as per the protocol.
- Securely retain all study-related materials (excluding identifiable data) for three years (such as: signed consent forms, de-identified data, data collection measures, and study advertisements).

If included in the IRB-approved protocol, activities that may continue after study closure include:

- Communicating with participants for non-data collection purposes.
- Distributing remuneration.
- Fulfilling grant-related responsibilities (excluding data collection/analysis).
- Analyzing and disseminating results from de-identified data.

For additional data collection post-closure, submit a new study application to the IRB.

3.9 Non-Engagement Research:

The term **Non-Engaged Research** refers to scenarios where an institution's involvement in a non-exempt human subjects research project does not meet the criteria for being considered engaged in research. Consequently, these institutions would not need to hold an OHRP-approved Federalwide Assurance (FWA) or certify IRB review and approval to HHS. The following scenarios provide examples of when an institution is typically not engaged in human subjects research. This list is not exhaustive, and additional scenarios may exist where an institution is not engaged in research.

Scenarios Indicating Non-Engagement:

- **Provision of Commercial or Other Services**: Institutions whose employees or agents perform services for investigators that:
    - Do not merit professional recognition or publication privileges.
    - Are typically performed by those institutions for non-research purposes.
    - Do not involve the administration of any study intervention being tested or evaluated under the protocol.

  Examples:
    - A qualified laboratory performing routine serum chemistry analyses as a commercial service.
    - A transcription company transcribing research study interviews.
    - A hospital drawing blood or collecting urine samples for research investigators.
    - A radiology clinic performs chest X-rays for research investigators.
- **Clinical Trial-Related Medical Services**: Institutions (including private practices) not selected as a research site whose employees or agents provide clinical trial-related medical services as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site, provided:
    - They do not administer the study interventions.
    - The services are typically provided for clinical purposes.
    - They do not enroll subjects or obtain informed consent.
    - Responsibility for overseeing protocol-related activities and reporting data remains with investigators from an engaged institution.
- **Short-Term Administration of Study Interventions**: Institutions not initially selected as a research site whose employees or agents administer study interventions on a one-time or short-term basis, provided:
    - It is in the subject's best interest as determined by an engaged institution investigator.
    - They do not enroll subjects or obtain informed consent.
    - Responsibility for protocol-related activities and data reporting remains with investigators from an engaged institution.
    - The IRB of the engaged institution is informed about the administration of study interventions at the non-selected institution.
- **Providing Information About Research**: Institutions whose employees or agents inform prospective subjects about the availability of research; provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document or other IRB-approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators; provide prospective subjects with information about contacting investigators for information or enrollment; and/or seek or obtain the prospective subject's permission for investigators to contact them;
  Example: A clinician providing patients with literature about a research study and obtaining permission to share the patient's contact information with investigators.
- **Use of Facilities for Research**: Institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for research by investigators from another institution.
  Examples:
    - A school allows distribution of a research survey in a classroom.
    - A business allowing recruitment of research subjects or collection of blood samples on site.
- **Release of Identifiable Information or Specimens**: Institutions whose employees or agents release identifiable private information or biological specimens to investigators at another institution, ensuring compliance with institutional requirements, applicable regulations, and informed consent provisions.
  Examples:
    - Schools releasing student test scores.
    - HHS agencies releasing beneficiary records.

    - Medical centers release human biological specimens.
- **Obtaining Coded Private Information or Specimens**: Institutions whose employees or agents obtain coded private information or specimens from another institution involved in the research, without being able to readily ascertain the identity of the subjects.
  Conditions:
    - An agreement prohibiting the release of the code exists.
    - The releasing institution's IRB-approved policies prohibit the release of the code.
    - Legal requirements prohibit the release of the code.
  Definition of Coded:
    - Identifying information replaced with a code.
    - A key to decipher the code exists but is not accessible to the receiving institution's employees or agents.

- **Accessing Identifiable Information at an Engaged Institution**: Institutions whose employees or agents access or utilize identifiable private information while visiting an engaged institution, with oversight by the engaged institution's IRB.
- **Study Auditing**: Institutions whose employees or agents access identifiable private information for study auditing purposes.
- **FDA Reporting**: Institutions whose employees or agents receive identifiable private information for FDA reporting purposes.
- **Authorship**: Institutions whose employees or agents author a paper, journal article, or presentation describing a human subjects research study.

3.10 Types of Nonengaged Research:

The IRB conducts a preliminary review of protocols to confirm that the research does not involve human subjects. If you are unsure whether your protocol involves human subjects research, please submit your proposal to the IRB for a preliminary review. The IRB will confirm whether the research is non-engaged or determine the required level of oversight.

3.10.1 Nonengaged Recruitment:

This refers to recruitment which occurs when an external entity requests that IRB-approved protocols from external institutions be forwarded by a UMassD entity to potential participants at UMassD.

These recruitment activities do not require IRB approval under the following conditions:

- **Intent:** The primary intent of nonengaged recruitment is to facilitate access to research opportunities for potential participants without involving the UMassD entity in the research process. By forwarding information about research studies, the nonengaged recruitment process contributes allows diverse potential participants to be informed about research opportunities, promoting inclusivity and broadening the participant pool and to the generation of generalizable knowledge.
- **Informing Prospective Subjects:** The nonengaged individual will communicate the availability of the research to potential participants, ensuring they are aware of the study's existence.
- **Providing Information:** The nonengaged individual will provide relevant research information, which may include a copy of the informed consent document or other IRB-approved materials, and details on how to contact study investigators for additional information or to express interest in participation. Most importantly, the nonengaged individual will not answer study specific questions, obtain consent, nor conduct research procedures, nor act as a representative of the research team.
- **Seeking Permission for Contact:** The nonengaged individual may seek permission from prospective subjects for investigators to reach out to them.

In this non-engaged capacity, the actions are restricted to the aforementioned activities, and there is no involvement in any substantive research tasks or decision-making processes. Once confirmation of understanding and agreement to these terms is received by the IRB, the IRB will issue a letter of non-engagement.

However, IRB approval is required if:

- **Direct Involvement in Recruitment Procedures:** If the UMassD entity is actively involved in the recruitment process beyond simply forwarding information, such as directly contacting potential participants or engaging in the consent process.
- **Sensitive or High-Risk Research:** If the research involves sensitive topics or high-risk procedures that could potentially affect the safety, well-being, or privacy of participants, IRB review is needed to ensure that appropriate safeguards are in place.
- **Engagement in Study Procedures:** If the UMassD entity or its members are directly involved in any research procedures, data collection, or interactions with participants, IRB approval is required to ensure that all ethical and regulatory requirements are met.
- **Data Handling and Confidentiality:** If the UMassD entity handles or processes any data collected from participants, especially if it includes identifiable or sensitive information, IRB review is needed to ensure that privacy and confidentiality measures are appropriately addressed.
- **Informed Consent Management:** If the UMassD entity is responsible for obtaining or managing informed consent from participants, IRB approval is required to ensure that the consent process adheres to regulatory and ethical standards.
- **Unclear or Complex Protocols:** If there is any ambiguity about the role of the UMassD entity or if the recruitment involves complex or unique aspects not covered by the general nonengaged recruitment guidelines, IRB review is needed to clarify responsibilities and ensure compliance.

The IRB will review the submitted details about the recruitment process and involvement to understand the investigator's roles. Researchers or UMassD entities must provide a detailed description of the recruitment activities, any data handling procedures, and the role of the UMassD entity in the study. If the UMassD entity is involved in research tasks or decision-making processes, the IRB will assess whether the recruitment activities to ensure compliance with ethical and regulatory standards. If necessary, the IRB may request additional information or modifications before granting approval. Note, this procedure may require the establishment of a reliance agreement.

3.10.2 Educational Research:

Educational Research encompasses systematic investigations aimed at understanding and improving teaching methods, instructional strategies, curriculum development, and student outcomes. Educational Research is designed to enhance educational practices and outcomes. It can involve various methods and approaches, including both localized studies and broader investigations. This type of research can be conducted by educators or researchers and may vary in scope and intent. It generally falls into two main categories: **Action Research** and **Pedagogical Research**. Educational Research must adhere to ethical boundaries set forth for human research, similar to other social and behavioral research and may need IRB approval.

Action Research: Involves systematic inquiries conducted by educators within their own practice to address immediate issues and improve teaching methods. It is often focused on specific educational settings with the goal of refining practices directly within that context.

- **Context-Specific Inquiry:** Conducted within the educator's own classroom or educational environment.
- **Local Impact:** Aims to directly address and improve immediate issues and practices.
- **IRB Oversight:** May not require IRB approval if it does not involve generalizable knowledge or broader dissemination and focuses on practical improvements within the specific setting.

Pedagogical Research: Involves systematic investigations aimed at understanding and improving educational practices on a broader scale. It often contributes to educational theories and practices that extend beyond the specific context.

- **Broader Scope:** Includes studies that aim to generalize findings and contribute to wider educational knowledge.
- **Generalizable Knowledge:** Seeks to develop or refine theories or practices applicable beyond the immediate setting.
- **IRB Oversight:** Generally, requires IRB approval if the research involves generalizable knowledge, publication, or public dissemination.

Educational Research does not require IRB approval under the following conditions:

- **Intent:** The primary goal is to improve teaching practices and student learning within the educational setting.
- **Professional Benefit:** The research is conducted to enhance the educator's own practice rather than for professional advancement or career benefits.
- **Generalizable Knowledge:** The research is not designed to contribute to generalizable knowledge or scientific theories; instead, it focuses on immediate improvements in the specific educational context.
- **Mandate:** The research is typically conducted as part of the educator's personal initiative rather than an institutional or funder's mandate.
- **Impact:** Findings are intended to directly influence and enhance teaching methods and learning outcomes within the specific educational setting.
- **Inclusivity:** The research may involve all students within the classroom or educational setting to address broad teaching issues.
- **Direct Benefit:** The primary benefit is to improve the educator's practice and student outcomes rather than providing direct benefits to participants.
- **Dissemination:** Results are usually shared within the educational institution or with other educators but are not intended for broader publication or presentation outside the educational context.

Once IRB confirms the project meets the above conditions, the IRB will issue a confirmation that IRB oversight is not required.

Educational Research studies require IRB approval if it involves:

- **Human Subjects:** Direct interaction or observation of students or educators, including interviews, surveys, or focus groups.
- **Data Collection for Generalizable Knowledge:** Studies intended to generalize findings beyond the specific context or institution.
- **Potential Risks:** Research involving sensitive topics or potential psychological, emotional, or social risks.
- **Dissemination Plans:** Research intended for dissertation, publication, presentation at conferences, or broader dissemination.

3.10.3 Classroom Projects:

This refers to educational inquiry activities conducted solely to fulfill a course requirement that lacks the intent to develop or contribute to generalizable knowledge and does not involve the public dissemination of findings. For more information, see IRB Guidance on Classroom Projects.

Classroom Projects do not require IRB approval under the following conditions:

- **Intent:** The primary goal is to educate individual students through inquiry or experiential approaches to discover known principles or phenomena.
- **Professional Benefit:** The project is designed to meet educational requirements, not for the professional benefit of the instructor or students conducting it.
- **Generalizable Knowledge:** Classroom projects are not designed to develop or contribute to generalizable knowledge and typically do not involve randomization to different practices or processes.
- **Institutional Mandate:** The activity is part of the coursework mandated by the educational institution.
- **Impact:** The findings are used only within the classroom context to meet educational objectives.
- **Inclusivity:** Data collected is intended to be used only within the classroom context, and data from all or most students participating in the project is expected to be included. Data will be destroyed upon completion of the course.
- **Direct Benefit:** Participants (students) benefit directly from the educational experience and skills gained through the project.
- **Dissemination:** Data gathered may be shared only with the course instructor, faculty advisor, or, in the case of an internship/practicum, the collaborating party. The intent to publish or present the findings beyond the classroom context is generally not presumed. When dissemination occurs, it is to demonstrate the educational process rather than to contribute to generalizable knowledge.
- **Exclusions**: The following are not considered classroom projects and may require IRB approval: Doctoral dissertations, master's and honors theses, funded research, or research conducted via external entities

Once IRB confirms the project meets the above conditions, the IRB will issue a confirmation that IRB oversight is not required.

Classroom Projects require IRB approval if:

- **Research Intent:** If the project aims to develop or contribute to generalizable knowledge or to influence broader practices beyond the educational context, it requires IRB approval.
- **Study Design:** If the project involves systematic investigation or experimentation that includes randomization, manipulation of variables, or significant risk to participants, IRB review is necessary.
- **Public Dissemination:** If there is an intent to publish or present the findings to a broader audience beyond the classroom or educational setting, it may necessitate IRB approval.
- **Sensitive Information:** If the project involves collecting sensitive or identifiable information about participants, the project requires IRB review to ensure adequate privacy protections are in place.
- **External Funding:** If the project is funded or sponsored by external entities, it may require IRB review, regardless of its educational context.
- **Potential Risks:** If the project introduces potential risks or harm to participants beyond the scope of typical classroom activities, IRB approval is required to assess and mitigate these risks.

3.10.4 Program/Service Evaluation/Assessment/Reporting:

This refers to a systematic method for collecting, analyzing, and using information to answer specific questions about the effectiveness and efficiency of projects, policies, programs, or services. The primary purpose is to assess whether the program/service is achieving its intended goals and to measure the current situation regarding a specific phenomenon or set of factors. These evaluations are typically used for internal decision-making or informational purposes and data may be shared only with the sponsor/client/requesting party and, where appropriate, the faculty advisor.

These activities typically do not require IRB approval under the following conditions:

- **Intent**: The primary goal is to improve a specific program or service.
- **Professional Benefit**: The project is not initiated by the evaluator and occurs regardless of whether the individual(s) conducting it may benefit professionally.
- **Generalizable Knowledge**: Program evaluations are not designed to develop or contribute to generalizable knowledge and do not involve randomization of individuals, though they may involve comparisons of variations in programs.
- **Institutional Mandate**: The activity is mandated by the program or its funder as part of its operations.
- **Impact**: Findings are expected to directly affect the conduct of the program and identify needed improvements.
- **Inclusivity**: Information on all or most participants within or affected by receiving a particular treatment or undergoing a particular practice or process is expected to be used. Exclusion of information from some individuals significantly affects conclusions.
- **Direct Benefit**: No direct benefit to participants is expected; the evaluation focuses on program improvements or determining whether the program should continue.
- **Dissemination**: The intent to publish or present is generally presumed at the outset of the project. Dissemination of information is to program stakeholders and participants and may be publicly posted (e.g., on a website) to ensure transparency of results. When published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools, or provide benchmarks or base rates, rather than to develop or contribute to generalizable knowledge.

Once IRB confirms the project meets the above conditions, the IRB will issue a confirmation that IRB oversight is not required.

Program/Service Evaluation/Assessment/Reporting require IRB approval if:

- **Intent to Contribute to Generalizable Knowledge:** If the evaluation is designed to develop or contribute to generalizable knowledge, such as through systematic research methods, comparisons, or statistical analyses intended for publication or presentation beyond the specific program or service context.

- **Involvement of Vulnerable Populations:** If the evaluation involves vulnerable populations, such as children, prisoners, or individuals with cognitive impairments, and includes procedures that might pose risks to these groups.
- **Informed Consent:** If the evaluation involves collecting data where participants are directly asked for their consent to participate in research activities or where their data is used in ways that might not align with standard program/service evaluation practices.
- **Risk of Harm:** If there is a risk of harm to participants beyond the typical scope of program/service evaluation, including sensitive or personal data that could impact participants' well-being or privacy.
- **Use of Deception:** If the evaluation involves deception or withholding of information that might impact participants' willingness to participate or their understanding of the study.

3.10.5 Quality Improvement (QI) Projects:

QI related projects refer to a systematic pattern of actions aimed at constantly optimizing productivity, communication, and value within an organization to measure the attributes, properties, and characteristics of a product or service in the context of the expectations and needs of customers and users. QI projects are designed to improve the quality of a service, program, or process within a specific institution.

QI Projects do not require IRB approval under the following conditions:

- **Intent**: The primary goal is to improve a practice or process within a particular institution or ensure it conforms with expected norms.
- **Professional Benefit**: The project occurs regardless of whether the individual(s) conducting it may benefit professionally.
- **Generalizable Knowledge**: QI projects are not designed to develop or contribute to generalizable knowledge and generally do not involve randomization to different practices or processes.
- **Institutional Mandate**: The activity is mandated by the institution or clinic as part of its operations.
- **Impact**: Findings are expected to directly affect institutional practice and identify corrective actions needed.
- **Inclusivity**: Information on all or most individuals receiving a particular treatment or undergoing a particular practice or process is expected to be included. Exclusion of information from some individuals significantly affects conclusions.
- **Direct Benefit**: Participants are expected to benefit directly from the activities.
- **Dissemination**: The intent to publish or present is generally not presumed at the outset of the project. Dissemination of information often does not occur beyond the institution evaluated, although it may occur in quality improvement publications or forums. When published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools, or provide benchmarks or base rates, rather than to develop or contribute to generalizable knowledge.

Once IRB confirms the project meets the above conditions, the IRB will issue a confirmation that IRB oversight is not required.

QI Projects require IRB approval if:

- **Research Intent:** If the QI project is designed to generate generalizable knowledge or contribute to scientific literature beyond improving internal practices, it requires IRB approval.
- **Study Design:** If the project involves randomization of participants, experimental interventions, or manipulation of variables that could affect participants' wellbeing or rights, it must undergo IRB review.
- **Involvement of Sensitive Information:** If the QI project collects, uses, or discloses sensitive or identifiable information that could impact participants' privacy, the project requires IRB review to ensure adequate protections are in place.
- **Human Subjects Involvement:** If the project involves human subjects in a way that goes beyond routine clinical or operational practices, such as interacting with participants or obtaining informed consent, IRB approval is necessary.
- **Potential Risk to Participants:** If the project introduces potential risks or harm to participants that are not typical of standard practices or procedures, IRB review is required to assess and mitigate these risks.
- **Dissemination of Results:** If the results of the QI project are intended for widespread dissemination or publication in a manner that aims to influence broader practices or contribute to scientific knowledge, IRB approval is necessary.

3.10.6 Social Media Research:

Social media research involves using any online and mobile resource for generating, sharing, or discussing ideas and content. This includes various platforms such as online communities (e.g., patient support groups), social networking sites (e.g., Facebook, Twitter), professional networking sites (e.g., LinkedIn), content production and sharing sites (e.g., YouTube, Tumblr), and location-based services (e.g., Tinder, Grindr). Research utilizing social media (e.g., public Twitter feeds, public Facebook profiles, information from public forums) is generally not considered Human Subjects Research as defined by federal regulations as long as there is no interaction or intervention with the individuals about whom data are being collected.

Social Media Research does not require IRB approval under the following conditions:

1. **Privacy and Reporting:** The proposal ensures to avoid quoting social media posts verbatim if not from public figures to prevent easy identification through search engines. Removes all private information about individuals when reporting findings.
2. **Publicly Available Data:** Social media posts intended for public engagement are considered publicly available data. However, the proposal is mindful of the potential for reputational harm and the privacy of third parties mentioned in posts.
3. **No Human Interaction:** The research involves no direct interaction with any individuals.

If needed, submit an IRB application to seek formal confirmation of non-human participant research status for the study. The IRB office may require a protocol submission depending on the study's nature.

Social Media Research requires IRB approval if:

1. **Interaction or Intervention:** If the research involves interacting with individuals through social media or intervening in any way, it requires IRB approval.
2. **Sensitive or Private Information:** If the research involves data that is not truly public or if there is a risk of identifying individuals through data analysis, IRB oversight is necessary.
3. **Potential Harm or Reputational Risk:** If the research could cause reputational harm or affect the privacy of individuals mentioned in the data, IRB approval is required.
4. **Ethical Concerns:** If the research raises ethical concerns about privacy, consent, or potential harm, it should be reviewed by the IRB.

3.10.7 Use of Publicly Available Data Sets:

Secondary data analysis of publicly available data is a common research method. Increasingly, federal agencies supporting research require investigators to make the data they collect publicly available. Additionally, many professional organizations and journals require that research datasets of published works be made accessible to encourage scholarly interpretation and replication of research. Data are not considered publicly available if access to the data is limited. Public Use Datasets are datasets prepared by investigators or data suppliers with the intent of making them available for public use. The data available to the public are not individually identified or maintained in a readily identifiable form.

All **public-use de-identified data sets** that are accessible from the sources listed below have been deemed acceptable for use in research. A public-use dataset is considered as a de-identified dataset that can be freely downloaded (or may require a short application to request access to the data) but does not require for UMassD to enter into a formal written agreement with the provider of the data. Under the federal regulations for human subjects (45 CFR Part 46), research involving publicly available data sets would not require IRB review – no application is required – as long as:

- the data come from sources that are publicly available, and
- the data is deidentified and uncoded and stripped of identifiers.

Restricted use data are not publicly available and are defined as files distributed by federal agencies, repositories, and research organizations upon which use restrictions are imposed. These files are usually, but not always, accompanied by a data use/transfer agreement, data access agreement, or user terms and conditions that detail restrictions on use of the data. The restrictions vary, but they typically involve secure data storage, encryption, password protected computers, access limitations or destruction parameters.

Data Analysis of Publicly Available Data Sets do not require IRB approval under the following conditions:

- The data set(s) is (are) published and publicly available without restriction (e.g., data are published by a reputable source in a publicly-available journal, textbook or web-site) and neither the researcher nor any collaborating researcher on the project(s) has access to links that would connect the data to the individuals from whom they were derived.
- The data set(s) are publicly available to researchers and others, but the data holder requires a "responsible use statement" or similar attestation to ensure appropriate use and protection of the data. Such an agreement or attestation may be automated. In this case, neither the researcher nor any collaborating researcher on the project can have access to any links that would connect the data to the individuals from whom they were derived, nor may any researcher on the project attempt to re-identify any person from whom the data were derived.
- The researcher will obtain a data set available from a Federal or State agency and will enter into an agreement with the data provider that includes language that: a) the data provided to the researcher does not contain any identifiers, including those specified under the HIPAA Privacy Rule; b) if the data are coded, the data provider will not release a link to the code to the researcher; and c) the researcher receiving the data set must agree to not attempt to re-identify any person from whom the data were derived.
- In all cases, the IRB expects that investigators have reviewed the data sources' terms of service, responsible use statements, and data access agreements, if any. Questions about compliance with such terms should be directed to the IRB.research@umassd.edu.

Once IRB confirms the project meets the above conditions, the IRB will issue a confirmation that IRB oversight is not required.

Examples of Non-Public Data:

- Data in the electronic medical record.
- Social media data labeled as "private" by the data owner, or not readily available without permission of the site Owner/Administrator under the Terms of Service of the site.
- Data protected by Copyright, data use agreement, terms of use agreement, etc.; **and**
- Data or biospecimens that have access restrictions [e.g. are only available to clinicians or qualified researchers or may only be accessed on a secure server].

Public Use Data Sets require IRB Approval if any of the following are met:

1. **Re-identifiable Data:** If the data originally contained identifiers and the data has not been fully de-identified or if there is a risk that the data could potentially be re-identified.
2. **Restricted Use Data:** If the data comes from restricted use data sets, which require a data use or transfer agreement detailing restrictions on use, such as secure storage, encryption, or access limitations.
3. **Merging Data Sets:** If the research involves merging public use data sets with identifiable or potentially identifiable data.
4. **Non-Public Data Integration:** If the research involves secondary analysis of non-public data sets that require agreements for procurement or use, including interaction or intervention with human subjects.
5. **Enhanced Analysis:** If the research involves enhancing a public use data set with additional identifiable information or if it is not clear whether the data meets the criteria for public use.
6. **Data Triangulation:** If the information or data that will be collected can be used together or triangulated in a way where a participant can be identified, prior to initiating data collection. This includes scenarios where combining multiple data sources might lead to the identification of individuals.

Investigator Responsibility:

1. **No IRB Approval Needed:** PIs whose research project only involves secondary analysis of publicly available data from public data sets/repositories which do not require an agreement do not need to obtain IRB approval or determination of exemption prior to access to the data and do not need to seek approval nor submit an application to, the IRB.
2. **Notification for Inclusion:** PIs whose research project only involves secondary analysis of public use data from a data set which is not identified may notify the IRB to have the data set included in UMassD's list.

3. **IRB Application Required:** PIs whose research project involves secondary analysis of public use data from one or more of the public data sets/repositories, data from a non-public data (requires an agreement to procure), and/or interaction or intervention with human subjects must submit an application to the IRB for review and approval of exemption request. PIs who intend to merge public use data sets or enhance one with identifiable or potentially identifiable data must apply for IRB review and approval of exemption request.
4. **Compliance with Agreements:** PIs must abide by the conditions of any applicable data use agreements governing the data to be accessed. If use of data is directed by the terms of a data use agreement that requires IRB review of research that may not meet the federal definition of human subjects research, the PI must submit an application for IRB review and approval.

IRB Responsibility:
1. The IRB will assess whether any identifiers or surrogates for identifiers remain, and if statistical methods or data summarization are necessary to ensure anonymity. The reviewer will consider the following factors when reviewing public use data set registration requests for data originally collected with identifiers:
   a. removal of any identifiers of a human subject or of persons named by a human subject.
   b. removal of any variables that by definition would serve as surrogates for the identity of a human subject.
   c. collapse or combine categories of a variable to remove the possibility of identification due to a human subject being in a small set of persons with specific attributes regarding a variable (e.g., due to the infrequency of subjects in a lower or upper range).
   d. collapse or combine variables to provide summary measures to mask what otherwise would be identifiable information.
   e. use of statistical methods, where necessary, to add random variation with variables otherwise impossible to mask; **and**
   f. removal of any variables that could be linked to identifiers by secondary users.
2. The IRB will then provide written notification of the results of the review of the public use data set registration request to investigators.

For a list of available public data sets, please see Appendix: Available Public Datasets.

3.10.8 Secondary Data Analysis

Secondary data analysis involves the re-examination of existing data originally collected for other purposes. UMass Dartmouth requires researchers to determine whether their use of secondary data constitutes human subjects research and may require IRB review.

Secondary Data Analysis Does Not Require IRB Review Under the Following Conditions:
- **Publicly Available Data**: The data is from publicly accessible sources, such as government databases, public records, or open-access datasets. Anyone can access the data without restrictions.
- **De-identified Data**: The data has been fully de-identified, with all direct and indirect identifiers removed, making re-identification of individuals impossible.
- **Anonymous Data Collection**: The data was collected anonymously, meaning no identifiers were attached to individuals at the time of data collection, and the dataset was designed to be completely anonymous.
- **Non-Human Subjects Determination**: The data does not involve living individuals or identifiable private information as defined by the Common Rule, meaning it does not meet the regulatory definition of human subjects research.

Caveat: UMass Dartmouth does not participate in the use of broad consent for secondary research. Therefore, researchers cannot rely on broad consent as a basis for exemption and must follow other applicable criteria. Once the IRB confirms secondary data analysis meets these conditions, it will issue a determination that IRB oversight is not required.

Secondary Data Analysis Requires IRB Review If:

- **Identifiable Private Information**: The data contains identifiable private information, such as names, dates, or other direct identifiers that can link the data to individuals.
- **Coded Data with Re-identification Potential**: If coded data can be linked back to individuals through a key accessible to the researcher, IRB review is required.
- **Incomplete De-identification**: The data is not fully de-identified, meaning there is still a possibility of linking it to individuals, particularly if indirect identifiers or unique combinations of variables are present.
- **Original Consent Limitations**: The original consent form did not authorize the use of the data for secondary analysis, or the new research falls outside the scope of the consent, requiring IRB review to ensure ethical compliance.
- **Sensitive or Vulnerable Populations**: Even with de-identified data, if the research involves vulnerable populations such as children, prisoners, or adults with decisional impairment, IRB review may be required to ensure protections are in place.
- **International or Sensitive Data**: For data obtained from international sources or involving sensitive topics, researchers must confirm adherence to local ethical standards, and IRB oversight may be necessary.

If the secondary data analysis meets any of these criteria, IRB approval is required to proceed. For additional information about honest brokers used for de-identification see section 5.13 Honest Broker.

Section 4: Submission Information:

4.1 Information the Investigator Provides to the IRB:

4.1.1 New Submission Documents to include for review:

1. Application Form: Completed IRB application form which includes qualifications to conduct the research, including necessary support services and facilities.
2. Research Protocol Proposal:
    - Title and summary of the research.
    - Purpose of the study, including expected benefits and how risks are balanced with benefits.
    - Study sponsor.
    - Inclusion/exclusion criteria, with scientific and ethical reasons for excluding certain subjects.
    - Justification for using special or vulnerable populations (e.g., children, prisoners).
    - Study design and appropriateness of methods.
    - Description of procedures to be performed.
    - Provisions for managing adverse reactions.
    - Consent procedures, including setting, subject autonomy concerns, language difficulties, and considerations for vulnerable populations.
    - Procedures for obtaining and documenting informed consent, including assent from minors, legally authorized representatives, witnesses, and translators.
    - Remuneration and compensation details.
    - Measures for protecting subjects' privacy.
    - Extra costs to subjects for participation.
    - Inclusion/exclusion of women, minorities, and children.
3. **CITI Training Certificates**: Certificates of completion for personnel engaged in research.
4. **External Entity Documents**: For studies involving an external entity, include a letter of support. If your work is non-exempt and involves an institution with an established IRB, please provide their external entities contact information as we may need to execute a reliance agreement. For reference, see IRB Guidance on Reliance Agreements.
5. **Student Research**: Refer to IRB Guidance on Students as Research Participants.
6. **Minor Research**: Simplified assent form for minors, in addition to the adult parental consent form.
7. **Recording Studies**: Consent form includes a recording section which incorporates paragraphs 2-5 of the recording consent template.
8. **Translated Documents**: Certificate of translation for any translated documents.
9. **International Research**: The International Research Checklist (in addition to the proposal) and a Letter of Cultural Appropriateness from the local ethics entity. For reference, see the IRB Guidance on International Research.
10. **Study Materials**: Copies of recruitment materials, advertisements, surveys, interview scripts, questionnaires, or other materials provided to subjects.
11. **Funding Applications**: Copies of relevant grant applications.
12. **Informed Consent Form**: Proposed informed consent form, including translated documents or request for waiver of informed consent.
13. **Investigator's Brochure**, *when one exists.*
14. **Case Report Form,** *when one exists.*

4.1.2 Amendments and New Information:

1. **Amendment and Report Form**: Completed form detailing changes and/or new information related to the study.
2. **Explanation of Changes**: Detailed explanation of the circumstances for the submission.
3. **New Study Instruments**: Include updated or new study instruments, as applicable.

4. **Tracked Changes**: Document revisions to previously approved IRB documents using tracked changes.
5. **Reports**: Updated reports of unexpected adverse events and unanticipated problems involving risks to subjects. Including, if available, data safety monitoring reports. Progress/interim reports that include reports of protocol breaches of confidentiality, violations and/or deviations, and any other instances of noncompliance.

4.2 Criteria for Approval:

The IRB ensures the following specific criteria are met for approving research involving human subjects:

1. **Minimization of Risks**: Risks to subjects are minimized:
    1. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, **and**
    2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. **Risk-Benefit Ratio**: Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. **Equitable Selection of Subjects**: Selection of subjects is equitable. In making this assessment, the IRB should consider the research's purposes and the setting in which it will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. **Informed Consent**: Each subject or their legally authorized representative must provide informed consent as required by 45 CFR 46.116. Consent should be appropriately documented or waived per 45 CFR 46.117.
5. **Deception or Withholding of Information:** If deception or withholding of information is necessary for adequate testing of the hypotheses and there is no practical alternative:
    1. Sufficient justification must be provided that the potential benefits to the subject or the importance of the knowledge to be gained outweigh any potential risks that may be present as a result of such deception.
    2. Assurances of acceptable debriefing must be provided, if appropriate. The PI must give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if, in the judgment of the IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period. In cases where deception is unavoidable and may result in emotional stress, full debriefing is mandatory immediately following completed participation.
6. **Adequacy of Facilities and Resources:** The adequacy of facilities and other resources necessary for the completion of the study and protection of subjects' rights must be assessed.
7. **Data Monitoring**: Adequate provisions must ensure data monitoring to protect subject safety.
8. **Privacy and Confidentiality**: Measures to protect subject privacy and maintain data confidentiality must be in place.
9. **Protection of Vulnerable Subjects**: When some or all subjects are likely vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons), additional safeguards are integrated into the study to protect their rights and welfare.
10. **Protocol Completeness:** The protocol explicitly outlines the design and procedures from inception to completion.

4.3 Training:

In order to conduct research, all key research personnel must complete a training course online. Studies will not be approved if required training has not been completed. All active staff must complete the necessary training via CITI program (*as applicable*):

1. Responsible Conduct for Research. [*required for all*]
2. Human Subject Research Investigators. [*required for studies involving human subjects*]
3. Data or Specimens Only Research. [*required for studies only involving data or specimens*]
4. Good Clinical Practice. [*required for clinical studies]*

On the CITIProgram website, log in via SSO to begin training. If you do not have a pre-existing account, create a new account using the UMassD email which will automatically add UMassD as an affiliation. If there is a pre-existing CITI account, then UMassD must be added as an affiliation. Once logged in, go to "Add Affiliation" then search for "University of Massachusetts Dartmouth". Once selected, the user is prompted to enter their UMassD email. The IRB is unable to access CITI accounts affiliated to any other institution. Once affiliated, the user must go to "Add a Course" to select course assignments as identified before from the UMassD CITI subscription. Alternatively, the IRB can accept comparable CITI certificates of completion which have not yet expired but are completed under another affiliation.

4.4 Timeline:

Different types of studies have different timetables for review. Exempt studies, posing minimal risk to human subjects, take approximately 2-3 weeks to approve from the date received by the IRB. Expedited studies take approximately 2-4 weeks to approve from the date received by IRB. Depending on the time of year, it could take longer than this time frame for IRB approval due to an increase in research studies needing IRB approval. It is important to remember studies requiring full board review require a convened full board meeting, which may require additional time. Full board studies are generally reviewed monthly, during scheduled full board IRB meetings. A study must be submitted on or before the agenda deadline to be reviewed by the board at that month's meeting. Notification of determinations reached at the full board meetings are emailed to PIs within three business days after the meeting date.

Section 5: Elements for Consideration:

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5.2 Recruitment and Advertisements:
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- 5.2.1 Advertisements

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5.1 Site Letters

Research conducted on private premises or off the University of Massachusetts Dartmouth's campus likely requires approval of the host site. For domestic study sites, the letter of support serves to grant permission for the researcher to conduct research at that site, should be on formal letter head, and signed by a party responsible for research and/or the conduct of similar activity at the site. For example, school district letters are typically signed by the superintendent for schools in that district. Letters from private institutions should be signed by a director, executive, owner, or other appropriate official. For international study sites, researchers must rely on local experts/leaders to provide insight on the host country standards of human participant protection and attest to the protocol's conformity to the standards for each international site via a letter of cultural appropriateness.

5.2 Recruitment and Advertising

5.2.1 General Recruitment

Recruitment and advertising materials are considered an extension of the informed consent and participant selection process. Consequently, recruitment activities cannot commence until the IRB has granted approval. All recruitment methods and materials, including flyers, letters, brochures, email advertisements, radio announcements, and similar items, must be reviewed and approved by the IRB before use. These materials must also be submitted for review and re-approval during the continuing review process. The content must avoid creating undue influence or containing misleading or exculpatory language.

Ethical Considerations:

- **Avoid Undue Influence:** Ensure any compensation or incentives are reasonable and do not unduly influence participants. Avoid high-pressure tactics that might create a sense of urgency.
- **Privacy and Confidentiality:** Handle personal information collected during recruitment confidentially and protect privacy. Implement measures to safeguard contact information.
- **Inclusivity and Fairness:** Ensure recruitment practices are inclusive and non-discriminatory, making efforts to reach under-represented groups. Recruitment materials should be accessible to people with disabilities and available in multiple languages if needed.
- **Cultural Sensitivity:** Tailor recruitment materials to respect cultural and social norms, avoiding culturally insensitive or offensive language and imagery.
- **Transparency:** Clearly disclose the identity of the researcher(s) and their institutional affiliation. Inform potential participants of any potential conflicts of interest that may affect the research. If applicable to the study design, or required by a funding agency, the PI is responsible for tracking the ethnicity or race of participants who are recruited into studies. In such cases, investigators should ask participants to self-identify at the time of consent.

Common Recruitment Methods:

All recruitment methods must be described in the protocol application, common recruitment methods include:

- **Advertisements:** Use flyers, notices, and/or media to recruit subjects, such as flyers posted in public settings, newspaper ads, and radio and television advertisements.
- **Direct Recruitment:** Approaching people in public settings, snowball sampling, use of social networks, and social media.
- **Research Subject Pools:** Utilizing the research subject pools for participant recruitment.
- **Introduction Letters:** Provide colleagues with an IRB-approved introduction letter describing the study. Researchers must not access participant/patient names, addresses, or phone numbers; interested individuals must initiate contact.
- **Referral Requests:** Send an IRB-approved letter asking for referrals of eligible participants. Researchers may provide the referring individual with IRB-approved recruitment material for distribution to potential participants. Interested participants must contact the researchers for additional information.

Recruitment from Medical Practices or Facilities

For studies involving patients from a medical practice or treatment facility, investigators not affiliated with the practice or facility must not directly recruit patients. Initial contact must be made by a physician or an employee of the practice or facility. Recruitment can, for instance, be in the form of a flyer posted in the waiting area or handed to potential participants by a physician or employee. Due to HIPAA regulations, medical practices or treatment facilities may not provide telephone numbers or addresses of their patients.

5.2.2 Advertisements

Advertisements should contain information that provides enough detail to allow the prospective participant to determine his/her eligibility and interest.

Elements of any advertisement to recruit participants should be limited to the following:

- **Name and Affiliation:** The name of the Principal Investigator (PI) and their UMass Dartmouth department.
- **Research Description:** An accurate and concise description of the research purpose or condition under study (e.g., "Comparing low fat vs. low carb diets for weight loss" or "Studying acculturation of Cuban immigrants").
- **Eligibility Criteria:** A summary of key eligibility criteria (e.g., acceptable age range, physical limitations) that will be used to include or exclude participants.
- **Benefits:** A straightforward and truthful description of any benefits to participants (e.g., "Free health screening").
- **Compensation:** If applicable, a statement about the availability and amount of compensation (e.g., "Participants may receive up to $100").
- **Commitment:** Information about the amount of time or other commitments required from participants.
- **Location and Contact:** The location where the research will take place and contact information for obtaining additional details.

Advertisements ***cannot*** incorporate elements that:

- State or imply a certainty of favorable outcome or other benefit beyond what is in the informed consent form.
- Use overly enticing language like "free" or "exciting."
- Visual effects which may create undue influence, use of text in all capital letters or an extra-large font while the rest of the ad is in lower case or a smaller font.
- For FDA regulated research studies (new drugs/devices) or studies on nutritional supplements:
    - Make claims that the supplement, drug, device or biologic is safe or effective for the purpose under investigation or that the supplement, drug, device or biologic is known to be equivalent or superior to any other supplement drug, device or biologic.
    - Use terms such as "new treatment," "new supplement" or "new medication" without identifying it as investigational.

Recruitment/Advertising Tips and Suggestions

- **Understand the Target Population:** Identify the media channels and platforms that are commonly used by the target population. Determine where they typically seek information and tailor your recruitment strategies accordingly. What media does the population read or view? Where do they go for information?
- **Efforts to Recruit Diverse Groups:** Make deliberate efforts to include participants from minority and under-represented groups. Clearly describe these efforts in the protocol application to ensure inclusivity.
- **Clarity and Accessibility:** Ensure that recruitment flyers and materials are easy to read and understand. Use lay language suitable for an 8th-grade reading level (similar to popular magazines and newspapers). Choose font styles and sizes that are easy to read, such as Times New Roman, Arial, or Garamond.
- **Email and Online Recruitment:** For recruitment via email, listservs, social media, etc., include the statement: "This research study was approved by the UMass Dartmouth IRB, Protocol # _____."
- **Privacy and Confidentiality:** Ensure all recruitment materials and methods respect the privacy and confidentiality of potential participants. Avoid using personal data without consent and ensure any personal information collected during recruitment is securely handled.

5.3 Compensation

The guidelines outlined below are meant to help investigators determine a reasonable amount of compensation that can be given to research participants and place some boundaries on what is and is not "reasonable." Compensation for research participants should be reasonable, considering the time involved, inconvenience to the participant, and any costs incurred while participating. The compensation should not be so large as to constitute a form of coercion. Compensation of approximately the current minimum wage would be considered reasonable.

IRB Considerations:
During the initial review of a research protocol, the IRB reviews both the amount of compensation proposed and the method and timing of disbursement to ensure neither are coercive or present undue influence. The following are some guidelines:

- **Compensation Details**: The amount of compensation in the informed consent document is clearly stated.
- **Accrual of Compensation**: Compensation should not be contingent upon completing the study but instead accrues as the study progresses.
- **Bonuses and Incentives**: Bonuses or incentives for completing a study or reaching milestones are acceptable, provided they are not coercive. The IRB will determine if the incentive amount is appropriate.
- **Compensation for Withdrawal:** Compensation for participants who withdraw should be provided promptly, ideally close to the point of withdrawal to avoid undue delay. For instance, compensating a participant soon after withdrawal from a long-term study is acceptable. However, it would not be inappropriate to compensate a participant at the end of a three-day study if they withdrew on one day.
- **Third-Party Payments**: Payments to a third party for a participant's involvement are discouraged, as they can be perceived as coercive.

Consent Form Considerations:
Researchers should ensure their compensation plan listed within the consent form addresses:

- **Conditions on Compensation**: An explanation of any conditions on compensation. *Example: "You will receive compensation at the rate of $15 per hour with an additional $5 bonus on study completion".*
- **Amount and Form**: Clearly outline the amount and form of compensation. *Example: "For this 1-hour study you will receive $20 upon study completion in the form of an Amazon gift card.".*
- **Distribution Method:** A description of how compensation will be distributed, including any required information collected. *Example: "At the conclusion of each study day, participants will receive an email with the amount and form of compensation specified above. Contact information will be stored separately from data and will not be made public."*
- **Compensation for Withdrawal**: Circumstances under which participants may or may not be compensated. *Example: You may stop participating in this study at any time at which point you will be eligible for the prorated compensation of $15 per hour".*

Documentation Considerations: Investigators responsible for keep a compensation which keeps track of:

- Participant ID
- Gift Card#
- Dollar amount
- Researcher Name
- Researcher Signature
- Date Distributed
- Participant Signature (or a check mark confirming disbursement)

For online gift cards, keep copies of the online receipt and, if applicable, confirmation that the participant received the gift card should be kept with the log. Ensure compensation records are kept confidential and separate from research data to protect participant privacy. If anonymity is required, the participant's signature may be omitted and replaced with a check mark confirming disbursement.

For more information, please see Guidance on Use of Gift Cards for Human Subject Participant Guidelines.

Course Credit Incentives
If participants in research will receive course credit instead of monetary compensation, researchers should consult the Guidance on Students as Research Participants resource for more information and guidance.

External Funding for Compensation
UMassD requires all external funding for compensation to be managed through either the researcher's department or the Office of Research Administration (ORA). Departmental funding will be distributed via college specific protocols and all other funding sources will be managed through a study account set up by the ORA. Upon receiving IRB approval for the study, researchers should contact the appropriate departmental or ORA personnel to establish their account. Student researchers will need their sponsoring faculty on the account. For more information, please contact ORA via email at ora.info@umassd.edu.

5.4 Informed Consent

Investigators shall obtain legally effective informed consent from a participant or the participant's legally authorized representative before involving a human participant in research unless a waiver of informed consent is approved is requested and approved in the IRB application process. Consent shall only be obtained under circumstances that provide sufficient opportunity to discuss and consider whether to participate and that minimize the possibility of coercion or undue influence. The information presented shall be in clear language and must include the information that a reasonable person would want to have to make an informed decision about whether to participate, and an opportunity to discuss that information.

The informed consent must begin with a concise and focused presentation of the key information which facilitates comprehension of the reasons why one might or might not want to participate in the research. The informed consent must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the understanding of the reasons why one might or might not want to participate. No informed consent may include any exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. A copy of the consent form shall be given to the person signing the consent form.

5.4.1 Elements of Informed Consent include:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- For research that involves the collection of biospecimens, include both of the following statements:
    - A statement that clarifies whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) **and**
    - A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

- For research that involves the collection of identifiable private information or identifiable biospecimens, include one of the following statements:
    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- A statement that the particular treatment, intervention, or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For FDA regulated research:
    - A statement which clarifies information about all experimental procedures the will be completed during the clinical trial.
    - A statement that clarifies the possibility that the FDA may inspect the records.
- For applicable clinical trials, the following statement is to be included: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time."

5.4.2 Written Documentation of Informed Consent

Documentation of consent entails prospective participants, their legally authorized representative (LAR), or the parents or legal guardians of children who are potential participants being presented with a consent document on which they sign their name to document that they agree to participate in the study. This can also be done electronically. A copy is given to the participant. Participants and their legally authorized representatives must be given ample time to review the consent with the study team. However, if certain criteria are met, the study team has the option to request alterations of the consent process. Below you will find the different types of obtaining informed consent. Please note that regardless of the method of consent, all approval criteria for the consent process must be met. Consent is usually obtained concurrently with an authorization to view the Personal Health Information (PHI), personally identifiable information (PII), or student education records for participants. At UMassD, authorization is obtained on the same document as the consent. You must describe your process for obtaining informed consent for participation in the protocol.

Situations When Written Documentation Is Used

5.4.2.1 Written Consent

The typical Written Consent process takes place in person. A potential participant or their Legally Authorized Representative (LAR) is provided a physical copy of the consent form during the consent process. The research team will discuss the study in depth with the potential participant/LAR and answer any questions they may have. Sufficient time will be provided to the individual/LAR to consider participation, including the opportunity to discuss the research study with anyone outside of the study team. If the participant/LAR chooses to take part in the research study, a written signature and date is obtained from the participant/LAR, as well as the person obtaining consent, and a signed/dated copy is provided to the participant.

5.4.2.2 Electronic Written Consent (eConsent)

Electronic Written Consent captures an electronic signature and date from the study participant as well as the person obtaining consent, often referred to as "eConsent", can take place either in person or remotely. Study teams may also opt to consent individuals in person using an electronic device such as a tablet or computer. Alternatively, they may remotely consent participants in their home or other sites, using email or electronic platform, with a telephone call or meeting via teleconference. The Investigator and/or their delegate is responsible for carrying-out an effective informed consent process, whether it is in person or remote. The protocol should describe this process, including steps to verify the identity of the participant, ensuring an in-depth discussion of the study and answering all questions. The OHRP & FDA Use of Electronic Informed Consent Guidance may be useful in developing your electronic/online informed consent process, including verifying the identity of participants that are consented electronically. Different platforms can be used to obtain valid electronic signature such as: Qualtrics, DocuSign, AdobeSign, RedCap among others. If your study is FDA-regulated or is obtaining HIPAA authorization, the platform must be secure and compliant with 21 CFR Part 11.

It is considered a best practice to document in the participant file that the informed consent process has occurred. The study team should document the consent process in the study record.

5.4.3 Waiver of Documentation

Potential participants, or the parents of children who are potential participants, are presented (either verbally or in writing) with the same information required in a written consent document, but documentation of the process (signing of the consent form) has been waived by the IRB. This process is often used in minimal risk research involving the administration of online or mailed surveys, telephone interviews, or when anonymous sensitive information is collected and there is a desire to not have written documentation that links the participant to the research study. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

Conditions for Approval

If the written script of the information to be provided orally (if consent is obtained in person) or electronically displayed include all required and appropriate elements of consent, the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if the research is not FDA regulated and one of the conditions below are true:

1. "*The only record linking the participant, and the research would be the informed consent form AND the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or LAR) will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern*." This criterion may be applicable to research on sensitive or stigmatizing topics such as HIV, domestic violence, illegal activities, etc.
2. "*The research presents no more than minimal risk of harm to participants AND involves no procedures for which written consent is normally required outside of the research context*." This criterion is often applicable to minimal risk surveys, interviews, and focus group research.
3. "*The participants or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to participants, AND there is an appropriate alternative mechanism for documenting informed consent*." This criterion may be applicable to minimal risk research with indigenous populations or international research.

It is **not appropriate** to request a waiver of documentation of informed consent for human subject projects that collect biospecimens.

Situations When a Waiver of Documented Consent Is Used

5.4.3.1 Verbal/Oral Consent

Some minimal risk studies may qualify for verbal consent. Verbal consent can take place over the phone, a teleconference platform such as Zoom, teams, or even in person. This can include use of a verbal informed consent script and/or providing the potential participant with a document describing the study (with required elements of informed consent) in combination with a discussion between the participant and study team. The study must meet the waiver of documentation of consent criteria for the study team to obtain verbal consent. Verbal consent does not require a signature from the participant; it is sufficient for the participant to verbally agree to take part in the research study as witnessed by a consenting study team member. It is considered a best practice to document in the

participant file that the verbal consent process has occurred. The study team should document the consent process in the study record, such as with a documentation of consent process form or note-to-file.

5.4.3.2 Online Consent

Some minimal risk studies may qualify for online consent or emailing of a document that does not capture the participant's electronic signature. For example, a simple online survey study may meet the criteria for a waiver of written documentation of consent. If so, the participant can simply select 'I agree' or 'I disagree' or 'continue' to consent to participate rather than providing an electronic signature. Different platforms can be used to obtain online consent without documentation of signature, such as REDCap, Qualtrics, Survey Monkey, etc. The platform must be able to determine who provides consent. Note: If PHI/PII is obtained with verbal/online consent, an alteration of HIPAA authorization must be obtained.

5.4.4 Waiver of Informed Consent

Some minimal risk studies, where it is not possible to obtain informed consent, may qualify for a waiver or alteration to the requirements of informed consent. This means that all or some of the elements of informed consent may be waived. The protocol should include the justification for how the study meets the required waiver/alteration criteria. For example, a data review protocol where many participants may no longer be coming to the institution and the study would not be feasible without the waiver of informed consent. This waiver applies in the special circumstances when the IRB determines that it is not necessary to obtain the participants' consent to conduct the research.

Situations When a Waiver of Informed Consent Is Used

The IRB often grants a waiver of consent for retrospective chart review studies. On rare occasions, prospective collection of data through intervention or interaction with participants may be granted a waiver of consent. With compelling reason, a waiver of consent may be granted for studies where secondary participants may be involved and it would be either prohibitive or potentially dangerous to obtain consent. For example, parental permission for a child to participate may be waived if consenting the parent could be detrimental to the child. As another example, some research designs require that participants be left unaware of the particular purpose of the research, because the participants' responses might be biased if they know in advance what the investigators are seeking. Such research designs do not preclude offering potential participants information about the research and giving them the opportunity to decide whether to participate.

5.4.5 Waiver of Parental Consent

The IRB may waive the requirements for obtaining parental or guardian permission if the determines that a research protocol is designed to study conditions in children or a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), and the following 2 additional criteria are also met:

1. An appropriate mechanism is in place to protect the children, and
2. The waiver is not inconsistent with federal, state, or local law (45 CFR 46.408(c)). The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition (45 CFR 46.408(c)). Note that an IRB may waive the requirement for obtaining parental or guardian permission under 45 CFR 46.408(c) even if the research involves more than minimal risk to the child subjects.

5.4.6 Alteration of Consent, Deception, and Debriefing

The IRB may approve research involving deception, incomplete disclosure, or alteration of informed consent if it meets all applicable regulations. Deception occurs when participants are deliberately given false information about some aspect of the research, while incomplete disclosure occurs when they are not given information about the real purpose or the research's nature. Under HHS regulations, the IRB can waive the requirement for obtaining informed consent or parental permission or to approve a consent procedure that leaves out or alters some or all of the elements of informed consent otherwise required under the regulations. However, the FDA allows this only in special circumstances.

Use of Debriefing for Deception Studies

Researchers may find the use of deception or incomplete disclosure necessary for their study. The IRB will closely review such techniques. Deception or incomplete disclosure should be justified in the IRB protocol submission, which should not be submitted for Exempt Review. Depending on the deception, the study will be reviewed under Expedited or Full Board Review processes.

Preparing Your Protocol Submission for Deception Studies

1. **Justifying the Use of Deception:**
    - Justify the use of deception in the Study Procedures Section, explaining why it is necessary to achieve the study's goals. Provide prior evidence and data showing that such methods do not negatively affect subjects' attitudes.
    - Explain the process to debrief participants in the Procedures Section. Include details on when, who, and how the debriefing will occur. Address if the deception is likely to cause psychological discomfort and how this risk will be minimized.
    - When incomplete information is provided in the consent document, it should be labeled simply as a consent document, not "informed" consent. The IRB must waive certain required elements of informed consent in such instances.
    - Provide a copy of the debriefing statement(s) and any scripts used to orally explain the study.
2. **Debriefing Requirements and Process:**
    - The debriefing must be an essential part of the consent process and is mandatory when the research involves deception. It provides a full explanation of the hypothesis, procedures, and reasons for deception.
    - Participants should be debriefed immediately after the study and given a debriefing statement to take with them. For online studies, debriefing should occur as soon as a participant completes the research activity, with an email follow-up if necessary.
    - The IRB must review and approve the debriefing statement.
    - The debriefing process must be explained in your IRB submission, including who will conduct it. The debriefer should be a knowledgeable research team member.
3. **Debriefing Form Should Include:**
    - Study title
    - Researcher's name and contact information
    - Thank participants for their participation
    - Explain the study's purpose, hypothesis, and aim in lay terms
    - Explain how and why participants were deceived
    - Describe how deception results will be evaluated
    - If applicable, give participants the opportunity to withdraw consent for the use of their data or recordings
    - Offer to provide study results
    - Provide references for further reading and a list of resources for participants if they experience distress

5.4.7 HHS Scenarios for Possible Waivers

For adults and children, a waiver or alteration of the requirements for obtaining informed consent can occur under any of the following three provisions set forth by HHS:

1. Research in general: an IRB may waive or alter the requirement of informed consent under 45 CFR 46.116(d), provided that the IRB finds and documents that all of the following four conditions are met:
    1. the research involves no more than minimal risk to the participants;
    2. the waiver or alteration will not adversely affect the rights and welfare of the participants;
    3. the research could not practicably be carried out without the waiver or alteration; and
    4. whenever appropriate, the participants will be provided with additional pertinent information after participation.
2. Public benefit or service programs: an IRB may approve a consent procedure that alters some or all the elements of informed consent, or waive the requirement to obtain informed consent under HHS regulations at 45 CFR 46.116(c), provided that the IRB finds and documents that both of the following conditions are met:
    1. the research could not practicably be carried out without the waiver or alteration; and

2. the research or demonstration project is to be conducted by or participant to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    1. public benefit or service programs;
    2. procedures for obtaining benefits or services under those programs;
    3. possible changes in or alternatives to those programs or procedures; or
    4. possible changes in methods or levels of payment for benefits or services under those programs.
3. Research in emergency settings: an IRB may also waive the requirement for obtaining informed consent if it finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings.

5.4.8 FDA Scenarios for Possible Waivers

The FDA only permits an IRB to approve a clinical investigation without participants' informed consent in the following circumstances:

1. Emergency Use From HHS: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html
2. Exception from Informed Consent for Planned Emergency Research FDA: https://www.fda.gov/media/80554/download
3. Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable FDA: https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation
4. Circumstances when the U.S. President may waive informed consent for military personnel for administration of an investigational product to members of the armed forces

5.4.9 Legally Authorized Representatives and Guardians

Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative. Investigators are to follow this procedure when obtaining permission for adults unable to consent or children to take part in research.

When research is conducted in Massachusetts, the following individuals meet these definitions:
For research that involves medical treatment:

- A "health care agent" refers to an individual authorized under M.G.L. c. 201D to make medical decisions on behalf of another who lacks the capacity to consent. This authority is granted through a health care proxy executed by a competent adult. If no health care proxy exists, medical care providers may accept consent from a "responsible party" as defined by common law principles.
- A "guardian" as defined in M.G.L. c. 190B § 5-101; however, the health care decision of a health care agent takes precedence over that of a guardian.

For minimal risk non-medical research:

- A "guardian" as defined in M.G.L. c. 190B, § 5-101. ("a person who has qualified as a guardian of a minor or incapacitated person pursuant to court appointment and includes a limited guardian, special guardian and temporary guardian, but excludes one who is merely a guardian ad litum.")
- For non-medical research that presents more than minimal risk, it is unclear whether a legally authorized representative for an incapacitated adult in Massachusetts can provide consent. The IRB should consult with legal counsel before approving such studies to ensure that the proposed representatives meet the federal definition of a "legally authorized representative."

In Massachusetts:

- All individuals under the age of 18 years are considered children. Massachusetts law recognizes two instances where teenagers under 18 may have the legal capacity to consent to medical treatment: the emancipated minor and mature minor rules (e.g., married, widowed, divorced, a parent, member of the armed forces, managing their own finances, or pregnant). Note that these rules apply to medical treatment

and not to participation in research, and they are specific to Massachusetts. For more information, consult legal counsel.

- Unless the IRB has waived the requirement for consent, when research involves children, consent must be obtained from biological or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care. Contact legal counsel before obtaining consent from someone other than a parent.
- Children aged seven and older should be given the opportunity to assent.
- Federal regulations provide additional protections for children involved as research subjects. They require adequate provisions for the assent of the child when capable, considering the child's age, maturity, and psychological state. Although there are formal requirements for consent forms, assent forms are less formal. Investigators should create assent content that effectively informs children about the study.

Guidelines for Assent Forms:

- For research involving children, the IRB requires consent from the parent/legal guardian and, if the children are aged 7 years or older, assent from the children.
- Assent is defined as the child's affirmative agreement to participate. Failure to object is not considered assent.
- The assent document should explain the study's purpose, any discomforts or inconveniences the child may experience, and that participation is voluntary.
- The length of the assent form should be proportional to the study's complexity and the participants' age.
- The use of headings may improve readability.

Exception: If the research involves abortion, a female under the age of 18 who is not and has never been married is considered a child.

For research outside Massachusetts, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.

5.4.10 Additional Considerations:

The person consenting participants to the research may be the principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, or research team member. Regardless of who is obtaining consent, the Principal Investigator is responsible for ensuring the correct procedures are carried out. All discussions for consent should be conducted in a private and quiet setting. If at any point a participant/representative indicates that he or she does not want to take part in the research study, the process stops.

The consent process and procedure for obtaining consent may occur with:
• an adult capable of providing consent;
• the legally authorized representative when the participant is an adult unable to give consent;
• one or both biologic or adoptive parents when the participant is a child; or in the absence of a parent, a person other than a parent authorized under applicable law to consent on behalf of the child to participate in the research.

If the participant is an adult unable to provide consent, the IRB must have approved the protocol to allow the enrollment of adults unable to consent. If permission is obtained from a legally authorized representative this person must be in the class or persons approved by institutional policy or the IRB.

If the participant is a child, the IRB must have specifically approved the protocol to allow the enrollment of children. Permission is obtained from both parents unless: one parent is deceased, unknown, incompetent, not reasonably available; only one parent has legal responsibility for the care and custody of the child; or the IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.

If the participant/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the participant/representative. If the participant/representative cannot speak English, the IRB must have specifically approved the protocol to allow the enrollment of participants able to speak in language that the participant understands.

Vulnerable populations may require additional elements of consideration. If you plan to involve: pregnant women/fetuses, neonates, minors, wards of the state, undocumented immigrants, prisoners, or other vulnerable populations, please contact the IRB during your protocol development.

5.5 Vulnerable Populations:

5.5.1 Pregnant Women/Fetuses and Neonates

Proposed studies involving pregnant women may qualify for exempt or expedited review when no more than minimal risk is involved. The IRB will make the final determination. Studies requiring full board review will be reviewed and approved in accordance with the criteria of 45 CFR 46 Subparts A and B. For social/behavioral research involving pregnant women, the IRB determined that it will allow pregnant women to be enrolled in research involving interview, focus group, survey, or similar procedures without any additional safeguards. These studies will be reviewed by the IRB following equivalent standards as set forth in the Common Rule.

Pregnant Persons or Fetuses
To approve federally funded research involving pregnant persons or fetuses, the IRB must determine that the research meets the following conditions:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals and non-pregnant women, provide data for assessing potential risks to pregnant women and fetuses.
2. The risk to the fetus is posed solely by interventions or procedures that offer the prospect of direct benefit for the woman or the fetus; or, if no such prospect exists, the risk to the fetus is no greater than minimal, and the research aims to acquire important biomedical knowledge that cannot be obtained by other means.
3. Any risk posed represents the smallest possible risk in achieving the research objectives.
4. If the research offers direct benefit to the pregnant woman or both the pregnant woman and the fetus, or no prospect of benefit when the risk to the fetus is minimal and the research aims to acquire important biomedical knowledge, the pregnant woman's consent is obtained in accordance with informed consent provisions.
5. If the research offers direct benefit solely to the fetus, the consent of both the pregnant woman and the father is required, except when the father is unavailable, incompetent, temporarily incapacitated, or when the pregnancy is the result of rape or incest.
6. All consent-providing individuals are fully informed of the reasonably foreseeable impact of the research on the fetus or neonate.
7. For pregnant children, assent and permission are obtained following the Special Protections for Children (45 CFR 46, Subpart D).
8. No inducements, monetary or otherwise, are offered to terminate a pregnancy.
9. Researchers involved in the study do not influence the timing, method, or procedures used to terminate a pregnancy.
10. Researchers involved in the study do not determine the viability of a neonate.

Neonates of Uncertain Viability
To approve research involving neonates of uncertain viability, the following conditions must be met:

1. Where appropriate, preclinical and clinical studies provide data for assessing potential risks.
2. All consent-providing individuals are fully informed of the reasonably foreseeable impact of the research on the neonate.
3. Researchers involved in the study do not determine the viability of a neonate.
4. The IRB determines that:
    - The research aims to enhance the probability of survival of the neonate to the point of viability, with the smallest possible risk to achieve this objective; or
    - The research aims to acquire important biomedical knowledge that cannot be obtained by other means, with no added risk to the neonate.
5. The legally effective informed consent of either parent or, if neither parent can consent due to unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either

parent's legally authorized representative is obtained. The father's consent is not required if the pregnancy is the result of rape or incest.

Nonviable Neonates
To approve research involving nonviable neonates, the following conditions must be met:

1. Where appropriate, preclinical and clinical studies provide data for assessing potential risks.
2. All consent-providing individuals are fully informed of the reasonably foreseeable impact of the research on the neonate.
3. Researchers involved in the study do not determine the viability of a neonate.
4. The vital functions of the neonate are not artificially maintained.
5. The research does not terminate the heartbeat or respiration of the neonate.
6. The research presents no added risk to the neonate.
7. The research aims to acquire important biomedical knowledge that cannot be obtained by other means.
8. The legally effective informed consent of both parents is obtained. If neither parent can consent due to unavailability, incompetence, or temporary incapacity, the informed consent of one parent is sufficient. The father's consent is not required if the pregnancy is the result of rape or incest. The consent of a legally authorized representative of either or both parents is not sufficient.

Viable Neonates
A viable neonate is one that has reached the point of gestation where it can survive outside the womb, either with or without medical assistance. This generally refers to neonates born after 24 weeks of gestation, though exact definitions can vary based on medical advancements and institutional standards. When research involves a viable neonate, it must comply with all applicable regulations for research involving children. This includes obtaining informed consent and assent as outlined in Subpart D of 45 CFR 46, which provides additional protections for minors involved in research. *See section on children/minors for more information.*

After Delivery, Placenta, Dead Fetus, or Fetal Material
To approve research involving after delivery, placenta, dead fetus, or fetal material, the following conditions must be met:

1. Research involving the placenta, dead fetus, macerated fetal material, or cells, tissues, or organs excised from a dead fetus must comply with all applicable federal, state, or local laws and regulations.
2. If information associated with the material is recorded in a manner that enables identification of living individuals, those individuals are considered research subjects, and all pertinent subparts of this section apply.

Research Not Otherwise Approvable
To approve research not otherwise approvable, the following conditions must be met:

1. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.
2. The Secretary of the Department of Health and Human Services, after consulting with a panel of experts in pertinent disciplines (e.g., science, medicine, ethics, law) and following a public review and comment period, including a public meeting announcement in the Federal Register, determines that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

5.5.2 Children/Minors

Research involving children is subject to the additional requirements of Subpart D. Under DHHS and FDA regulations, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. When any protocol involves children as research subjects, an expert in pediatrics should participate in the protocol's review.

Risk/Benefit Determinations and Review Process
The IRB must classify studies that involve minors into one of four groups, each with specific added responsibilities. Proposed studies involving children may qualify for exempt or expedited review if the study falls into one of the

federally approved categories defined in 45 CFR 46.101. Exemption categories 1-5 do not apply to FDA-regulated studies. The exemption noted at 45 CFR 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research involving children unless the research involves the observation of public behavior, and the investigator(s) do not participate in the activities being observed.

The IRB may approve only research that satisfies the following conditions:

1. **Research not involving greater than minimal risk.**
    - The IRB must find and document that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians. Consent from one parent is sufficient.
2. **Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects, only if:**
    - The risk is justified by the anticipated benefit to the subjects;
    - The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
    - Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians. Consent from one parent is sufficient.
3. **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, only if:**
    - The risk represents a minor increase over minimal risk;
    - The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
    - The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
    - Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians. Consent must be obtained from both parents if they have custody and are reasonably available.
4. **Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem that affects the health or welfare of children, which the IRB does not believe meets the above requirements of this section, only if:**
    - The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem that affects the health or welfare of children; and
    - The Secretary of the Department of Health and Human Services or the Commissioner of the Food and Drug Administration, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following the opportunity for public review and comment, has determined that either:
        1. The research satisfies the above requirements of this section, as applicable, or
        2. The following:
            - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem that affects the health and welfare of children;
            - The research will be conducted in accordance with sound ethical principles;
            - Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians. Consent must be obtained from both parents if they have custody and are reasonably available

Procedures

In considering the risks of a research study involving children:

1. The IRB interprets minimal risk in relation to the normal experiences of average, healthy, normal children.
2. In evaluating risk, the IRB considers the equivalence of potential harm or discomfort anticipated in research with the harm or discomfort that average, healthy, normal children may encounter in their daily lives or experience in routine physical or psychological examinations or tests.
3. The IRB considers the risk of harm or discomfort in relation to the ages of the children to be studied and assesses the duration, as well as the probability and magnitude of potential harm or discomfort in determining the level of risk.

4. The IRB interprets the phrase used in the regulations - "a minor increase over minimal risk" - as only slightly above minimal risk.
5. The IRB must determine that adequate provisions are made for soliciting the assent of children aged 11 and above.

Children in State Custody Criteria for Obtaining Consent to Enroll in a Research Study
For children residing in Massachusetts, the Department of Children and Families (DCF) may be involved with a family in two primary ways. Only the involvement through Care and Protection (C&P) impacts the process for obtaining consent to enroll in a research study, as outlined in state regulations 110 CMR 11.23 and DCF Policy #91-005 (revised 07/08/2008).

1. Care and Protection (C&P) Consent Requirements:
    - If the child is still residing with parents or family members, obtain consent from the DCF social worker managing the case. This social worker is authorized to consent for care, treatment, and research.
    - If the child is in foster care, obtain consent from the DCF social worker. Foster parents cannot provide consent unless specifically authorized by DCF. Additionally, if DCF is seeking court approval for the removal of parental rights, this may delay obtaining consent.
2. Child Requiring Assistance (CRA) Consent Requirements:
    - In a CRA, parents retain legal custody and must provide consent for medical decisions and research participation. DCF does not need to provide additional consent.
3. Determining Consent Authority:
    - If there is uncertainty regarding how DCF is involved or if there is a need for assistance with paperwork, contact the Boston Children's Hospital Office of General Counsel for guidance.
4. Applying Federal Consent Requirements:
    - Research Not Involving Greater Than Minimal Risk:
        - Obtain consent from the DCF social worker managing the child's case.
    - Research Involving Greater Than Minimal Risk with Prospect of Direct Benefit:
        - Ensure the risk is justified by the anticipated benefit.
        - The benefit-risk ratio should be favorable compared to available alternatives.
        - Obtain consent from the DCF social worker managing the child's case.
    - Research Involving Greater Than Minimal Risk and No Prospect of Direct Benefit:
        - The risk should be a minor increase over minimal risk.
        - The intervention should be comparable to experiences inherent in the child's current situation.
        - The research should yield vital generalizable knowledge.
        - Obtain consent from the DCF social worker managing the child's case.
    - Additional Federal Requirements for Greater Than Minimal Risk with No Direct Benefit:
        - The research must be related to the child's status as a ward or conducted in settings where the majority of participants are not wards.
        - Appoint an advocate who has no association with the research, investigator(s), or DCF, and who will act in the best interests of the child.
5. Procedures for Investigators:
    - Initial Protocol Application: Indicate whether the protocol could involve children in state custody and if you plan to offer the study to them. If Including Children in State Custody, document required findings and appointment of an advocate for research involving greater than minimal risk with no direct benefit.
    - Changes in Custody Status: Notify the IRB if the custody status changes. Ensure consent is updated accordingly if the child’s custody status changes between C&P and CRA.

Research in K-12 Educational Settings
Research involving K-12 educational settings requires careful consideration of ethical, practical, and regulatory issues. This document provides guidance on the essential elements of formulating an IRB submission for research in these settings, with a focus on gaining access to the setting, ethics and compliance, and protocol development considerations.

Gaining Access to the Setting

1. **Approval from Educational Authorities:**
    - Obtain formal approval from school administrators, district officials, or other relevant authorities. This should include a detailed description of the research, including objectives, methods, and any potential impact on the educational environment.
    - Include a letter of support from the school or district in your IRB submission.
    - Some school systems may require researchers to obtain criminal background checks before conducting research (e.g., CORI, SORI). Researchers must follow the requirements of the school system.
2. **Teacher and School Involvement:**
    - Discuss the role of teachers and other school staff in the research process. Clarify their responsibilities and any permissions required from them.
    - Provide information on how the research may affect their workload and classroom environment.
    - If necessary, engage with the broader school community, including parent-teacher associations and school boards, to garner support and address any concerns related to the research project.

Protocol Development Considerations

1. **Consent and Assent:**
    - **Consent for Recording:** Ensure that only participants who have consented to be recorded are included in video/audio recordings. If a participant has not agreed to be recorded, they must be out of the recording range, or their image/audio must be deleted from any recordings collected during the research process. Subsequent use of recordings must exclude participants who did not agree to be recorded.
    - **Informed Consent Process:** Provide clear and comprehensible information to parents about the research, including its purpose, procedures, potential risks and benefits, and their right to withdraw their child from the study at any time without penalty. Ensure that consent forms are written in language that is easily understandable for parents and guardians. Provide translations if necessary for non-English speaking parents.
    - **Child Assent:** Obtain assent from children in an age-appropriate manner. Explain the research in simple terms and ensure that children understand their participation is voluntary and that they can withdraw at any time. Use age-appropriate assent forms and adapt the language based on the child's developmental level.
    - **Special Considerations:**
        - **Students with Disabilities:** Include accommodations and considerations for students with disabilities or special educational needs in your consent and assent process.
        - **Non-English-Speaking Students:** Provide consent and assent materials in relevant languages to accommodate non-English speaking students and their families.
2. **Cultural Sensitivity:** Ensure the research design, methods, and interactions are culturally sensitive and respects the diverse backgrounds of students and their families.
3. **Data Destruction:** Outline the timeline and method for data destruction once the research is concluded to ensure that participant information is appropriately disposed of.
4. **Post-Research Communication:** Describe how findings will be communicated to participants, parents, and the school community after the research is concluded. Consider how you will share results in a meaningful and accessible way.
5. **Long-Term Impact:** Address any long-term impact the research may have on the school environment and how you will handle any ongoing issues that arise from the study.
6. **FERPA/PPRA Compliance:** FERPA restricts researchers' access to student records without written permission from parents. However, there are conditions under FERPA [20 U.S.C. 1232g(b)(1)(F)] under which student records can be disclosed without parental consent. Investigators must contact each institution and follow that institution's FERPA policy in addition to UMassD IRB requirements. PPRA outlines eight categories of protected information for survey responses. For more information, see FERPA (Family Educational Rights and Privacy Act) and PPRA (Protection of Pupil Rights Amendment).

5.5.3 Adults with Decisional Impairment

Research involving adults with decisional impairment—due to psychiatric, cognitive, developmental disorders, substance abuse, chronic pain, or temporary conditions such as sedation—poses unique ethical considerations. These

individuals may still be capable of providing informed consent; however, additional protections are required to safeguard their rights and welfare. If evidence indicates they cannot provide informed consent due to incapacity to understand, a legally authorized representative must sign and date the consent document. The IRB will determine whether the target population is appropriate, the research focuses on issues unique to the populations, the level of risk, and its participants are capable of providing consent/assent and whether a legally authorized representative must provide consent. Additional protections may be required, such as a witness to the consent process or requiring the PI to assess each individual's ability to provide consent, including asking participants to articulate the study's purpose, risks, and benefits in their own words. If participants cannot answer such questions, consent from a legally authorized representative must be obtained. The IRB must ensure that research involving this population adheres to federal and state regulations and maintains the highest ethical standards.

IRB Considerations:

1. **Selection of Subjects:**
   Absent extenuating circumstances, adults with decisional impairment may only be enrolled in:
   - Research that does not involve more than minimal risk.
   - Research that involves greater than minimal risk but presents the prospect of direct benefit to the individual.

   UMassD generally does not enroll adults with decisional impairment in:
   - Research involving greater than minimal risk with no prospect of direct benefit, even if it may yield generalizable knowledge about the participant's disorder or condition.
   - Any other research not otherwise approvable.

   A PI may request an exception to these principles by providing:
   - A description of why impaired adults should be enrolled.
   - Specific steps to protect these individuals.
2. **Assessing Competency:**
   When an adult is competent to give informed consent when they can:
   - Receive and understand information.
   - Process information.
   - Appreciate the situation and its consequences.
   - Weigh potential benefits, risks, and alternatives.
   - Make and communicate a decision.
   - Distinguish between research and treatment.

   Competency assessments may include general measures such as the Clinical Dementia Rating, Mini-Mental Status Exam, or activities of daily living scale. These should not be the sole mode of evaluation; higher-risk protocols may require formal medical assessments and open-ended interviews focusing on the study's risks, benefits, and alternatives.
3. **Informed Consent Process:**
   A two-part consent process is recommended:
   - **Assessment of Comprehension**: Understanding the factual details of the study.
   - **Personalized Understanding**: Understanding how the study's benefits, risks, and alternatives apply to the individual's situation.

   Consider using an independent professional to assess competency, especially for higher-risk studies. The PI must ensure that informed consent is obtained from capable individuals or their legally authorized representatives The consent process must clearly distinguish between research and treatment, ensuring participants are aware that they are consenting to research, not clinical care.
4. **Surrogate Decision Maker:**
   If an adult participant cannot provide consent and has not expressed dissent, a legally authorized representative must provide consent. According to federal law, this representative could include:
   - A court-appointed guardian with authority to make health care decisions.
   - A person designated as a health care agent under a valid health care proxy with express authority to consent to research.
   - A durable power of attorney with health care decision-making authority that includes express authority to consent to research.

   The research team must document the process for determining the legally authorized representative and attach or reference the relevant documentation in the research record.
5. **Participant Turning 18:**

If a child participant turns eighteen during the study, informed consent must be obtained from the now adult participant to continue their participation. If the now adult participant is impaired, the PI must follow the consent policies for impaired adults, and a new consent document must be signed with the appropriate legally authorized representative.

6. **Involvement of an Adult with Decisional Impairment in a Protocol Not Previously Considered:** If a impaired adult is enrolled in a protocol where their involvement was not anticipated, and the IRB did not consider the special protections for this population, the investigator must contact the IRB to discuss any necessary special arrangements to include the participant in the research.

5.5.4 Economically or Educationally Disadvantaged Individuals

Economically and educationally disadvantaged individuals may face unique vulnerabilities in research contexts. These vulnerabilities necessitate additional protections to ensure that their participation is ethical and informed. The IRB must carefully review protocols involving these populations to prevent coercion and ensure adequate understanding of the research.

IRB Considerations:

1. Protections and Safeguards:

- The IRB may require the use of a witness to the consent process of the consent process to ensure that participants are properly informed, and consent is obtained ethically.
- The IRB must evaluate whether the proposed protections for economically and educationally disadvantaged participants are adequate, strategies for minimizing coercion and ensuring clear understanding should be detailed in the proposal. Participants with educational disadvantages may struggle to understand complex research concepts. Investigators must present information in an accessible format, using clear and simple language, and provide additional explanations as needed. Compensation must be set at a level that fairly compensates participants for their time and effort without being so high that it unduly influences their decision to participate. The risks associated with participation should be clearly communicated. The IRB may require adjustments to the proposed protection measures to better safeguard the rights and welfare of economically and educationally disadvantaged individuals by revising consent procedures or altering compensation structures.
- The IRB may recommend continuous monitoring of the research protocol to ensure that the protections remain effective throughout the study and review feedback from participants to make recommendations for necessary adjustments to the research protocol.

2. Voluntary Participation:

- Incentives, whether financial or medical, must be proportionate to the risks, discomforts, and inconveniences of participation. Excessive incentives can be coercive, particularly for those with limited resources.
- Recruitment Materials must avoid promises of free treatment or overly emphasize the medical care provided during research. These materials should be written at an appropriate level for the target population and clearly convey the nature of the study and any associated risks.

3. Informed Consent Process:

- Use appropriate methods and materials for delivering consent information, considering educational deficits, learning disabilities, or cultural differences. Present research information in a format that suits the participant's comprehension level (e.g., visual aids, verbal explanations) and in a language they understand.

5.5.5 Non-English-Speaking Individuals

Research involving non-English speaking participants presents unique challenges with informed consent as well as their inclusion and exclusion in research. Ensuring participants can fully understand and consent to research requires careful attention to language barriers and cultural differences. While these studies may qualify for exempt or expedited review, the Chair or authorized designee reserves the right to require full board review. The IRB must ensure that protocols involving non-English speaking participants are designed to address these challenges adequately.

IRB Considerations:

1. Informed Consent:

- **Translation of Materials**: Consent forms, informational documents, and other study materials must be translated into the participant's primary language. Translations should be done by qualified individuals or professional services to ensure accuracy and clarity. The IRB requests attestation to verify that translations are accurate and culturally appropriate.
- **Communication**: Consent discussions and any verbal explanations must be conducted in the participant's primary language. Utilize qualified interpreters or bilingual research staff to facilitate these discussions.
- **Comprehension**: The participant's understanding of the research study is assessed; this can include follow-up questions or discussions to confirm comprehension or via a key point in the participant's language to reinforce understanding. Monitor participant feedback to address any issues that arise related to language barriers or comprehension.

2. Recruitment and Outreach:

- **Culturally Appropriate Materials**: Recruitment materials are available in the participant's primary language and tailored to their cultural context and avoid using jargon or complex language that may not be easily understood.
- **Community Engagement**: If appropriate, engage with community leaders or organizations that serve non-English speaking populations to facilitate recruitment and build trust.

3. Consent Process:

- When using interpreters, the interpreters must be impartial and understand the confidentiality requirements of the research. PIs must inform the participant that the interpreter's role is to facilitate communication, not to provide personal opinions or advice.
- Obtain written or verbal consent in the participant's primary language. Document the use of an interpreter and the translation of consent materials in the research records.

4. Cultural Sensitivity:

- **Understanding Cultural Differences**: PI must demonstrate awareness of cultural norms and practices that may affect the participant's perceptions and understanding of research within the research protocol. The submission adapts communication and consent processes to respect cultural differences.
- **Training for Research Staff**: PI is responsible for ensuring research staff are trained in cultural competency and understand the specific needs of non-English speaking participants.

5. Confidentiality and Data Security:

- **Language and Data Handling**: Implement measures to ensure that non-English speaking participants' data is securely handled, including using secure methods for storing and transferring data.
- **Access to Data**: Restrict access to study data to individuals who understand the participant's primary language to avoid misinterpretation.

5.5.6 Refugees and Undocumented Immigrants

Research involving refugees and undocumented immigrants presents unique ethical challenges due to their substantial vulnerabilities. As this population often faces legal, social, and economic difficulties, it is crucial to adhere to ethical principles and ensure that their participation is handled with utmost sensitivity and respect. Below is IRB guidance on the process and considerations for reviewing research involving these groups.

IRB Considerations:

- **Study Design and Purpose**: Respect the autonomy of participants by avoiding intrusive questions about their immigration status or social networks. The research questions and protocols are relevant and beneficial to the specific needs of refugees or undocumented immigrants and does not exploit their vulnerabilities. The study offers potential benefits to the participants or their communities.
- **Recruitment and Consent**: The study provides clear information, ensuring participants understand their rights and the scope of data use. A waiver of signed consent is requested if the study poses a risk to participants or consent is obtained before data collection.
- **Data Security**: The study does not directly ask about immigration status or personal social networks. Data protection measures are in place, including encrypted digital storage and secure physical storage for paper records. Ensure confidentiality and consider using a Certificate of Confidentiality (COC) from the respective entity/funding agency to protect privacy. ***Be aware of the COC's limitations in fully safeguarding undocumented immigrants.***
- **Cultural and Linguistic Sensitivity**: Study materials are tailored to accommodate different languages and cultural contexts. Materials are understandable and appropriate for the participants' education levels.

- **Continuous Communication**: PI plans to maintain an ongoing dialogue with participants about their involvement in the study, ensuring they are kept informed about the research progress and any findings that may affect them.
- **Plan for Adaptation:** PI plans to regularly review and adapt research protocols based on participant feedback and address unforeseen issues or risks.
- **Reporting:** Present research findings in a way that respects participants' confidentiality and highlights their contributions and experiences authentically.

5.5.7 Prisoners

Incarceration places prisoners under constraints that may impact their ability to make truly voluntary and uncoerced decisions about participation in research. Prisoners are therefore considered a vulnerable population that warrants additional protections. Research involving prisoners must adhere to 45 CFR 46 Subpart C, which provides specific protections for this population. Key provisions ensure voluntary consent, confidentiality, and appropriateness of research. These protections apply to research involving individuals who are prisoners at enrollment or become prisoners during the study.

Categories of Permitted Research: The IRB must ensure the research falls into one of the following categories:

1. Study of incarceration effects, criminal behavior, or prisons, presenting no more than minimal risk and inconvenience.
2. Study of institutional structures or prisoners as incarcerated persons, presenting no more than minimal risk and inconvenience.
3. Research on conditions particularly affecting prisoners, such as prevalent health issues, with required consultation and notice by the Secretary.
4. Research on practices intended to improve health or well-being, with required consultation and notice if control groups are involved.

Examples of Prisoner Definitions

- **Prisoner**: Includes individuals sentenced to institutions, detained by statutes, or those pending legal proceedings.
- **Not Prisoners**: Includes individuals in community-based programs, voluntarily admitted psychiatric patients, or those incarcerated briefly without affecting research participation.

IRB Review Process

Protocol Submission Requirements

- Justification for prisoner inclusion.
- Procedures conducted within facilities.
- Involvement of detention facility staff.
- Recruitment and consent processes.
- Confidentiality and data protection measures.
- Incentives and distribution methods.
- Risk minimization and transportation arrangements if necessary.

IRB Reviewer Considerations

- Researchers are experienced or working with a mentor knowledgeable about research with prisoners.
- Research protocols are adjusted to account for the controlled nature of detention facilities.
- Detailed descriptions of research procedures, consent processes, confidentiality measures, and follow-up care are provided.

Convened IRB Review: All new research involving prisoners must be reviewed via a convened IRB.

1. **Prisoner Representative**: A qualified prisoner representative must be present at the IRB meeting when research involving prisoners is reviewed. This individual must be a voting member and review all materials related to the research.
2. **IRB Composition**: A majority of the IRB members (excluding prisoner members) must have no association with the prison(s) involved apart from their IRB membership.

3. **Findings Required**: The IRB must make the following findings before approving research involving prisoners:
    - The research falls into one of the permissible categories under 45 CFR 46.306(a)(2).
      1. Studies of possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
      2. Studies of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
      3. Research on conditions particularly affecting prisoners as a class, for example:
        - Vaccine trials and other research on hepatitis which is more prevalent in prisons than elsewhere.
        - Research on social and psychological problems (alcoholism, drug addiction, and sexual assaults). The study may proceed only after the HHS Secretary (through OHRP) has consulted with appropriate experts and has published notice of approval in the Federal Register.

      4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. Non-therapeutic research with a control group must be approved by the IRB and subsequently reviewed by the HHS Secretary. The Secretary's ruling, informed by consultation with experts, will be published in the Federal Register.
    - Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
    - Risks are commensurate with those accepted by non-prisoner volunteers.
    - Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that research project.
    - Information is presented in understandable language.
    - Privacy and confidentiality issues are addressed in the prison environment, such as the availability of private rooms to conduct interviews and involving prison staff in any part of the study.
    - Adequate assurance exists that parole boards will not consider a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole. AND
    - Where the IRB finds it necessary, adequate provisions are made for follow-up care.
4. **Minutes:** IRB meeting minutes must summarize protocol reviews, board discussions, stipulations, and actions taken. Documentation of Subpart C findings is required.
5. **Certification:** For HHS-funded research, the HRPP office will submit an electronic certification to OHRP indicating the study's approval, category, and compliance with six criteria under 45 CFR 46.306(a)(2). Research may not commence until OHRP approval is received.

Expedited Review: Expedited review procedures for research involving prisoners may only be used under specific conditions:

- Minor changes in previously approved research.
- Continuing review of research that is closed to new subjects, has completed all interventions, and is limited to long-term follow-up.
- Research with no subjects enrolled, no additional risks identified or limited to data analysis.
- Continuing review of minimal risk research with no additional risks.

Enrollment of Incarcerated Subjects

If the research population includes people who are likely to be jailed during a study — and whose participation the investigator would like to continue — the study should be reviewed as prisoner research. When individuals who

may be incarcerated during the course of the study—such as individuals on parole, those facing substance use challenges/addiction, individuals involved in sex work, or those experiencing homelessness—it is crucial to address these considerations with respect and cultural sensitivity as these individuals are at an increased risk of being arrested when compared to the general population. Research involving these populations should be reviewed under the standards applicable to research involving prisoners.

Key Considerations:

1. **Anticipate Potential Incarceration:** Investigators should assess and anticipate the likelihood that participants may become incarcerated during the study. This includes understanding the unique risks faced by these individuals and how such situations might impact their participation.
2. **Study Continuity:** The study protocol should outline how activities will be managed if a participant becomes incarcerated. Clearly specify which aspects of the study will continue and how the research team will handle potential disruptions in a manner that is respectful and maintains the participant's dignity.
3. **Adherence to Standards:** Research involving individuals who may be incarcerated must adhere to the same ethical and review standards as other research involving prisoners. This includes ensuring that the study meets the ethical requirements and protections specified for research involving incarcerated individuals.

By approaching the inclusion of these populations with sensitivity and respect, researchers can help ensure that the research is conducted ethically and with consideration of the unique circumstances of participants.

When a participant becomes a prisoner during a non-prisoner study:

- All research procedures must cease immediately.
- An amendment must be submitted to include prisoners if continued participation is desired.
- If continued participation is deemed in the best interest of the prisoner, the IRB Chair may allow it until the amendment is reviewed.

5.5.8 Students

Studies that focus on students as participants may raise concerns with issues of coercion, undue influence and privacy. While these studies may qualify for exempt or expedited review, the Chair or authorized designee reserves the right to require full board review. For more information, please see IRB Guidance on Students as Research Participants.

5.5.9 Employees

Studies that focus on UMassD employees as participants may raise concerns of coercion, undue influence and privacy. While these studies may qualify for exempt or expedited review, the Chair or authorized designee reserves the right to require full board review. The IRB may consult with employees when considering approval of a study that involves them as participants.

Within each application that involves employees as participants, the PI must outline procedures to ensure that the employees will not be subject to undue influence or coercion and to ensure that the employee's privacy will be respected. While a PI/supervisor may use his/her own direct report employees as participants, the preference of the IRB is that the PI recruit employees with whom the PI does not have a direct relationship. For example, if the research study is an analysis of the performance evaluation process, the PI may recruit employees from the general population of the institution as opposed to employees from the PI's department. If colleagues or subordinates are recruited the PI must provide a rationale for their recruitment other than for convenience's sake.

Additional suggestions to minimize concerns of coercion, undue influence and privacy include the general recruitment of participants through IRB approved advertisements, collection of data in an anonymous method, the use of an independent third party to recruit, consent and/or collect data. The IRB will also closely review how study data is reported back to management.

The employee's participation must be voluntary and based on disclosure of complete and accurate information. Employees should not be asked to participate in any study that will interfere with their job obligations. An employee's decision to participate or not participate cannot have any bearing on the employee's performance evaluation.

5.6 Internet-Based Research

Internet-based research involves using the internet to collect data through online tools, studying online behaviors, or using online datasets. While offering powerful capabilities for data collection, analysis, and transmission, it also presents unique risks such as privacy ambiguities, data security concerns, and challenges with obtaining signed informed consent. All human subjects research utilizing the internet must be submitted for IRB review.

Types of Internet-Based Research

- **Online Surveys:** Using platforms like Qualtrics, Survey Monkey, Google Forms, etc., to gather data.
- **Behavioral Studies:** Examining how people use the internet by collecting and analyzing online activity data.
- **Online Data Use:** Utilizing datasets, databases, and repositories available on the internet.
- Crowdsourcing for Research: Using platforms like MTurk, Prolific, CrowdFlower, Clickworker, Appen, etc to recruit participants and perform tasks via online pool.

Common Concerns in Internet Research

- Lack of anonymity
- Privacy ambiguities
- Data security
- Participant authentication
- Data destruction
- Server/cloud storage

Preparing Your IRB Submission for Internet Research

1. **Recruitment:**
    - Include the title and description of the study in your application.
    - Clearly state the compensation, time required, and any qualification screeners.
    - Specify any software requirements and the type of tasks involved.
    - List the researcher's name and affiliation.
    - Include a link to the online survey if applicable.
2. **Consent:**
    - The first page of the survey should be the consent document, with "I Agree" and "I Do Not Agree" options. The "I Agree" option leads to the survey; the "I Do Not Agree" option exits the survey.
    - Address how participants will be informed about the study and any risks involved.
3. **Debriefing:**
    - If using deception or incomplete disclosure, include a debriefing form at the end of the survey.
    - The debriefing form should explain the study's true purpose, how participants were deceived, and offer participants the option to withdraw their data.
    - For particularly sensitive topics, ensure all participants, including those who exit early, receive the debriefing form. State in the consent form that participants may be contacted through the online survey platform for debriefing.
4. **Confidentiality:**
    - Anonymity cannot be guaranteed in online research environments. Avoid collecting personally identifiable information unless absolutely necessary. If participant IDs are collected, ensure they are kept confidential, not linked to survey data, and deleted after use.Protect participant identities and data by avoiding the collection of unnecessary identifiers, ensuring secure data handling, and understanding the platform's TOS regarding data use and protection.
    - Ensure worker IDs are kept confidential, not linked to survey data, and deleted after use.
    - Review the Terms of Service (TOS) of the online survey platform and software for policies on data collection, tracking, and third-party data sales to understand how participant data is managed and protected. Develop a protocol for handling data breaches and coordinate with IT to ensure data security. Communicate these measures to participants through the consent process.
    - Have a protocol in place for data breaches, possibly in consultation with IT, and communicate this in the consent form.

5.7 Crowdsourcing for Research

Crowdsourcing refers to the practice of obtaining input, ideas, or content by soliciting contributions from a large group of people, typically via an online platform. Crowdsourcing platforms enable researchers to connect with a diverse, often global, participant pool for data collection.

Examples of Crowdsourcing Platforms:
Several crowdsourcing platforms are commonly used in academic research:

- **Amazon Mechanical Turk (MTurk):** A popular platform offering access to a large, diverse pool of participants for various tasks and surveys.
- **Prolific:** A platform focused on academic research, providing high-quality data from a pre-screened participant pool.
- **CrowdFlower (now Figure Eight):** Offers a large-scale workforce for data labeling, classification, and other tasks.
- **Clickworker:** Provides a platform for microtasks, including data categorization, content creation, and surveys.
- **Appen:** Specializes in tasks related to AI and machine learning, including data annotation and linguistic data collection.

How Are Academic Researchers Using Crowdsourcing Platforms?
Researchers use crowdsourcing platforms to recruit participants for surveys, experiments, and various research tasks. These platforms facilitate quick and cost-effective recruitment, often providing access to a more diverse participant pool than traditional methods. Researchers post tasks or surveys, specifying the details such as task description, compensation, and estimated completion time.

What Do Academic Researchers Need to Consider When Submitting a Crowdsourcing Study to the IRB?

- **Recruitment:** The task or survey title and description on the crowdsourcing platform serve as recruitment materials and must be included in the IRB application.
- **Compensation and Timing:** Specify the amount of compensation and the expected time for processing payments. Inform participants about any delay in payment.
- **Task Requirements:** Detail any software or technical requirements necessary to complete the task (e.g., specific browsers or software). If there is a screening process, clarify whether participants are paid for screening and how qualifications are assessed.
- **Task Details:** Describe the nature of the task (e.g., writing, video watching) and its requirements. Higher compensation may be necessary for tasks requiring more effort.
- **Researcher Information:** Include the researcher's name and institutional affiliation in the task description.

IRB Considerations:
When submitting a crowdsourcing study to the IRB, researchers should:

- **Include Platform Details:** Provide information about the crowdsourcing platform and how it will be used for recruitment and data collection.
- **Detail Recruitment Materials:** Submit the task or survey description, including compensation and any specific requirements or qualifications.
- **Describe Data Management:** Outline how participant data will be handled, including any steps taken to ensure confidentiality and security.
- **Address Consent and Debriefing:** Ensure that the consent process is clear and that any debriefing procedures are well-defined.
- **Consider Participant Impact:** Evaluate any potential risks to participants and ensure that appropriate measures are in place to mitigate these risks.

5.8 International Humans Subjects Research

When it comes to international research, IRB concerns and considerations typically include:

1. **Cultural Sensitivity:** Being aware of and respecting cultural norms and practices of the participants, local communities, and stakeholders. This includes understanding how cultural differences might impact consent

processes and the interpretation of risks and benefits and ensuring that research benefits are shared and that local perspectives are considered, as applicable.

2. **Local Standards:** Ensuring that research adheres to both the laws and ethical guidelines of the host country, as well as international ethical standards like those from the Declaration of Helsinki. This includes following local data protection and privacy laws and obtaining a letter from a local ethical oversight body granting permission to conduct research in the host country. It also involves implementing mechanisms for ongoing monitoring and oversight that account for both local and international standards.
3. **Informed Consent:** Ensuring the consent process is culturally appropriate and that participants fully understand the research and its implications. This may involve translating consent forms and providing appropriate consent procedures.
4. **Risk Assessment:** Evaluating potential risks and benefits in the context of the local setting. This includes considering how what is deemed minimal risk in one country might differ in another, and addressing issues related to the vulnerability of participants, such as economic or social disadvantages that might be more pronounced in some regions.

Studies planning to conduct human subject's research internationally should complete the International Research Checklist and obtain a letter of cultural appropriateness. For more information, see IRB Guidance on International Research Involving Human Participants.

5.9 Establishing/Utilizing Subject Recruitment Databases

Researchers and the IRB share the responsibility for establishing a recruitment environment that adequately protects the rights and welfare of prospective participants (Belmont Report; 45 CFR §46.111(a)(3)). This ethical and regulatory guidance requires appropriate procedures for the initial identification, contact, and recruitment of potential subjects, demonstrating respect for the dignity and autonomy of participants while preserving confidential information and minimizing undue influence.

Generally, subject contact information acquired in a study should be destroyed at the end of the study. UMassD researchers wishing to maintain subject information for future recruitment must submit a request to the IRB. Such information would be intentionally maintained as a prospective tool to recruit volunteers for research. Databases must be maintained by one responsible, qualified UMassD researcher, and in most cases, subjects will fill out a consent form agreeing to the inclusion of their information into such a system.

NOTE: A collection of names, contact information, and date of birth only is not considered a subject recruitment database. This information may be maintained with the subject's permission. However, if personal information is to be maintained with the name, UMass researchers must seek approval to maintain a subject recruitment database.

Establishing a Recruitment Database

Establishing a subject recruitment database requires prior IRB review and approval. Applications to establish databases are requested via email outlining the researcher's plan for establishing a database and should address the following guidance:

1. **Responsibility and Access:** The database must be controlled by a qualified UMassD investigator (CITI-trained faculty member) who will oversee the data. Only qualified and authorized researchers with current IRB approval can access the data. The plan must describe:
    - Roles of other researchers with access.
    - Data update procedures.
    - Frequency of subject contact.
    - Expanded procedures for databases with sensitive data.
2. **Informed Consent:** A separate informed consent document specific to the recruitment database must be used. Standard elements of informed consent apply.
3. **Privacy and Confidentiality Protection Plan**: Describe how confidentiality will be protected, including:
    - Training for personnel and limiting access to authorized and qualified individuals.
    - Methods of organizing, storing, and protecting information against accidental or inappropriate release. Password protection and other security measures for portable devices.
4. **Recruitment Methods:** Provide all proposed methods for recruiting to the database. Standard recruitment methods apply. Recruitment from existing subject lists should occur only if subjects have previously agreed to further contact.

5. **Data Retention and Destruction:** Specify retention duration and detailed destruction protocols for when data is no longer needed or if a participant withdraws consent.
6. **Participant Communication:** Outline methods for keeping participants informed about the use of their data and any updates to the recruitment database. Provide mechanisms for participants to offer feedback or express concerns about their data.
7. **Participant Withdrawal**: Explain the process for participants to withdraw their information from the database. Detail how withdrawal will be managed to ensure participant rights and data integrity.
8. **Monitoring, Security, and Compliance**
    - Implement procedures for regular audits to ensure compliance.
    - Use encryption for storing and transmitting data.
    - Discuss strategies for minimizing risks associated with maintaining the recruitment database.
    - Implement physical security measures for non-electronic data formats.
    - Ensure the recruitment process is inclusive and does not disproportionately target or exclude specific groups.
    - Ensure the database complies with local, state, and federal regulations.

5.10 Confidentiality, Anonymity, and Privacy

Designing Confidential Systems
Researchers should design systems to ensure data confidentiality. Master-code sheets connecting participant IDs and names must be securely stored, password-protected, and/or encrypted. Data should be anonymized, and master-code sheets should be destroyed as soon as possible. To minimize risks to participants, research should be designed to be anonymous whenever feasible.

Considerations for Sensitive Data Collection:

- Exercise caution when collecting sensitive data from participants in public spaces to avoid accidental disclosure.
- Be aware of privacy concerns during recruitment, as volunteering for a study may reveal private details.
- Safeguard data collected or transmitted over the internet, considering potential privacy implications.

5.10.1 Anonymity is about identifiers. It refers to information/data or specimens that cannot be linked to the person from whom they were obtained because the information/data or specimens do not contain direct identifiers (e.g., name, address, birth date, IP address, etc.). In this case, the collected data is completely anonymous so the researcher cannot identify the participant.

5.10.2 Privacy refers to a participant's right to control the access of others to their personal information. The research proposal should outline strategies to protect privacy including how the investigator will access information from or about participants. Processes for protecting privacy should be described.

Guidance for Researchers Regarding Privacy
Follow the below guidelines to protect the research participants' privacy during screening, consenting, and conducting the research:

- Conduct research procedures in person and in a private setting.
- Capture and review data in a private setting.
- Limit access to research data and activities to authorized personnel only.
- Limit the collection of participant information to the amount necessary to achieve the aims of the research.
- Approach participants in a setting or location that preserves their physical privacy and minimizes the risk of information being overheard by unauthorized individuals.

Privacy concerns people and the collection of data, whereas confidentiality concerns the data itself.

5.10.3 Confidentiality
Confidentiality refers to the researcher's agreement with the participant about how the researchers manage participant data, including its storage, handling, and dissemination, and what will happen after the study is over and the data is presented (e.g., data will be destroyed after three years). The research proposal should outline strategies

to maintain confidentiality, detailing controls for data storage, handling, and sharing of data. Researchers can develop a data security that meets minimum standards and is particular to their study.

Guidance for Researchers Regarding Confidentiality
Consider how the research data/specimens will be labeled to align with research methodologies and requirements:

- **Identifiable:** Data and/or specimens will be directly labeled with personal identifying information.
- **Coded:** Data and/or specimens will be labeled with a code that the research team can link to personal identifying information.
- **Anonymous:** Data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information.

At a minimum, ensure the following measures will be taken to ensure confidentiality:

- Store physical information/specimens with appropriate safeguards, such as in locked cabinets or restricted areas limited to authorized personnel.
- Protect electronic data with security measures such as unique usernames/passwords and dual-factor authentication where feasible.
- Restrict copying and use of study materials.
- Install and regularly update security software (firewalls, antivirus, anti-intrusion) on all devices used in the study.
- Encrypt data on removable drives and during transfer.

IRB Considerations
The IRB evaluates research proposals strategies for maintaining confidentiality to assess:

- Adequacy of methods to shield participants' identity protect confidentiality.
- Plans for long-term confidentiality protection of research data, including a schedule for destruction of identifiers associated with the data.
- The recruitment materials clearly describe the study parameters.
- Adequacy of consent forms in describing confidentiality risks and data access and under what circumstances data may be shared (i.e., with government agencies, sponsors).
- The HIPPA authorization section should clearly identify what will be accessed, who will have access and for what purpose access is required, if appropriate.

5.10.4 The Health Insurance Portability and Accountability Act (HIPPA)

HIPAA is the federal legislation that governs all uses and disclosures of Protected Health Information (PHI), for both the living and the dead, to protect individual privacy. While UMassD is not a Covered Entity, some research projects may take place within other organizations that are Covered Entities such as healthcare facilities. In such cases, researchers must be prepared to use and control PHI in compliance with the provisions of HIPAA and any commitments the HIPAA defines the 18 identifiers that create PHI when linked to health information. The following identifiers are those of the individual or of relatives, employers, or household members of the individual.

- Names;
- All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census:
- The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
- The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Phone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social Security numbers;

- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

5.11 Custody of Research Data

All Research Data shall be preserved in the custody of, or as arranged by, the Principal Investigator on behalf of UMassD, and may include preservation with the grantor agency. The Principal Investigator (PI) has the primary responsibility for the collection, management, integrity, preservation, security, and destruction of Research Data, appropriate marking and reporting of all UMassD's intellectual property that may be included in, or derived from, the Research Data.
This includes ensuring that:

- **Protocols Compliance:** All research team members follow protocols, including ethical conduct without fabrication, falsification, or plagiarism.
- **Training:** All team members receive the required UMassD IRB trainings (e.g., CITI).
- **Documentation:** The study process is reconstructible, including retention of documents.
- **Data Security:** Data is stored and maintained properly and safely for the required retention periods.
- **Data Destruction:** Data is accurately and securely destroyed after the required retention period.
- **Data Quality:** Data is maintained with clarity, completeness, and organization so that an external reviewer can determine adherence to the IRB-approved protocol, institutional policies, and regulatory requirements.

For student theses and projects, the faculty sponsor (i.e., thesis chair/mentor) retains the primary responsibility of ensuring these responsibilities, regardless of whether the student is listed as a PI or Co-PI. In the event of the PI's incapacity, their supervisor must immediately designate an appropriate person to take custody of research data or take custody of the research data until other appropriate arrangements are made for alternative custody.

5.11.1 Storage and Transfer of Research Data

When storing research information, access should be limited to those individuals who have a specific research need to access the information.
Requirements for storing data include:

- **Access:** Limit access to research data to individuals with a specific research need.
- **Security Measures:** Implement complex passwords, avoid sharing accounts, limit room and system access, use locked storage areas (e.g., file cabinets, offices), and encryption when necessary.
- **Paper Documents:** Store in locked boxes and/or locked cabinets in designated research areas at UMassD. Use secure methods for transportation, such as locked briefcases or lockboxes.
  Online Materials: Use secure online storage systems, including UMassD-based secure online storage.
  Data Transfer: Use encrypted, secure transfer systems or approved transfer processes/systems required by the sponsor agency to share files between collaborators or sponsor agencies.

5.11.2 Retention of Research Data

The PI must ensure retention of research data documenting the methods and accuracy of data collection and interpretation is retained. If a participant subsequently withdraws from a study, the PI must document this and retain the database if there are publications/presentations based on the database containing the withdrawn participant's data.

Research Data disclosed or referenced in publications, including the primary experimental results, must be retained for a minimum of three (3) years from the date of study closure or the final expenditure report to the funding agency, whichever is longer.

In addition, any of the following circumstances may justify longer periods of retention:

- Sponsored research grants, contracts, and cooperative agreements may mandate different retention periods (including state and local sponsors which may require longer retention periods following the final project close-out).
- Data must be kept for as long as may be necessary to protect any intellectual property, including FDA drug/biologic applications resulting from the work
- If there are questions or allegations about the validity of the data or appropriate conduct of the research, the PI must retain all of the original research data until such questions or allegations have been completely resolved.
- If any charges regarding the research arise, such as allegations of scientific misconduct or conflict of interest, data must be retained until such charges are fully resolved
- Any research that involves collecting identifiable health information is subject to HIPAA requirements. As a result, records must be retained for a minimum of 6 years after each subject signed an authorization.
- If a student is involved, data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work

Data retained beyond these periods is at the discretion of the PI or the laboratory/department head. Research data is normally retained in the administrative unit (i.e. PI office/labor department office/lab) where generated and must be retained in a UMassD facility unless specific permission to do otherwise is granted by the Provost.

5.11.3 Access to Research Data

UMassD Access: Designated agents of UMassD have the right to access research data for research performed at UMassD, supported by UMassD-administered funds, or using UMassD facilities. Both the PI and UMassD retain the right of access regardless of the location of the PI or the Research Data. Access will be for reasonable cause, at reasonable times, and after reasonable notice, except in emergencies.

Sponsored Agencies: Sponsored agencies may also have access rights depending on funding and agency requirements.

Public Access: The public may request access to research data from federal agencies through the Freedom of Information Act (FOIA) and from UMassD for published research findings used by the Federal Government in agency actions. In these instances, consultation with the UMassD IRB, UMassD counsel, and the sponsoring agency is required, and information released may be restricted or limited as per laws and HIPAA regulations. This may include presentation of the data in a format (e.g., aggregate) to protect participants' privacy, avoid violating stipulated terms of the informed consent, and prevent triangulation of data to identify or contact participants. Sponsors such as the NIH, NSF, and others have policies governing the sharing of data and dissemination of research results, which the PI must comply with.

Information or data that would violate the confidentiality of sources or subjects involved in the Research shall not be disclosed except in accordance with law or regulation.

5.11.4 Transfer of Research Data

When required by law, regulation or contract, or to fulfill other obligations, UMassD may transfer title or custody of Research Data and records at its discretion (for instance, if required by a sponsor or funding agency). In such cases, UMassD, insofar as possible, will ensure access by Principal Investigators, Investigators and other appropriate individuals to that Research Data.

Research Data that is required to be transferred or shared with a sponsor/funding agency should be transferred using a secure encrypted transfer system, in accordance with UMassD and the sponsor/funding agency policies. If another method is used, it must be secure and approved by UMassD and the sponsor/funding agency.

When individuals other than the Principal Investigator who are involved in research projects leave UMassD, they may take copies of Research Data for projects on which they have worked unless restricted by the specific terms of the applicable agreement with the sponsor of the research. Original data, however, must be retained at UMassD by the Principal Investigator.

If a Principal Investigator leaves UMassD, they are allowed to retain or take copies of the Research Data. Additionally, they can request that a project be moved to another institution. Research Data may be transferred with the approval of the Provost for Research (or a designee), and with written agreement from the PI's new institution that guarantees: 1) its acceptance of custodial responsibilities for the data, and 2) UMassD's access to the data, should that become necessary. UMassD may impose conditions beyond those stipulated in this policy on such transfer, and may ask the PI to leave copies of the Research Data with UMassD. In addition, other UMassD investigators associated with a collaborative research project may make copies of Research Data prior to a permitted transfer by the Principal Investigator, unless restricted by the specific terms of the applicable agreement with the sponsor of the research. When UMassD permits the Principal Investigator to leave UMassD with original Research Data, he or she must retain the Research Data for the period required by this policy and recognize that UMassD may need access to the Research Data. Departing PIs have an obligation to hold the Research Data in trust for UMassD and must return the Research Data to UMassD if requested during the retention periods contemplated by this policy. In addition, during the required retention period, such Research Data must be available to external sponsors, designated governmental officials, and other UMassD investigators associated with the collaborative research project, as appropriate. Investigators should note that many contractual agreements require the sponsor's consent before Research Data are transferred or removed from UMassD. Before transferring the original Research Data, the Principal Investigator is responsible for ensuring that any special conditions stated in the grant, contract, or agreement are met.

5.11.5 Ownership of Research Data and University Disposition

Consistent with federal policy and prevailing high education practice, Research Data belongs to UMassD and PI. When research is generated pursuant to a contract or agreement, ownership of the data is defined by the contract or agreement, which may include a data management plan. The contract will be the determining document for the resolution of disputes. It is recommended that the IRB and/or UMassD counsel is consulted prior to finalizing this agreement. The details of the contract should define all policies, procedures and issues related to ownership, including publication and dissemination of findings. For research that is sponsored by a federal and state agency, ownership is generally shared between UMassD and the government agency. PIs should seek guidance from administrative officials at both institutions. In the event that data retention and maintenance practices are found to be contrary to this Policy, UMassD may make disposition of these Research Data and related property rights in a manner that is consistent with law and policy.

5.12 Data and Safety Monitoring

Data and Safety Monitoring is a critical component of research that ensures the safety of participants, and the integrity of the data collected. It involves systematic review and oversight of the research process to identify and address potential risks and issues that could impact participant safety or data quality.

When is Data and Safety Monitoring Recommended?

- **Minimal Risk Research:** While a formal DSMP is generally not required for minimal risk research, it is still advisable to have clear methods in place to protect confidentiality, privacy, and participant safety. Such measures should be proportionate to the minimal risk involved and include adequate provisions for monitoring.
- **Good Clinical Practice (GCP) Compliance:** For minimal risk clinical trials that adhere to GCP standards, the development of a DSMP is recommended to ensure ongoing adherence to protocol and protection of participant welfare.

When is Data and Safety Monitoring Required?

- **Greater Than Minimal Risk Research:** A Data and Safety Monitoring Plan (DSMP) is mandatory for research involving more than minimal risk. This requirement ensures that adequate measures are in place to monitor participant safety, data validity, and overall study integrity. The complexity of the DSMP should align with the level of risk and complexity of the study.

- **NIH-Funded Phase III Clinical Trials:** For NIH-funded Phase III clinical trials, a Data and Safety Monitoring Board (DSMB) is required to oversee the trial's progress and assess its safety and efficacy.

A **Data and Safety Monitoring Board** (DSMB) is an independent committee established to oversee data throughout the study. Its role is to ensure that the study continues to be scientifically and ethically justified. The DSMB monitors the data to assess whether the research should continue, be modified, or be stopped based on the study's safety and efficacy.

DSMB Recommendations That Require Response or Action:

- **Real-Time Submission:** Reports containing DSMB recommendations that require immediate action must be submitted to the IRB in real-time.
- **Response:** Each report should be accompanied by a detailed response from the study team addressing the issues raised by the DSMB. This ensures that any recommended actions are acknowledged and acted upon appropriately.
- **Submission:** Submit these reports via a modification submission to the IRB promptly. Such reports may sometimes constitute a reportable event, necessitating timely IRB review and action.

Overall, the goal of data and safety monitoring is to ensure all research activities are conducted ethically and with due consideration for participant safety and data integrity. The IRB reviews the DSMP as part of the research protocol to ensure compliance with regulatory requirements and to assess whether the monitoring plan is adequate given the study's risk profile.

5.13 Honest Broker:

An **Honest Broker** acts as a firewall between investigators and subjects' identifiable information, enhancing participant confidentiality and compliance with ethical standards. By managing the access and use of sensitive data, the Honest Broker facilitates research while protecting participant identities.

Definition and Role

An Honest Broker is an individual who has access to the desired data through their hospital or institutional responsibilities and is not listed as a researcher on the respective study. Their primary functions include:

- **Data De-identification**: The Honest Broker can generate or receive datasets and strip out subject identifiers, creating either a de-identified dataset or a limited dataset.
- **Access Management**: They access medical record information and provide researchers with de-identified or limited datasets, ensuring compliance with data privacy regulations.

Creation of a Data Set

When utilizing an Honest Broker, researchers should consider the following:

- If the Honest Broker is providing a limited dataset, they must present an internal data use agreement to the researcher before receiving the dataset.
- The Honest Broker can assign a code to the data, but researchers must not have access to the information linking the code to individual identities. This code allows the researcher to request additional medical information through the Honest Broker.
- If coded data is provided without the means to decode it, the information will be treated as de-identified or a limited dataset, depending on the elements included.

Additional Protections for Confidential Information

- **Enhanced Confidentiality**: The Honest Broker can implement additional protections, such as encrypting data and specimens, preventing researchers from identifying individuals from whom the data was obtained. This is especially relevant for prospectively collected data.
- **Limitations on Re-identification**: Utilizing an Honest Broker may prevent investigators from re-identifying individual subject data or specimens, which could hinder further data collection or participant recruitment for subsequent studies. This decision should be made with care, considering the research objectives.

Converting Identifiable Data

Using an Honest Broker can alter the regulatory category of research involving existing specimens (from clinical care or prior research) by providing investigators with data and biospecimens that are not readily identifiable. This change in status may exempt the research from prior IRB review and approval. If investigators remove identifiers themselves, they must obtain an exemption determination.

- **Limited Data Sets**: If the data provided contains dates or zip codes, it is classified as a limited dataset. Both the data provider and recipient must enter into a data use agreement before sharing the data/specimens. At some institutions, such as the Children's Hospital of Philadelphia (CHOP), this sharing does not require IRB review or approval. However, other institutions may have stricter requirements.

Best Practices

- Clearly define the Honest Broker's responsibilities in the research protocol.
- Ensure secure protocols for data transfer and sharing of de-identified or limited datasets.
- Document all data handling processes, including records of data requests and transfers, for audit and IRB review purposes.
- Provide training for the Honest Broker on ethical guidelines and institutional policies regarding data handling.
- Assess the effectiveness of the Honest Broker's role and processes throughout the research project.

Ethical Considerations

- Maintain participant trust by ensuring the protection of their privacy.
- Foster transparency about the role of the Honest Broker in the research process.
- Evaluate potential conflicts of interest to ensure the Honest Broker remains independent from the research team.

5.14 Sensitive Topics Response Guidance

The IRB supports research aimed at understanding and addressing sensitive and impactful topics, such as self-harm, suicidal ideation, homicidal ideation, abuse, substance misuse, eating disorders, sexual victimization, and violence. Recognizing the importance of these research efforts, the IRB also emphasizes the need to protect participant welfare, particularly for vulnerable populations. This guidance provides comprehensive action plans for studies involving sensitive topics, with particular attention to researchers who may not be experts in these areas.

Action Plan

If a study deals with sensitive topics, —such as substance/alcohol/child/elderly abuse, eating disorders, self-harm, suicidal ideation, or homicidal ideation— or uses tools and measures to assess depression, anxiety, trauma, and similar areas, subjects should be forewarned in the informed consent form that they will be asked questions on these topics. Subjects should also be given contact information for counseling services should they experience distress due to their participation. Studies that include prompts regarding self-harm, suicidal ideation, homicidal ideation, require an IRB-approved action plan to support participants at risk of imminent harm. Imminent risk is characterized by a heightened intent to cause harm, often indicated by frequent thoughts of suicide, a plan to carry out self-harm, or threats of violence towards others. Researchers need to determine and state if they are qualified in identifying imminent risk in their proposal. If PI is unsure or unqualified in identifying imminent risk, they are strongly encouraged to have a consultant who has expertise in suicidality, or suicidality research protocols, or have a licensed mental health professional involved during data collection.

The action plan should address the following:

1. **Prompt Review:** Review responses to self-harm or suicidal ideation questions within 24 hours.
2. **Identifying and Assisting High-Risk Participants:**
    - **For Students:** Immediate support (direct contact with students, consulting resources, calling emergency services, walking them to the CCPH, etc.).
    - **For Non-Students:** Referral to mental health resources and emergency services, as necessary.
    - **Confidentiality:** Inform participants in consent documents about confidentiality limits in cases of imminent risk.

- **Follow Up:** Depending on the nature of the study, it may be appropriate to also give subjects a separate handout at the conclusion of the study with a list of counseling services in case they experience any distress after completing the study.

General Considerations

1. **Assessment Tools:** Tools measuring suicidal or homicidal ideation, and other relevant correlated symptoms (e.g., depression, hopelessness, forms of self-harm, eating disorders, etc..), must be carefully considered for their necessity in the research. Ensure that these tools are justified based on the research aims. Additionally, tools used for assessing potential child or elderly abuse should be evaluated for their relevance and appropriateness. Researchers should confirm that the use of these tools is aligned with the study's objectives and complies with applicable reporting requirements and ethical guidelines.
2. **Populations Involved:** Higher-risk groups may need additional protection and cultural sensitivity training. Outline clear action plans for minors and ensure parental consent and child assent forms include information about suicide questions and action plans.
3. **Actively Suicidal Populations:** Consider consent capacity, access to firearms and other lethal means, and state laws on involuntary commitment.
4. **Databases:** Avoid collecting suicidal ideation data on subject pool screening forms that cannot be reviewed promptly.
5. **Research Pre-planning:** Plan for participant safety with additional monitoring, even though research shows asking about suicidality does not increase risk. Ensure non-anonymous surveys and interviews with suicide questions are reviewed within 24 hours, including weekends.
6. **Technological Data Gathering:** Test systems before deployment and regularly monitor them during the study.
7. **NIH Considerations:** NIH-funded studies may need additional staffing and data sharing plans.

Survey Types and Responses

1. **Anonymous Surveys:**
    - Inform participants that responses are anonymous, and support cannot be provided.
    - Provide a list of support services at the beginning (and optionally at the end) of the survey.
    - Justify the benefits of asking suicide questions in anonymous surveys.
2. **Identifiable Online Surveys:**
    - Inform consent that confidentiality may be broken if suicidal intent is disclosed.
    - Review responses within 24 hours.
    - Define imminent risk and outline the action plan in the protocol and consent document.
3. **Non-Anonymous In-Person Surveys and Interviews:**
    - Inform consent that confidentiality may be broken if suicidal intent is disclosed.
    - Review responses before the participant leaves.
    - Define imminent risk and outline the action plan in the protocol and consent document.
    - For imminent risk, ensure participants receive official support services immediately.

Reportable Events:

Disclosures of suicidal intent, as well as questions or disclosures related to child and elderly abuse, may or may not be reportable depending on the study's aims and protocol. Specifically:

- **Suicidal and Homicidal Intent:** Disclosures of suicidal or homicidal intent should be evaluated in the context of the study's focus. In studies specifically aimed at understanding suicidality, such disclosures may be managed according to the study's protocol. In studies not focused on suicidality, any unexpected disclosures should be reported to the IRB.
- **Abuse and Mandatory Reporting:** Questions or disclosures involving child or elderly abuse must be assessed based on the study's objectives. In studies not specifically targeting these issues, any unexpected disclosures should be reported to the IRB. Researchers are also reminded to comply with mandatory reporting laws applicable in their jurisdiction.

Researchers are responsible for determining the relevance of such disclosures to their study and ensuring that all reportable events are communicated to the IRB promptly.

Mental Health Guidance: For studies asking about issues such as depression, anxiety, trauma, etc.. but not specifically suicide, consider what responses will trigger concern. For moderate to severe depression, provide a list of resources. Inform consent forms should state that researchers are not clinicians and will not follow up on depression scores.

5.15 Recording:

If you wish to record subjects, please refer to IRB Guidance on Recording.

5.16 Focus Group Research:

Informing Participants:
When planning a focus group, it is essential to clearly inform participants about the content and scope of the discussion. Participants should be made aware of the specific topics to be covered and the identity of the other participants involved in the session. This transparency allows individuals to make an informed decision about their participation. This is particularly crucial when the focus group addresses sensitive or potentially distressing topics, which might be categorized as more than minimal risk. Researchers should refer to the appropriate types of review to assess the risk level associated with their project.

Risks and Confidentiality:
Given the nature of focus groups, complete confidentiality cannot be assured. Researchers should outline the steps taken to protect the confidentiality of the data and emphasize the importance of participants refraining from sharing or discussing the content of the focus group with others outside the session. For research classified as minimal risk, including a paragraph in the informed consent document addressing these confidentiality concerns is generally sufficient.

Paragraph for Informed Consent:
"Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others."

For studies that involve more than minimal risk, it may be necessary to include a non-disclosure agreement that participants must consent to in the informed consent form.

Non-Disclosure Statements:
"I agree to maintain the confidentiality of the information discussed by all participants and researchers during the focus group session. If you cannot agree to this stipulation, please consult with the researcher(s) as you may be ineligible to participate in this study."

5.17 Research Using the International Affective Picture System (IAPS)

The International Affective Picture System (IAPS) contains images designed to evoke emotional responses, categorized as pleasant, neutral, or unpleasant. Research involving these images requires careful consideration of potential psychological impacts, particularly with unpleasant images. This document provides guidance on submission and protocol requirements to ensure participant safety and compliance with IRB standards.

General Requirements for All IAPS Research

1. **IRB Review:** All protocols involving unpleasant IAPS images must be submitted for full board review. Ensure to provide a thorough justification for using unpleasant images, including the specific research goals or insights they are intended to achieve.
2. **Consent Form Statement:** Include the following in the consent form:"If you decide to take part in this study, you will be asked to view a variety of pictures categorized as pleasant, neutral, or unpleasant. If any of the media presented makes you feel too uncomfortable to continue, you are free to withdraw from the study at any time without losing credit or payment. The images may include descriptions such as [*insert specific description here*]. You may end your participation at any time if any aspect of the research makes you uncomfortable. If

you experience discomfort or have concerns after viewing the images, please contact the principal investigator at [*insert contact information*] or reach out to [*list psychological services with contact information*]."

3. **Protocol Requirement:**
    - **Ethical Justification:** Emphasize the ethical considerations and justifications for using potentially distressing images, ensuring that the research aims and benefits outweigh the risks.
    - **Detailed Description:** Provide a detailed description of the nature of the images, including representative samples. Attach an information sheet that explains the content and potential emotional impact of the images to all personnel involved in the study. Include specific examples of the types of images being used and how they are categorized (pleasant, neutral, unpleasant).
    - **Image Distribution:** Clearly specify the percentage of pleasant, neutral, and unpleasant images shown. For example: "Subjects will view 25% pleasant, 50% neutral, and 25% unpleasant images."
    - **Risk Management:** Clearly identify all potential risks associated with the use of unpleasant images. Describe the measures in place to minimize risks to participants, including psychological support and procedures for withdrawal.
    - **Anonymity:** Ensure that any participant data remains anonymous, especially if the images are categorized as unpleasant and could potentially lead to emotional responses.
    - **Personnel Training:** Explicitly describe how research personnel will be informed about the study and how their understanding of the nature of the images will be verified.
    - **Debriefing:** Ensure all participants receive a debriefing.
    - **Emergency Contact:** Include information on immediate support or emergency contact resources for participants who may experience distress during or after the study.

5.18 Research Involving Exercise

Research involving physical exercise introduces unique risks and safety concerns, particularly for participants with underlying health conditions. Investigators must carefully consider factors such as participant screening, the qualifications of the research team, data security, follow-up procedures, and emergency safety measures. This section outlines key elements that Principal Investigators (PIs) must address in their IRB proposals when conducting exercise-related research, ensuring participant safety and compliance with regulatory standards.

Training & Expertise of Researcher(s)

The experience and training of individuals conducting research involving exercise must be clearly detailed in the IRB proposal. For studies involving physical activity, at least one certified CPR/First Aid professional must be present during all data collection sessions. Informed consent documents must outline these qualifications to ensure participants are aware of the safety precautions in place. Additionally, if the study involves specialized equipment (e.g., treadmills, heart monitors), the training of research personnel on the correct use and maintenance of such equipment must be provided in detail.

PIs should also specify the specific qualifications of the personnel in relation to the subject group (e.g., experience working with elderly participants, clinical expertise in cardiovascular conditions). This helps ensure that the research team has the appropriate background for handling participants safely.

Screening for Appropriate Participation

Investigators must implement comprehensive screening procedures to identify cardiovascular, pulmonary, or metabolic risk factors, as these conditions present heightened risks in exercise testing. The screening process should minimally include:

- A detailed health questionnaire to assess personal and family history of cardiovascular, pulmonary, or metabolic conditions.
- Pulse measurement to detect abnormal heart rates.
- Blood pressure measurement to identify potential issues.

Subjects identified as high risk must be treated with additional safeguards, and the IRB proposal must provide details on the screening procedures, any justification for deviations, and how high-risk subjects will be handled or excluded. If higher-risk participants are included, a robust risk assessment must accompany the proposal, outlining clear steps to mitigate adverse outcomes, such as enhanced medical oversight and safety monitoring. The informed

consent process for higher-risk participants should include a comprehensive discussion of the risks, potential consequences of their health status, and the specific safeguards in place for their protection.

Inclusion/Exclusion Criteria
Based on the outcomes of the screening process, the IRB proposal should clearly define inclusion and exclusion criteria, explaining the rationale behind excluding certain individuals due to health risks. This ensures that only appropriate candidates, capable of safely participating in the study, are included. PIs should emphasize the justification for including higher-risk populations if applicable, detailing why these groups are necessary for the research and what additional safeguards will be implemented.

Appropriate Safeguards During Exercise Intervention
Researchers must provide a comprehensive safety plan tailored to the population and the exercise being tested. For high-risk subjects or intense exercise regimens, enhanced safeguards, such as physician oversight or immediate access to emergency medical care, may be required.

In the IRB proposal, PIs should include:

- Whether higher-risk subjects will be enrolled and, if so, a detailed risk assessment.
- Certification and experience of researchers in CPR/First Aid and other relevant qualifications, along with evidence of recent training updates.
- Details about **emergency medical equipment** on-site, such as defibrillators, oxygen tanks, and other necessary tools based on the type of exercise being performed.
- Clear plans for continuous monitoring of participants during exercise (e.g., heart rate, oxygen levels, signs of distress).
- Assessment of the local emergency response system, including the average response time and proximity to medical facilities.

Post-Exercise Follow-Up
For high-risk studies or strenuous exercise regimens, the IRB proposal should include a plan for post-exercise monitoring. This follow-up could involve checking participants' vitals after the activity or scheduling follow-up visits to detect any delayed adverse effects such as muscle soreness, dizziness, or more serious conditions like cardiac issues. This ensures that participants are continuously protected even after the exercise intervention has ended. PIs should outline specific criteria for when participants would require medical follow-up and describe the procedure for addressing any delayed adverse events that might emerge after participation.

Identifying Minimal Risk vs. Greater than Minimal Risk Research
When determining whether exercise-related research is minimal or greater than minimal risk, the IRB will assess the intensity of the exercise and the health status of the participants. The IRB proposal must explain how these factors have been accounted for, particularly when it comes to more vulnerable populations. For instance, a treadmill walking test could pose minimal risk for a healthy, young adult but could be considered greater than minimal risk for an elderly person recovering from surgery. PIs should clearly distinguish between the different risk levels and justify their classification of the study. The proposal should also provide risk mitigation strategies, particularly when enrolling vulnerable populations, and justify why the potential risks are outweighed by the potential benefits of the research.

General Safety & Emergency Plan
The PI must ensure safety throughout the research process, including participants' interaction with equipment, movement between stations, and environmental factors (e.g., crowded rooms, equipment obstructions). The IRB proposal must include:

- A detailed location-specific emergency plan, covering what actions will be taken in the event of an emergency, and contact information for local medical responders.
- Emergency contact details for all participants, ensuring immediate communication in the event of an adverse event.
- The emergency plan must ensure that emergency phones (either landlines or mobile) are functional and accessible, with instructions on which number to call and precise location details to direct responders effectively.

Dehydration and Heat-Related Risk Management
Studies that involve high temperatures or strenuous physical activity should include protocols for monitoring, managing and mitigating dehydration and heat-related risks. The IRB proposal should detail hydration strategies, cooling procedures, and break schedules to prevent heat exhaustion or dehydration during exercise, especially for vulnerable populations.

Injury Reporting
If an injury occurs during exercise-based research, the study must be paused, and the PI must notify the IRB within 48 hours. If the injury was not anticipated, the PI must submit an adverse event report detailing the incident and any changes made to the protocol to prevent further injury. The study cannot resume until the IRB has reviewed the incident and granted approval to continue. The injury reporting protocol should include criteria for temporary suspension of the research in the event of serious or multiple injuries and describe the communication process with participants and the IRB during this time.

Normal Training vs. Research
When conducting research with athletes or teams, the PI must clearly define which activities are part of normal training and which procedures are specific to the research study. This distinction must be detailed in the IRB proposal and the informed consent process, so participants understand what elements of the activity are required for research versus their regular training.

Privacy of Results
When performance data is collected in group settings or can be observed by non-research staff, the IRB proposal must address how participant confidentiality will be maintained. If other individuals may observe the exercise sessions, this must be disclosed in the consent process. Even if data remains confidential, participants should be informed that their performance may be viewed by others. The proposal should also outline **s**pecific measures to secure personal health data, particularly if sensitive health conditions are being monitored or recorded during the screening and exercise process.

5.19 Complaints

This section outlines the process for submitting and handling complaints related to IRB activities. It ensures that complaints are managed fairly and consistent with institutional policies and regulatory requirements. All complaints and related proceedings will be handled with strict confidentiality to protect the privacy of the individuals involved. Concerns or recommendations regarding the human research protection program, including the IRB review process, should be directed to the IRB email address: IRB.research@umassd.edu.

1. Filing a Complaint: To file a complaint, individuals should provide a detailed description of the issue, including:

- The name of the study and Principal Investigator (PI).
- A clear account of the complaint, including specific deviations from approved protocols or IRB policies.
- Any relevant documents supporting the complaint.

2. Review and Evaluation: Upon receipt of a complaint, the IRB will:

- Acknowledge receipt of the complaint within [specific time frame, e.g., 5 business days].
- Review the complaint to assess the validity and relevance.
- Gather additional information if necessary to understand the context and impact of the complaint.

3. Resolution: The IRB will determine appropriate actions based on the complaint review, which may include:

- Discussing the issue with the PI and/or relevant parties.
- Requesting corrective actions or modifications to the research protocol.
- Implementing additional monitoring or oversight measures.
- If the complaint involves serious violations/concern or remains unresolved at the IRB level, it will be escalated to the Institutional Official (IO) for further review and action.

5. Follow-Up: The IRB will document all complaints and actions taken. The complainant will be informed of the resolution and any actions implemented.

5.20 Community-Based Participatory Research (CBPR)

Community-Based Participatory Research (CBPR) is a collaborative research approach that emphasizes equitable involvement of community members throughout the research process, from design to dissemination. In CBPR, community members and researchers work as partners, combining knowledge and action to address community-defined issues and improve well-being. By integrating education and social action, CBPR strives to achieve positive outcomes both within the community and in the broader knowledge base.

CBPR requires attention to ethical considerations, mutual respect, and flexibility. Researchers must ensure the protocol reflects community needs, includes input from community partners, and promotes long-term collaboration. Below are key elements to consider in protocol development.

Elements to Consider in Protocol Development

- **Community Partnership and Engagement**: Engage community stakeholders as co-investigators from the beginning, ensuring their active role in shaping the research topic, design, data analysis, and dissemination. Maintain balanced decision-making between researchers and community members. Provide ongoing feedback and adjust approaches based on community insights.
- **Community Consultation and Risk Minimization**: Identify and address potential risks to both individuals and the community (e.g., privacy, cultural sensitivity, literacy issues) in consultation with community members. Establish safeguards tailored to community norms and values, ensuring the research respects community-specific concerns.
- **Local Oversight and Ethical Review**: Determine if local ethical oversight is needed, such as from a community advisory board, tribal council, or local ethics committee.
- **Data Ownership, Sharing, and Confidentiality**: Develop clear agreements on data ownership, access, and sharing to protect community interests and privacy.
- **Disclosure of Research Findings and Potential Impact**: Collaborate with the community to determine how research findings will be shared, addressing any potential group harms or sensitive interpretations. Ensure findings are disseminated in ways that benefit the community and minimize any unintended consequences.
- **Community Benefit and Long-Term Relationship Building**: Design studies that deliver tangible benefits to the community, such as through program implementation or resource development. Establish plans for sustained partnerships beyond the research period, fostering trust and continued collaboration.
- **Flexibility and Responsiveness**: Allow for adjustments in procedures and data collection tools based on community feedback and evolving needs in the field.

IRB Consideration:

- Evidence of an equitable and collaborative partnership with the community.
- Defined roles and responsibilities for both academic and community partners.
- Letters of support from community stakeholders.
- Detailed plans for community engagement and benefit.
- Appropriate funding distribution and training opportunities for all involved.
- Strategies for positive, long-term community impact and relationship building.

Section 6: IRB Procedures:

6.1 Regulatory Review

The first step in the IRB review process is for all submissions to undergo a Regulatory Review, where the IRB performs the following steps:

1. **Verify Completeness**: Review the submission to confirm all required materials are provided by the Investigator. Then the IRB verifies the completeness and appropriateness of the application, proposal, consent forms, training documentation, site letters, translations, subject-facing materials, and any other relevant documents provided for review.
2. **Identify Regulatory Requirements**: Identify and document all applicable local, state, or international regulatory requirements that must be considered for the submission. This ensures compliance with specific determinations such as waivers, the involvement of vulnerable populations, and use of medical devices, etc.
3. **Level of Risk and Review**: Evaluate risk to participants and determine the likely level of review (Exempt, Expedited, Full Board, 118, or Non-Engaged) based on the submission's content and associated risks.
4. **Review of New Information**: When new information is provided, follow the above steps, and additionally review the new documentation/information to assess if it involves updates related to new funding, financial conflicts of interest, increased or new risks, protocol deviations, unexpected harm related to research, compliance issues, breaches of confidentiality, informed consent issues, or external reports. The IRB then assesses the impact of this new information on the study and participant safety, determining if it involves an Unanticipated Problem (UP), increased risk, or noncompliance.
5. **Consult Expertise as Needed**: When the IRB lacks the necessary expertise for the review, it seeks external consultation to resolve review requirements and manage study team responses. This may involve consulting with experts in the relevant field or involving licensed mental health professionals for studies dealing with sensitive topics.
6. **Document Findings**: Document findings for the Chair and/or DIEC to review. Then the submission is assigned to a Designated Reviewer for a Non-Convened Review or Committee Review. If Committee Review is required, the Designated Reviewer and Chair collaborate to ensure issues raised during the Regulatory Review are addressed in advance of or at the meeting.

6.2 Selection of a Designated Reviewer

The second step in the IRB review process is the assignment of designated reviewer which entails:

- **Conflict of Interest (COI)**: Ensuring the reviewer has no conflicts of interest that could affect their objectivity. If a COI is identified, the reviewer must notify the Chair and DIEC to establish reassignment.
- **Review Expertise**: Verifying the reviewer has the necessary expertise to conduct the review effectively. The DIEC and Chair are always available to assist reviewers with questions related to regulations and specific sponsor requirements. If the reviewer has concerns of lacking the required expertise, they should request reassignment from the Chair and DIEC. Sufficient expertise includes:
    - **Relevant Knowledge**: Possessing the necessary ethical, scientific, and scholarly knowledge pertinent to the study's research area to accurately assess the study's design, methodology, and potential impact on participants.
    - **Experience with Populations**: Having knowledge of or experience with the target population, particularly if the research involves vulnerable populations and is funded by an entity with specific requirements for including these populations.

- **FDA-Regulated Test Articles**: Being knowledgeable about FDA regulations and their implications for study design and participant safety if the research involves FDA-regulated test articles.
- **Federal Agency Requirements**: Understanding the specific requirements and regulations associated with federal agencies (e.g., DOD, DOE, DOJ, ED, EPA, NIH) if the research is sponsored by these agencies.
- **Community-Based Participatory Research**: Familiarity with community-based participatory research methods and their ethical considerations if the study employs these approaches.
- **Prisoner Research**: Qualification as a prisoner representative or expertise in ethical considerations related to research with incarcerated individuals if the study involves prisoner research.
- **International Research**: Knowledge of the relevant country's regulations, cultural context, and ethical standards if the research is conducted internationally.

The Designated Reviewer is responsible for reviewing each submission to ensure:

- **Completeness:** The protocol explicitly outlines the design and procedures from inception to completion.
- **Minimization of Risks**: Risks to subjects are minimized:
  - By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, **and**
  - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- **Risk-Benefit Ratio**: The risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The reviewer should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy).
- **Equitable Selection of Subjects**: The selection of subjects must be equitable and conducted in a manner that is fair and just. Ethical considerations include:
  - Ensuring the research does not disproportionately burden or exclude specific groups, particularly vulnerable or marginalized populations, unless justified by the research objectives. The benefits of the research should be distributed fairly among all potential subjects.
  - Ensuring the recruitment process does not exploit vulnerable populations or individuals in a disadvantaged position. Avoid selecting subjects based on their ease of access or likelihood to consent without regard for their situation.
  - Guaranteeing all subjects are able to make an informed and voluntary decision about their participation. Recruitment strategies should facilitate understanding of the research, its risks and benefits, and ensure subjects are not subjected to coercion or undue influence.
  - When appropriate, aim for a diverse and representative sample to enhance the generalizability of the research findings and reflect a range of experiences and characteristics relevant to the study.
- **Protection of Vulnerable Subjects**: When subjects are considered part of a vulnerable population, additional safeguards must be integrated into the study to protect their rights and welfare, which includes ensuring that:
  - The research design incorporates specific protections to address the vulnerabilities of the population involved.
  - Consent processes are adapted to accommodate the needs and circumstances of vulnerable subjects.
  - The study includes mechanisms for monitoring and responding to any adverse effects or signs of coercion.
- **Informed Consent**: Each subject or their legally authorized representative must provide informed consent as required. Ensuring:
  - The consent process is comprehensive and includes all necessary information about the study's purpose, procedures, risks, benefits, and alternatives.
  - Consent is appropriately documented, or an appropriate waiver is requested and justified.
  - The consent process is conducted in a language and at a literacy level that the subject can understand, and that subjects have adequate time to consider their participation.

- **Deception or Withholding of Information:** If deception or withholding of information is necessary for adequate testing of the hypotheses and there is no practical alternative:
    - Sufficient justification is provided that the potential benefits to the subject or the importance of the knowledge to be gained outweigh any potential risks that may be present as a result of such deception.
    - Assurance of an acceptable debriefing process is in place to provide subjects with a full explanation of the deception and its purpose, as well as any potential effects or risks resulting from participation. If the research design includes deception, ensure that:
        - The debriefing occurs as soon as possible after participation, or at a time deemed appropriate by the IRB if immediate debriefing could affect data collection.
        - If the deception might cause emotional distress, the debriefing must be thorough and timely, addressing any concerns or questions the subjects might have.
- **Adequate Facilities and Resources:** The facilities and resources necessary for the protection of subjects' rights and the completion of the study are adequate, which includes:
    - Evaluating the physical, technological, and personnel resources available to ensure they meet the study's needs.
    - Confirming the facilities are safe and conducive to the study's conduct.
    - Ensuring there are contingency plans for emergencies or unexpected issues that may arise during the study.
- **Data Monitoring**: There are robust provisions for data monitoring to protect subject safety. This includes:
    - Implementing a data monitoring plan that specifies how data will be reviewed and analyzed to ensure ongoing participant safety.
    - Establish criteria for halting the study if interim findings indicate unexpected risks or adverse effects.
    - Appointing a data monitoring committee or individual, if required, to oversee data collection and analyze interim data to ensure subjects' safety and welfare.
- **Privacy and Confidentiality**: Adequate measures are in place to protect subject privacy and maintain data confidentiality, which includes:
    - Implementing secure data storage and handling procedures to prevent unauthorized access or disclosure of personal information.
    - Ensuring that data is de-identified or anonymized as appropriate and that any identifiers are kept secure.
    - Informing subjects of how their data will be used, stored, and shared, and obtaining consent for any use beyond the scope of the initial study.

At the review's completion, the designated reviewer documents findings via notes for the Chair and/or DIEC.

6.3 Non-Convened Review

The Non-Convened review procedure begins when the Chair or DIEC determines the submission may be reviewed and approved via a Non-Convened Review. Once the Designated Reviewer completes the review, the IRB may proceed as follows:

If not specifically Human Subjects Research, the reviewer will make one of these determinations:

- **"Not Human Research":** The reviewer determines the submission does not meet the definition of Human Research. Notify Chair and DIEC of review.
- "**Human Research Not Engaged":** The reviewer determines the submission meets the definition of Human Research but does not engage the institution.
- "**Additional Information Necessary":** The reviewer determines the review requires additional information to be provided to assess if human subject's research is being conducted. The reviewer's documented notes outline a list of concerns which must be addressed before a determination can be made.

If the submission involves Human Subject Research per OHRP definition, then take one of the following actions:

- **"Requires Revisions":** The submission requires revisions before it can be granted the action of "Approve." The reviewer's documented notes outline a list of concerns which must be addressed via

revision/modifications, or a justification/clarification must be provided before approval can be issued. This action requires the resubmission be re-reviewed by the assigned Designated Reviewer, DIEC, or Chair.

- **"Return/Deny":** The submission does not meet the criteria for approval and the submission is found to have extensive deficiencies. The reviewer's documented notes include a list of concerns which must be addressed via required revisions/modifications and/or justification/clarification. This action requires the resubmission be re-reviewed by the assigned Designated Reviewer, DIEC, or Chair.
- **"Approve":** The submission meets the criteria for approval.

If exempt, designate the corresponding review category and confirm:

- The research is not FDA-regulated.
- The research does not involve nor interacts with Prisoners, nor is conducted or funded by DHHS, Dept. of Defense (DOD) and is NOT aimed at involving a broader subject population that only incidentally includes prisoners.
- The research is not classified nor conducted or funded by the Department of Energy (DOE).
- The research presents no more than Minimal Risk to subjects.
- The selection of subjects is equitable, the research is appropriate for the population being studied.
- If the research involves interactions with subjects, standard requirements for informed consent are met, or an appropriate waiver requested.
- The research does not involve any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

If expedited review, designate the corresponding review category and confirm:

- The research is not classified.
- The research presents no more than Minimal Risk to subjects.
- If prisoners are involved, the prisoner representative reviewed the submission and concurs with determination.
- The research does not involve the identification of subjects and/or their responses in a manner that would reasonably place them at risk of criminal or civil liability, damage their financial standing, employability, insurability, reputation, or cause stigmatization, unless reasonable and appropriate protections are implemented to ensure that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The standard requirements for informed consent are met, or an appropriate waiver requested.
- If the submission involves a modification, this does not affect the design of the research nor add more than a minimal risk to the subjects.

- **"Committee Review":** The reviewer determines the submission warrants review Full Board.

If new information is provided for review, take one of the following actions:

- **"Accept/Acknowledge":** The reviewer examines the new information provided by the study team and determines that no further action or additional information is required. This means the IRB accepts the documentation and considers the matter resolved without the need for further review or action.
- **"Request Additional Information/Modifications":** The reviewer examines the new information provided by the study team and determines further information is required before the review can proceed. The reviewer's documented notes include a list of concerns which must be addressed via required revisions/modifications and/or justification/clarification. This action requires the resubmission be re-reviewed by the assigned Designated Reviewer, DIEC, or Chair.
- **"Rescind Approval":** A prior approval of a document, site, investigator, and so forth was incorrectly provided by the PI and therefore approval is rescinded. The research may not continue once approval is rescinded. The reviewer's documented notes include a list of concerns which must be addressed via required revisions/modifications and/or justification/clarification. This action requires the resubmission be reviewed by the assigned Designated Reviewer, DIEC, or Chair.
- **"Committee Review":** The reviewer determines the submission warrants review Full Board.

6.4 Committee Review

This review procedure begins when the Chair, DIEC, or Designated Reviewer determine a submission requires review via a Committee Review. New or revised submissions of studies approved via committee review, or which present more than a minimal risk to subjects, must occur at Committee Review. A quorum of IRB members (established by the presence of at least half the committee plus one) is required for the meeting to proceed. The Chair and DIEC set the maximum number of agenda items based on complexity, available time, and urgency of approval requirements, adjusting limits as needed.

6.4.1 Meeting Review Procedure:

During a Committee Review, the Designated Reviewer leads the discussion in collaboration with the Meeting Chair and IRB members who collectively share the responsibility of:

- Having the appropriate expertise to discuss scientific/scholarly review.
- Reviewing all submitted materials for consistency, reviewing the findings/concerns identified via the Regulatory Review, and identifying any additional findings/concerns or information is necessary to answer questions about the submitted materials.
- Assessing if the criteria of approval are met. If one or more criteria are not met, consider what specific and directive changes would make the protocol approvable.
- For reviews related to an Unanticipated Problem Involving Risks to Researchers or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, Termination of IRB Approval or new information is provided, determine whether additional information is necessary, or if the submission, approval interval, corrective action plan, or monitoring plan requires modification.
- Summarizing the IRB's consensus and providing notes to the DIEC for the generation of minutes and correspondence.

6.4.2 Meeting Vote:

During meetings, the Meeting Chair and DIEC ensure:

- All members who are part of quorum vote. If quorum is lost, ensure no further action is taken until quorum is restored.
- Notes and/or concerns from absent members are included in discussions, though absent members may not vote.
- To determine the voting status of alternate members, ensuring the number of voting members does not exceed the number of regular members on the IRB roster.
- If a guest/observer attends, ensure they do not participate in deliberations, unless requested to serve as a consultant. Guests/observers can participate in the vote and must agree to maintain confidentiality of the IRB proceedings.
- After sufficient discussion of each agenda item, call for a vote from IRB members present at Committee Review as "For," "Against," or "Abstaining" in the motion for:
    - **"Approval":** The research meets the criteria for approval and more than 50% of the quorum votes in favor or protocol approval. For initial and continuing review, include in the motion, the level of risk (minimal risk or greater than minimal risk), and either that continuing review is not required, or the period of continuing review.
    - **"Requires Revisions":** The research will meet the criteria for approval with minor prescriptive changes or requirements that can be verified without considering the criteria for approval. Summarize the IRB required modifications and reasons. For initial and continuing review, include in the motion, the level of risk (minimal risk or greater than minimal risk), and either that continuing review is not required, or the period of continuing review. If the protocol is ambiguous, request to obtain written information from the sponsor or investigator
    - **"Table":** Further information is necessary to supplement the initial, continuing, or modification submission to meet the criteria for approval and requires re-review by the Committee Review. Summarize the IRB reasons for motion and detail information necessary. Review of submissions may also be tabled when quorum is lost. A tie votes for and against "Approval" / "Conditional Approval" also results in the tabling of a registration review.
    - **"Return/Deny":** When the initial, continuing, or modification submission does not meet the criteria for approval and the IRB considers the research to have extensive deficiencies. Summarize the IRB reasons for motion and detail all information required to meet criteria.

- **"Suspend":** Based on new information, the previously approved research no longer meets the criteria for approval, or when only some research activities meet the criteria for approval, or when the IRB has revision recommendations to make the research meet the criteria for approval. Summarize the IRB reasons and/or recommendation for the motion, include which research activities must stop or be modified, and detail all information required to meet criteria. The IRB may lift suspension when resubmission addresses concern and meets criteria of approval via Non-Convened Review.
- **"Terminate":** When the IRB determines that based on new information the previously approved research no longer meets the criteria for approval and the IRB has no recommendations to make the research approvable. Summarize the IRB reasons for the motion.

6.5 Administrative Processes:

The DIEC is responsible for administrative oversight of the IRB review process. The DIEC schedules meetings, creates the meeting agenda, disseminates submission documents, and relevant meeting materials electronically, records minutes and then distributes minutes for IRB members to review.

- **Schedule:** The IRB meets monthly. If there are no submissions which require Committee Review, the meeting is then cancelled by the Chair or DIEC. If there is a time sensitive matter which requires Committee Review, submissions with specific funding timelines, noncompliance or serious and/or unexpected events/problems, an emergency ad hoc meeting can be called to order by the Chair or DIEC, as necessary. Meetings may be conducted by teleconferencing and a written record of the meeting is created by the DIEC to document committee actions and requirements.
- **Agenda:** The agenda is provided to IRB members electronically in advance of meeting and includes:
  - New Protocols, Renewals, Modifications, or New Information submissions.
  - All relevant submission documents and designated reviewer pre-review notes.
  - Identifies Conflicts of Interest.
  - Lists the submissions issued as approved, require revisions, and have been withdrawn via Non-Convened Designated Review since last meeting.
  - Previous Committee Review meeting minutes for review and approval.
  - Administrative updates relating to IRB announcements and/or educational materials.
- **Meeting Preparation:** As a part of meeting preparation, the DIEC ensures:
  - All attendees are provided with or have access to the materials at least one week before meetings.
  - Each agenda item has a reviewer, and Designated Reviewers are prepared to present assignments.
  - IRB members (regular, alternate, IRB chairs) confirm availability to be present at the meeting and that the meeting quorum will be appropriately met. If the meeting will not meet the quorum requirements, make arrangements to meet quorum requirements.
  - The IRB has appropriate expertise to review submissions listed on the agenda. If the IRB does not have the relevant expertise available, a consultation may be requested from university employees or external consultants. If a consultant is requested, ensure to determine if there is a Conflict of Interest. Ensure documenting agreement of the consultant to maintain confidentiality of information provided, prior to Committee Review invitation. If the consultant provides a written report, provide the report to the IRB members for review.
- **Minutes:** Meeting minutes are drafted and distributed to all IRB members by DIEC before the next meeting for review and approval. Committee Review minutes include the meeting date, time of start and finish, attendance, conflicts of interest, and discussion of agenda items. The minutes section of each registration includes information on:
  - **Submission Information:** Lists the IRB Number, Project Title, PI, Sponsor Name, Grant Number, Review Category, Designated Reviewer, Vulnerable Populations, Level of Risk, and Basis for Level of Risk.
  - **Discussion Summary:** Includes a brief discussion summary, including mention of any previous actions, consultation reports, and controverted issues or concerns relating to the submission are identified with proposed resolutions.
  - **Determinations:** Include all applicable determinations (waivers; subparts b, c, d; devices; etc).
  - **Motion:** Each motion requires specific information to be captured:
    - For a motion of "Approval" no other information needs to be recorded.
    - For a motion of "Requires Revisions" related to an initial or continuing review submission records the reasons and required modifications.

        - For a motion of "Table" and "Return/Deny" record the IRB's reasons and recommendations.
        - For a motion of "Suspend" record the specific activities suspended, reason for suspension, and the IRB's recommendations, if any.
        - For a motion of "Lift Suspension" no other information needs to be recorded.
        - For a motion of "Terminate" record the IRB's reasons.
    - **Vote:** Each vote must be captured for each voting members vote as:
        - "For": Voting for the motion.
        - "Against": Voting against the motion
        - "Abstain": Present for the vote, but not voting "For" or "Against"
        - "Absent": Present for the meeting but not present for the vote.
        - "Recused": Present for the meeting but not present for discussion and vote due to a Conflicting Interest.
- **Correspondence:** Drafting all IRB correspondence (approval letters, notices, post review requests for revisions, and acceptance memos) for review and approval by Chair prior to distribution.

6.5.1 Post Review:

The post review process begins when a Designated Reviewer or Committee Review determines whether a submission requires revision to secure approval or cannot be approved.

Communication of Findings and Actions:

- The IRB communicates its findings and actions to the investigator.
- The IRB reports its findings and actions to the institution as required.
- When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and offers the opportunity to respond in person or in writing.

Timeliness of Communications:

- Communication of review results to investigators is completed within 7 business days of the IRB meeting or receipt of completed review.
- Reporting of Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval, and Unanticipated Problems Involving Risks to Subjects or Others to outside agencies, as applicable, must occur within 30 days of the determination of a reportable event.

Appeal of IRB Decisions:

- If an investigator disagrees with an IRB decision, they may submit a written appeal to the IRB Chair or DIEC within 30 days of receiving notification of the decision.
    - The appeal should include information supporting the disagreement.
    - For appeals involving research reviewed by a Designated Reviewer, the appeal is reviewed by the Designated Reviewer, IRB Chair, and DIEC.
    - For appeals involving research reviewed by the convened board, the appeal is reviewed by the convened board. The investigator may request to address the board to provide clarification or additional information.
    - The investigator will be notified in writing of the decision.
- The IO may override the IRB's decision to approve research; however, the IO or institution cannot approve research that has not been approved by the IRB or overrule other IRB decisions.

6.5.2 IRB Follow Up:

- Check in with investigators who have not resubmitted within 14 days of request for revisions.
- Remind investigators whose study is exempt within 30 days of the anniversary of approval that their study will continue to be considered open unless a closure report is submitted.
- Remind investigators whose study is non-exempt within 30 days of the expiration that their study will require a continuing review application.
- Notify investigators whose approval has lapsed due to lack of continuing review.
    - When possible, contact the investigator to determine if enrolled subjects should continue in the research because it is in their best interest.
    - Inform the investigator:
        - Which subjects may continue

- What procedures may continue
- All other research activities must stop, including advertisement, recruitment, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information
- New subjects may not be enrolled
- The continuing review progress report must be submitted as soon as possible

6.5.3 Consultant Review:

The IRB utilizes consultants to enhance IRB reviews when a project requires specialized expertise beyond the scope of IRB membership. Consultants may be needed for:

- Expertise related to a particular intervention or procedure.
- Understanding of the characteristics of a research population, including customs, social mores, or religious beliefs.
- Knowledge of the scientific or scholarly validity specific to the research design.
- Experience related to a research site or international locale, including local laws.
- Expertise related to protecting participants, including informed consent, privacy, and data confidentiality.

During the initial review of a submission, if the Designated Reviewer identifies the need for additional expertise is needed to complete the review, the designated reviewer must notify the DIEC or IRB Chair. Once identified, the DIEC, IRB Chair, or IO will consult with IRB members, University, affiliate administrators, or faculty to identify suitable experts.

The convened IRB may also determine that additional expertise is required:

- If the IRB decides that additional expertise is necessary before approval, the review and approval are deferred until the consultant's review is completed and presented at a subsequent meeting.
- If the IRB approves the submission with conditions but deems consultation necessary for finalizing changes, the consultant will work with the Designated Reviewer and DIEC to confirm the necessary information from the PI.

Consultants are not appointed members of the IRB and do not have voting rights. Their role is limited to providing expertise for specific submissions. Once an appropriate consultant is identified, the DIEC is ensures:

- The consultant has no conflicts of interest that might affect the review before engaging in the review process. Consultants with conflicts may only participate under these conditions:
  - They restrict their input to the information requested by the IRB, or
  - They disclose their conflict to the IRB before presenting their comments if no alternative expert is available.
- Consultants receive relevant materials and must provide written comments and recommendations. These documents are attached as the agenda.
- Consultant reviews, summaries, findings, considerations, and recommendations are presented to the Designated Reviewer via email or at IRB meeting by the consultant or IRB Chair.

6.5.4 IRB Record Requirements:

A. Documentation of IRB Activities

The IRB prepares and maintains adequate documentation of IRB activities within the Office of Sponsored Programs, including the following:

1. **Research Proposals and Consent Documents:**
   - Copies of all research proposals reviewed.
   - Approved sample consent documents.
   - Continuing reports submitted by investigators.
2. **Minutes of IRB Meetings:**
   - Members present (any consultants/guests/others shown separately).
   - Results of discussions on debated issues and record of IRB decisions.
   - Record of voting (showing votes for, against, and abstentions).

3. **Continuing Review Activities:**
    - Records of continuing review activities.
    - Updated consent documents and summaries of ongoing project activities.
    - Consent documents are stamped to show IRB approval and date of approval expiration.
4. **Correspondence:**
    - Copies of all correspondence between the IRB and the investigators.
5. **Significant New Findings:**
    - Any statements of significant new findings (unanticipated risks or adverse reactions) were provided to subjects.
6. **Adverse Reactions Reports:**
    - Adverse reactions reports and documentation that the IRB reviews such reports.
7. **Emergency Use Reports:**
    - Emergency use reports.
8. **General Project Information:**
    - General project information provided to subjects (e.g., fact sheets, brochures).

Retention and Accessibility of Records

These documents and records shall be retained for at least three (3) years after the research is completed. The records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

B. Preservation of Informed Consent Forms

All forms submitted or retained as evidence of informed consent must be preserved by the investigator indefinitely. Should the Principal Investigator (PI) leave UMassD, signed consent forms are to be transferred to the DIEC to be secured within the Office of Institutional Ethics & Compliance.

Section 7: Additional Regulatory Requirements

7.1 DHHS-Regulated Research

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-withdrawal-of-subject/index.html

Participant Withdrawal:

1. **Clarification of Withdrawal Intent:**
   - When a participant decides to withdraw from a clinical trial, the investigator should ask whether the participant wishes to withdraw from all components of the trial or only from the primary interventional component.
   - If the participant only withdraws from the primary interventional component, research activities involving other components, such as follow-up data collection, may continue with the participant's previously given consent.
   - The investigator should explain to the participant the importance of obtaining follow-up safety data.
2. **Retention and Analysis of Collected Data:**
   - Investigators are allowed to retain and analyze already collected data from participants who withdraw or whose participation is terminated by an investigator, provided such analysis falls within the scope described in the IRB-approved protocol.
   - This applies even if the data includes identifiable private information.
3. **Destruction or Exclusion of Data (Non-FDA Regulated Research):**
   - For research not subject to FDA regulation, investigators, in consultation with the funding agency, can choose to honor a participant's request to destroy or exclude their data from analysis.
4. **Informed Consent and Data Retention:**
   - Investigators should explain during the informed consent process whether already collected data will be retained and analyzed even if the participant chooses to withdraw from the research.

When research is covered by a certificate of confidentiality, researchers:

1. **Disclosure Restrictions:**
   - Researchers may not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of an individual or any information, document, or biospecimen containing identifiable, sensitive information created or compiled for the research without the individual's consent.
   - Researchers may not disclose or provide this information to any person not connected with the research.
2. **Permissible Disclosures:**
   - Disclosure is allowed when:

- It is required by Federal, State, or local laws (excluding civil, criminal, administrative, legislative, or other proceedings).
- It is necessary for the medical treatment of the individual and made with their consent.
- It is made with the consent of the individual.
- It is made for other scientific research in compliance with applicable Federal regulations governing the protection of human participants in research.

3. **Limitations:**
    - Researchers must inform participants of the protections and limitations of certificates of confidentiality.
        - For studies previously issued a Certificate, NIH does not expect participants to be notified of changes in protections, unless determined appropriate by the IRB.
        - Participants in the study cohort recruited prior to issuing a Certificate and are no longer active are not expected to be notified of the Certificate or changes in protections, unless determined appropriate by the IRB.
4. **Compliance by Other Researchers:**
    - Researchers conducting research covered by a certificate of confidentiality, even if not federally funded, must ensure that other researchers or organizations comply with applicable requirements if identifiable, sensitive information is provided to them when research is covered by a certificate of confidentiality.

7.2 FDA-Regulated Research

http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.68
http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.69
http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.100
http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.110
http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.140

Verification of Electronic Signatures:
The regulation 21 CFR part 11 indeed mandates the verification of an individual's identity before using their electronic signature for consent forms during electronic, digital, or remote consent processes. This is to ensure the authenticity and integrity of the electronic signatures.

Participant Withdrawal:

- **Data Retention**: Data collected up to the point of withdrawal should remain part of the study database and cannot be removed. This aligns with maintaining the integrity of the data collected during the participant's involvement.
- **Continued Follow-Up**: Investigators are permitted to ask participants who withdraw if they are willing to provide continued follow-up. This follow-up might involve collecting additional data on clinical outcomes, which must be distinguished from study-related interventions. The privacy and confidentiality of the participant's information must be safeguarded.
- **Informed Consent for Continued Follow-Up**: If continued follow-up is not covered in the original consent form, the investigator must obtain informed consent for this additional participation. This requires IRB approval if it involves modifying the consent form or adding new elements not initially covered.
- **Access Restrictions**: If a participant withdraws and does not consent to continued follow-up, investigators must refrain from accessing the participant's medical or other confidential records related to the study. This ensures respect for the participant's withdrawal and privacy.
- **Review of Pre-Withdrawal Data**: Investigators may review and use data collected before withdrawal and may consult public records, such as those establishing survival status. This is permissible to ensure the study's results are comprehensive and accurate, provided it adheres to confidentiality requirements.

7.2.1 For FDA-regulated research involving investigational drugs:

a. **FDA Restrictions on Promotion**: Investigators and their representatives must adhere to FDA restrictions on the promotion of investigational drugs, meaning that they are prohibited from making any promotional claims that suggest the investigational new drug is safe or effective for the purposes for which it is under investigation;

this restriction is in place to prevent the commercial promotion of the drug before it has been officially approved for commercial distribution, although it does not limit the full exchange of scientific information or the dissemination of findings through scientific or lay media. Moreover, investigators are strictly prohibited from commercially distributing or test marketing the investigational new drug.

b. **General Responsibilities of Investigators**: Investigators are required to ensure that the investigation is conducted in accordance with the signed investigator statement, the investigational plan, and applicable regulations; they must also protect the rights, safety, and welfare of participants under their care and manage the investigational drugs properly. Additionally, in compliance with 21 CFR §50, investigators must obtain the informed consent of each participant before administering the drug, unless exceptions provided in 21 CFR §50.23 or §50.24 apply. Specific responsibilities are further detailed in 21 CFR §50 and §56.
c. **Control of Investigational Drugs**: The investigational drug must be administered solely under the personal supervision of the investigator or a sub-investigator who is responsible to the main investigator; furthermore, the drug must not be supplied to individuals who are not authorized to receive it under the regulations stipulated.
d. **Recordkeeping and Record Retention**: Investigators must maintain detailed records of the drug's disposition, including dates, quantities, and participant usage, and if the investigation is terminated, suspended, discontinued, or completed, they are required to return unused drug supplies to the sponsor or otherwise dispose of them in accordance with 21 CFR §312.59. Additionally, investigators must prepare and maintain accurate case histories for each participant, documenting all relevant observations and data, including signed consent forms and medical records; these records must confirm that informed consent was obtained prior to participation. Required records must be retained for 2 years after the date a marketing application is approved for the drug or, if no application is filed or if it is not approved, until 2 years after the investigation is discontinued and FDA is notified.
e. **Investigator Reports**: Investigators are obligated to submit all progress reports to the sponsor, who is responsible for collecting and evaluating the results; they must promptly report any adverse effects that might reasonably be attributed to the drug, with immediate reporting required for serious adverse effects. Upon completing their participation in the investigation, investigators must provide the sponsor with a comprehensive final report. Furthermore, investigators must disclose sufficient financial information to the sponsor to facilitate accurate certification or disclosure statements as required by 21 CFR §54, with prompt updates to this information if relevant changes occur during the study and for 1 year following its completion.
f. **Assurance of IRB Review**: Investigators must ensure that an IRB, compliant with the requirements outlined in 21 CFR §56, will be responsible for the initial and ongoing review and approval of the clinical study; they are also required to report all research activity changes and unanticipated problems involving risk to human participants or others to the IRB promptly, and must not make changes to the research without IRB approval, except when necessary to eliminate immediate hazards to participants.
g. **Inspection of Records and Reports**: Investigators must allow authorized FDA officers or employees reasonable access to inspect, copy, and verify any records or reports related to the study as mandated by 21 CFR §312.62; however, they are not obliged to divulge participant names unless the records necessitate a detailed case study or there is reason to suspect the records do not reflect actual case studies or results.
h. **Handling Controlled Substances**: If the investigational drug falls under the Controlled Substances Act, investigators must implement adequate security measures, including storing the drug in a securely locked, substantially constructed cabinet or enclosure with limited access, to prevent theft or diversion into illegal distribution channels.

7.2.2 For FDA-regulated research involving investigational devices:

a. **General Responsibilities of Investigators**:

- Investigators must ensure that the investigation is conducted according to the signed agreement, the investigational plan, and applicable FDA regulations. They are responsible for protecting the rights, safety, and welfare of participants under their care and for managing the investigational devices. Additionally, informed consent must be obtained in compliance with 21 CFR §50.

b. **Specific Responsibilities of Investigators**:

- **Awaiting Approval**: Investigators may assess potential participant interest but must not request written informed consent or allow participation until IRB and FDA approvals are obtained.
- **Compliance**: Investigators must conduct the investigation in line with the signed agreement, investigational plan, and applicable FDA regulations, including any conditions imposed by the IRB or FDA.

- **Supervising Device Use**: Devices must only be used under the investigator's supervision, and investigators must not supply the device to unauthorized individuals.
- **Financial Disclosure**: Investigators must provide the sponsor with accurate financial information for certification or disclosure statements required under 21 CFR §54 and update this information promptly during and up to 1 year after the study's completion.
- **Disposing of Device**: Upon completion or termination of the investigation or at the sponsor's request, investigators must return any remaining device supplies to the sponsor or dispose of them as directed.

c. **Recordkeeping**:

- **Correspondence**: Maintain all correspondence with investigators, IRBs, sponsors, monitors, or FDA, including required reports.
- **Device Records**: Document receipt, use, or disposition of the device, including type, quantity, receipt dates, batch numbers, and names of those who received, used, or disposed of the device; record reasons for return, repair, or disposal of the device.
- **Case Histories**: Maintain case report forms and supporting data, including signed consent forms, medical records, and documentation of informed consent; include records of adverse device effects, participant condition upon entry and throughout the investigation, and exposure details (dates, times, and other therapies).
- **Protocol Deviations**: Keep the protocol and documents showing dates and reasons for deviations.
- **Additional Records**: Retain any other records required by FDA regulations or specific to the investigation.

d. **Inspections**:

- **Entry and Inspection**: Allow FDA employees access to inspect any establishment where devices are held, including manufacturing or processing sites.
- **Records Inspection**: Permit FDA employees to inspect and copy all records related to the investigation.
- **Records Identifying Participants**: If the FDA suspects inadequate informed consent or incomplete reports, investigators must allow inspection of records identifying participants.

e. **Reports**:

- **Unanticipated Adverse Device Effects**: Report to the sponsor and IRB within 10 working days of learning about the effect.
- **Withdrawal of IRB Approval**: Report IRB withdrawal of approval within 5 working days.
- **Progress Reports**: Submit progress reports to the sponsor, monitor, and IRB at least annually.
- **Deviations**: Notify the sponsor and IRB of deviations made in emergencies within 5 working days. For other deviations, obtain prior approval from the sponsor, and if they affect scientific soundness or participant welfare, from the FDA and IRB.
- **Informed Consent**: Report any use of a device without informed consent to the sponsor and IRB within 5 working days.
- **Final Report**: Submit a final report to the sponsor and IRB within 3 months after study completion or termination.
- **Other Information**: Provide accurate, complete, and current information about any aspect of the investigation upon request from IRB or FDA.

7.3 NIH Specific Policies

7.3.1 NIH Policy for Certificates of Confidentiality

The NIH issued its Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality (CoCs) protect sensitive, identifiable information from legal disclosure. Effective October 1, 2017, CoCs are automatically issued for applicable NIH awards, and the award serves as confirmation of CoC protections. Also, NIH will no longer provide a paper certificate. The award itself may be used as confirmation that CoC protections are in place. The policy applies to research commenced or ongoing on or after December 13, 2016. For ongoing studies, re-consenting participants is generally not required, but IRBs may choose to inform participants about changes in protection. The NIH CoC website has now been updated and includes updated consent language and FAQs.

Although CoCs are intended to prohibit disclosure of sensitive, identifiable information in response to legal demands, applicability has been broadened to include the following:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

Institutions and investigators can also send questions to: NIH CoC Coordinator.

For more information see, Appendix: Federal Agencies that issue Certificates of Confidentiality

7.3.2 NIH Policy for Data Management and Sharing

The National Institutes of Health (NIH) has issued the final NIH Policy for Data Management and Sharing (DMS Policy) to promote the management and sharing of scientific data generated from NIH-funded or conducted research. ***This Policy is effective January 25, 2023,*** and applies to research funded or conducted by NIH that results in the generation of scientific data. The DMS policy establishes the requirements to submit Data Management and Sharing Plans to the NIH. Investigators are responsible for adherence to their plans and referring to the NIH for latest guidance and policy changes.

Policy Impact on IRB Submissions
As part of the criteria for IRB approval outlined in the federal regulations, the IRB must confirm that informed consent has been sought from participants and that there are adequate provisions to maintain confidentiality of data. Hence, this policy has impact on confidentiality plans and informed consents submitted to the IRB.
Data Management and Sharing Plans should be submitted to the IRB so that the IRB may review plans for data sharing, along with measures of security, confidentiality, and any limitations to data sharing.

- Data Management and Sharing Plans should align with the confidentiality plan outlined in the standalone protocol.
- The NIH emphasizes that "access to scientific data derived from humans should be *controlled*, even if de-identified and lacking explicit limitations on subsequent use." Additionally, controlled-access repositories should be considered if the data "could be considered sensitive, such as including information regarding potentially stigmatizing traits, illegal behaviors, or other information that could be perceived as causing group harm or used for discriminatory purposes."
- Likewise, "privacy protections should be considered regardless of whether the data meet technical and/or legal definitions of "de-identified" and can legally be shared without additional protections."
- Questions on NIH requirements for Data Management and Sharing Plans should be directed to the IRB.

Data sharing and use should be clearly communicated in consent processes. The NIH encourages researchers to "develop robust consent processes that prioritize clarity regarding future sharing and use of scientific data, including limitations on future use, and general aspects regarding how data will be managed." Likewise, "scientific data that are collected, shared, or used without informed consent also deserve privacy considerations."

- Investigators should ensure that their Data Management and Sharing Plans align with what is presented as part of the informed consent process. This ensures that participants' autonomy is respected.

- NIH recommends that "scientific data be de-identified to the greatest extent that maintains sufficient scientific utility. Unless participants explicitly consent to sharing identifiable data (e.g., under the broad consent provision of the Common Rule), data should generally be shared only in a de-identified format."

7.3.3 NIH Single IRB Policy

The NIH Single IRB (sIRB) Policy, effective January 25, 2018, requires all participating sites in multi-site studies involving non-exempt human subjects research funded by NIH use a single IRB to conduct ethical reviews. A single IRB of record will be designated to review and approve the research, ensuring protection of human subjects across all participating sites. This policy aims to streamline the review process, reduce administrative burdens, and enhance efficiency while ensuring the protection of human subjects. The policy applies to domestic sites conducting the same research protocol under NIH funding, excluding career development, research training, and fellowship awards. By centralizing the review process with a single IRB, the NIH seeks to maintain high standards of human subjects protection while minimizing redundant efforts across multiple sites. The NIH single IRB policy applies to multi-site human subjects research regardless of the funding mechanism (e.g., grants, cooperative agreements, contracts or other mechanisms such as Cooperative Research and Development Agreements (CRADAs), and Interagency Agreements (IAA)). The policy applies whether the sites are subawards to a primary award recipient or separate awards are made for participating sites. The NIH Single IRB policy does not apply to Other Transaction Agreements (OTAs). UMassD has established procedures for selecting and working with sIRBs. Researchers should contact the IRB for guidance on sIRB selection and reliance agreements.

Key Points

- **Responsibilities of the Lead Institution:** The lead institution (the one applying for the NIH grant) selects the sIRB based on its capability to provide appropriate review and compliance. The lead institution must establish an IRB Review Agreement with the sIRB, detailing the review process, communication procedures, and handling of modifications or reports.
- **Responsibilities of Participating Sites:** Local Context must be provided for each site address local regulatory issues and obtain any additional approvals or consents required. Sites must enter into a Reliance Agreement with the lead institution and the sIRB, formalizing reliance on the sIRB and outlining site responsibilities.
- **Coordination:** The lead institution and participating sites must coordinate with the sIRB to provide required information and address issues promptly. The sIRB provides ongoing oversight, while the lead institution and sites must report adverse events, protocol deviations, and significant issues as specified in the IRB Review Agreement.
- **Exceptions:** Exceptions to the sIRB policy may apply in cases involving sensitive populations or site-specific concerns. Justification and NIH approval are required for exceptions.

7.4 Research Subject to EU General Data Protection Regulations (GDPR)

https://gdpr-info.eu

1. **GDPR Applicability:** Data and/or specimen collection involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland is subject to EU General Data Protection Regulations. Researchers must ensure compliance with these regulations.
2. **Prospective Data Collection:** For all prospective data and/or specimen collection activities subject to EU GDPR, consult institutional legal counsel or the institution's Data Protection Officer to confirm that the following elements are consistent with institutional policies and GDPR interpretations:
    - Study design elements related to data security measures.
    - Procedures for the rights to access, rectification, and erasure of data.
    - Procedures for broad/unspecified future use consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.
3. **Retrospective Data Collection:** For retrospective data and/or specimen collection activities subject to EU GDPR, submit data use agreements through the Agreements system to ensure consistency with institutional policies and GDPR interpretations:
    - Study design elements related to data security measures.
    - Procedures for the rights to access, rectification, and erasure of data.

- Procedures for broad/unspecified future use consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

4. **Regulatory Consistency:** When FDA or DHHS regulations apply in addition to EU GDPR regulations, ensure that procedures related to withdrawal from the research, as well as the management of information and biospecimens, remain consistent with the applicable regulations and procedures.

7.5 Clinical Trials (ICH-GCP)

https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

Clinical Trials (ICH-GCP) refers to the guidelines established by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) to ensure the quality and integrity of clinical trials. ICH-GCP, or Good Clinical Practice, is a set of internationally recognized standards for conducting clinical trials involving human participants.

1. Investigator's Qualifications and Agreements:

a. The clinical trial should be conducted in accordance with the ethical principles originating from the Declaration of Helsinki, aligned with good clinical practice (GCP) and applicable regulatory requirements.
b. The investigator should be qualified by education, training, and experience to assume responsibility for the trial's proper conduct; they must meet all qualifications specified by regulatory requirements and provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, or regulatory authorities.
c. The investigator should be thoroughly familiar with the appropriate use of the investigational product as described in the protocol, the current Investigator's Brochure, product information, and other sources provided by the sponsor.
d. The investigator should be aware of and comply with GCP and applicable regulatory requirements, including ICH-GCP training.
e. The investigator/institution should permit monitoring and auditing by the sponsor and inspection by appropriate regulatory authorities. f. The investigator should maintain a list of appropriately qualified persons to whom significant trial-related duties have been delegated.

2. Adequate Resources:

a. The investigator should demonstrate a potential for recruiting the required number of suitable participants within the agreed recruitment period, based on retrospective data if necessary.
b. The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
c. The investigator should have an adequate number of qualified staff and facilities available for the duration of the trial to conduct it properly and safely.
d. The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product, and their trial-related duties and functions.

3. Medical Care of Trial Participants:

a. A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.
b. During and following a participant's involvement in the trial, the investigator/institution should ensure that adequate medical care is provided for any adverse events, including clinically significant laboratory values related to the trial. The investigator/institution should inform participants when medical care is needed for intercurrent illnesses of which the investigator becomes aware.
c. It is recommended that the investigator inform the participant's primary physician about the participant's trial participation if the participant has a primary physician and agrees to the primary physician being informed.
d. Although a participant is not required to provide reasons for withdrawing prematurely from the trial, the investigator should make a reasonable effort to ascertain the reasons while fully respecting the participant's rights.

4. Communication with IRB:

a. Before initiating a trial, the investigator/institution should have written and dated approval from the IRB for the trial protocol, written informed consent form, consent form updates, participant recruitment procedures (e.g., advertisements), and any other written information to be provided to participants.

b. As part of the investigator's/institution's written application to the IRB, the investigator/institution should provide a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator's Brochure to the IRB.
c. During the trial, the investigator/institution should provide the IRB with all documents pertinent to review.

5. Compliance with Protocol:

a. The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authorities and which was given approval by the IRB. The investigator/institution and the sponsor should sign the protocol or an alternative contract to confirm agreement.
b. The investigator should be able to demonstrate, based on retrospective data, if necessary, the potential for recruiting the required number of suitable participants within the agreed recruitment period.
c. The investigator should have enough qualified staff and facilities available for the foreseen duration of the trial to conduct it properly and safely.
d. During and following a participant's participation in the trial, the investigator/institution should ensure that adequate medical care is provided for any adverse events, including clinically significant laboratory values related to the trial. The investigator/institution should inform a participant when medical care is needed for intercurrent illnesses of which the investigator becomes aware.
e. The investigator should not implement any deviation from or changes to the protocol without agreement from the sponsor and prior review and documented approval by the IRB of an amendment, except where necessary to eliminate immediate hazards to trial participants or when the changes involve only logistical or administrative aspects of the trial (e.g., change in monitors, change of telephone numbers).
f. The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol. g. The investigator may implement a deviation from or change to the protocol to eliminate an immediate hazard to trial participants without prior IRB approval. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendments should be submitted:
    i. to the IRB for review and approval,
    ii. to the sponsor for agreement, and, if required,
    iii. to the regulatory authorities.

6. Investigational Product:

a. Responsibility for investigational product accountability at the trial site rests with the investigator/institution.
b. Where allowed or required, the investigator/institution may assign some or all their duties for investigational product accountability at the trial site to an appropriate pharmacist or another suitable individual under their supervision.
c. The investigator/institution and/or a designated pharmacist or appropriate individual should maintain records of the product's delivery to the trial site, inventory at the site, use by each participant, and return to the sponsor or alternative disposition of unused product. These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product and trial participants. Investigators should maintain records that adequately document that participants were provided the doses specified by the protocol and reconcile all investigational products received from the sponsor.
d. The investigational product should be stored as specified by the sponsor and in accordance with applicable regulatory requirements.
e. The investigator should ensure that the investigational product is used only in accordance with the approved protocol.
f. The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product to each participant and check at appropriate intervals that each participant is following the instructions properly.
g. Randomization Procedures and Unblinding: The investigator should follow the trial's randomization procedures, if any, and ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product.

7. Informed Consent of Trial Participants

a. In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirements and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Before the trial begins, the investigator should have the IRB's written approval

opinion of the written informed consent form and any other written information to be provided to participants.

b. The written informed consent form and any other written information to be provided to participants should be revised whenever important new information becomes available that may be relevant to the participant's consent. Any revised written informed consent form, and written information should receive the IRB's approval opinion in advance of use. The participant or their legally acceptable representative should be informed promptly if new information becomes available relevant to the participant's willingness to continue participation in the trial. The communication of this information should be documented.

c. Neither the investigator, nor the trial staff, should coerce or unduly influence a participant to participate or to continue to participate in a trial.

d. None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the participant or the participant's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

e. The investigator, or a person designated by the investigator, should fully inform the participant or, if the participant is unable to provide informed consent, the participant's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval opinion by the IRB.

f. The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the participant or the participant's legally acceptable representative and the impartial witness, where applicable.

g. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the participant or the participant's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the participant or the participant's legally acceptable representative.

h. Prior to a participant's participation in the trial, the written informed consent form should be signed and personally dated by the participant or by the participant's legally acceptable representative, and by the person who conducted the informed consent discussion.

i. If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to participants, is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that informed consent was freely given by the participant or the participant's legally acceptable representative.

j. Both the informed consent discussion and the written informed consent form and any other written information to be provided to participants should include explanations of the following:
    i. That the trial involves research.
    ii. The purpose of the trial.
    iii. The trial treatments and the probability for random assignment to each treatment.
    iv. The trial procedures to be followed, including all invasive procedures.
    v. The participant's responsibilities.
    vi. Those aspects of the trial are experimental.
    vii. The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant.
    viii. The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.
    ix. The alternative procedures or courses of treatment that may be available to the participant, and their important potential benefits and risks.
    x. The compensation and/or treatment available to the participant in case of trial-related injury.
    xi. The anticipated prorated payment, if any, to the participant for participating in the trial.
    xii. The anticipated expenses, if any, to the participant for participating in the trial.

xiii. That the participant's participation in the trial is voluntary and that the participant may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.
xiv. That the monitors, the auditors, the IRB, and the regulatory authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally acceptable representative is authorizing such access.
xv. That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential.
xvi. That the participant or their legally acceptable representative will be informed promptly if information becomes available relevant to the participant's willingness to continue participation in the trial.
xvii. The people to contact for further information regarding the trial and the rights of trial participants, and whom to contact in the event of trial-related injury.
xviii. The foreseeable circumstances and/or reasons under which the participant's participation in the trial may be terminated.
xix. The expected duration of the participant's participation in the trial.
xx. The approximate number of participants involved in the trial.

k. Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the participants. During a participant's participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to participants.

l. When a clinical trial (therapeutic or non-therapeutic) includes participants who can only be enrolled in the trial with the consent of the participant's legally acceptable representative (e.g., minors, or patients with severe dementia), the participant should be informed about the trial to the extent compatible with the participant's understanding and, if capable, the participant should sign and personally date the written informed consent.

m. Except as described above, a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the participant), should be conducted in participants who personally give consent and who sign and date the written informed consent form.

n. Non-therapeutic trials may be conducted in participants with consent of a legally acceptable representative provided the following conditions are fulfilled:
i. The trial's objectives cannot be met by a trial in participants who can give informed consent personally.
ii. The foreseeable risks to the participants are low.
iii. The negative impact on the participant's well-being is minimized and low.
iv. The trial is not prohibited by law.
v. The approval opinion of the IRB is expressly sought on the inclusion of such participants, and the written approval opinion covers this aspect. Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be closely monitored and withdrawn if they appear unduly distressed.

o. In emergency situations, when prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, should be requested. When prior consent of the participant is not possible, and the participant's legally acceptable representative is not available, enrolment of the participant should require measures described in the protocol and/or elsewhere, with documented approval opinion by the IRB, to protect the rights, safety and well-being of the participant and to ensure compliance with applicable regulatory requirements. The participant or the participant's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate should be requested.

p. If the study is a clinical trial and supported by a Common Rule agency, one IRB- approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. Contact the study sponsor with any questions.

8. Records and Reports

a. The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.

b. Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

c. Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections. Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

d. The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements. The investigator/institution should take measures to prevent accidental or premature destruction of these documents.

e. Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. The sponsor is responsible for informing the investigator/institution when these documents no longer need to be retained.

f. The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

g. Upon request of the monitor, auditor, IRB, or regulatory authority, the investigator/institution should make available for direct access all requested trial- related records.

9. Progress Reports

a. The investigator should submit written summaries of the trial status to the IRB annually, or more frequently, if requested by the IRB.

b. The investigator should promptly provide written reports to the sponsor, the IRB and, where applicable, the institution on any changes significantly affecting the trial's conduct and/or increasing the risk to participants.

10. Safety Reporting

a. All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify participants by unique code numbers assigned to the trial participants rather than by the participants' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authorities and the IRB.

b. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

c. For reported deaths, the investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).

d. Premature Termination or Suspension of a Trial If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial participants, should assure appropriate therapy and

e. follow-up for the participants, and, where required by the applicable regulatory requirements, should inform the regulatory authorities. In addition:

   i. If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the IRB and should provide the sponsor and the IRB a detailed written explanation of the termination or suspension.

ii. ii. If the sponsor terminates or suspends a trial, the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the IRB and provide the IRB a detailed written explanation of the termination or suspension.

iii. If the IRB terminates or suspends its approval opinion of a trial, the investigator should inform the institution where applicable and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

11. Final Reports by Investigator: Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB with a summary of the trial's outcome, and the regulatory authorities with any reports required.

7.6 Department of Defense (DOD) Research

https://www.esd.whs.mil/portals/54/documents/dd/issuances/dodi/321602p.pdf

1. **IRB Review and Approval:** Research protocols involving human participants must receive IRB review and approval before obtaining approval from the Department of Defense (DoD), if this is a requirement of the specific DoD funding component. Researchers should consult with the relevant DoD funding component to determine whether prior IRB approval is necessary.
2. **Collaboration for Military Research:** Civilian researchers who wish to access military volunteers should collaborate with a military researcher who is familiar with the specific requirements of the services involved. This collaboration ensures compliance with service-specific guidelines and facilitates access to military populations.
3. **Compensation for DoD Employees:** Employees of the Department of Defense, including those in temporary, part-time, and intermittent positions, may need to check with their supervisors before accepting payment for participation in research. DoD employees are prohibited from receiving payment for conducting research while on active duty.
4. **Command Permission:** Service members must adhere to their command's policies regarding participation in research involving human participants, both when on-duty and off-duty. Compliance with these policies is necessary for ensuring proper authorization and adherence to military regulations.
5. **Research-Related Injury:** The DoD may impose stricter requirements for handling research-related injuries compared to those outlined in DHHS regulations. Researchers should be aware of and comply with these additional requirements to address any injuries or adverse events effectively.
6. **Educational Requirements:** There may be specific educational or certification requirements for personnel involved in DoD research. These requirements ensure that researchers are adequately trained and qualified to conduct research within the DoD framework.
7. **Institutional Evaluation:** When assessing whether to support or collaborate with an institution for research involving human participants, the DoD may evaluate the institution's education and training policies. This evaluation helps ensure that the research personnel are properly qualified to conduct the research.
8. **Dual Compensation Limitations:** The Department of Defense has specific rules regarding compensation for research activities. Federal employees are prohibited from receiving compensation for research conducted during their duty hours. Non-Federal individuals may receive compensation for research participation, including blood draws, up to $50 per draw. For other types of research participation, non-Federal persons may be compensated a reasonable amount as approved by the IRB, based on local prevailing rates and the nature of the research.
9. **Surveys and DoD Review:** Surveys conducted on DoD personnel must be submitted to and approved by the DoD Information Management Control Officer (IMCO) following IRB approval. If a survey involves multiple DoD components, additional review is required to ensure compliance with DoD policies.
10. **Large Scale Genomic Data (LSGD) Protections:** Research involving large-scale genomic data collected from DoD-affiliated personnel requires additional safeguards. These include administrative, technical, and physical measures to prevent unauthorized disclosure of data. The research must also apply for an HHS Certificate of Confidentiality and undergo a DoD Component security review.
11. **Confidentiality of Data:** Data or information sent to a DoD component under a pledge of confidentiality for statistical purposes must be used exclusively for those purposes. Such data may not be disclosed in identifiable form for any other purpose without the informed consent of the respondent.
12. **Multi-Site Research Agreements:** For multi-site research, a formal agreement between institutions is required. This agreement should clearly define the roles and responsibilities of each party involved in the research to ensure coordination and compliance with research protocols.

13. **Reporting to DoD:** Researchers must report several types of information to the applicable DoD Component Office of Human Research Protections within 30 days. This includes significant changes to the research protocol that have been approved by the IRB or Ethics Committee, such as changes to key investigators or institutions, decreases in benefit or increases in risk to participants in greater than minimal risk research, the addition of vulnerable populations or DoD-affiliated personnel as participants, and changes in the reviewing IRB. Notifications must also be made if the organization is informed by any federal body, state agency, governing body of Native American or Alaskan Native tribes, or other entities about an investigation involving DoD-supported research protocols. Additionally, researchers should report any problems involving risks to participants or others, suspension or termination of IRB approval, or serious or continuing noncompliance related to DoD-supported research. Results of the IRB's continuing review, if required, should be submitted, along with any changes in status for previously enrolled participants, such as pregnancy or imprisonment, if these changes were not reviewed and approved by the IRB in accordance with applicable regulations. Finally, closure of a DoD-supported study must be reported.
14. **Approval for Sensitive Research:** For research that may affect the health or welfare of pregnant women, fetuses, or neonates, written approval from the DoD Office for Human Research Protections is required before starting the research. This ensures that such sensitive research is conducted with appropriate oversight and ethical considerations.

7.7 Department of Energy (DOE) Research:

https://www.directives.doe.gov/directives-documents/400-series/0443.1-BOrder-c/@@download/file

1. **IRB Review and Approval:** Research that involves studying humans in a systematically modified environment, including intentional modifications such as using tracer chemicals to characterize airflow or testing new materials in occupied homes or offices, must be submitted to the appropriate IRB for review and determination. This includes studies involving social media data, Human Terrain Mapping (HTM), and all exempt human subjects research (HSR) determinations.
2. **Protection of Personally Identifiable Information:** Personally identifiable information (PII) collected during HSR projects must be protected in accordance with DOE Order 206.1, the Department of Energy Privacy Program. Researchers must submit protocols that include PII to the Central DOE IRBs.
3. **Reporting:** Prior to initiating any new human subjects research project, researchers must report to the DOE human subjects research Program Manager (and, if applicable, the NNSA HSP Program Manager) if the research involves an institution without an established IRB, a foreign country, potential for significant controversy, protected classes of research subjects, or the generation or use of classified information. This includes projects that meet the regulatory definition of exempt research under 10 CFR Part 745.104.
4. **Notifications:** The IRB and the DOE HSP Program Manager (and NNSA HSP Program Manager, if applicable) must be notified within 48 hours of any adverse events, unanticipated problems, complaints, suspensions or terminations of IRB approval, significant noncompliance, suspected or confirmed data breaches involving PII, and serious adverse events and corrective actions. "Immediately" is defined as upon discovery.
5. **Classified Research:** Human participant protections for classified research apply to all classified research conducted or supported by the DOE and its national laboratories, including contracts and Human Terrain Mapping research.
6. **International Research Requirements:** Researchers conducting human subjects research in foreign countries must adhere to the country-specific human subjects research requirements and consult with the IRB about the applicability of these requirements.
7. **FWA and IRB Approval:** Human subjects research conducted with DOE funding, at DOE institutions, or by DOE or contractor personnel, whether domestic or international, requires both Federalwide Assurance (FWA) or comparable assurance and approval by the cognizant IRB. Research involving multiple DOE sites must be reviewed and approved by a Central DOE IRB or another appropriate IRB as authorized by the DOE or NNSA HSP Program Manager. An IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) is required between the organizations conducting the research and the IRB.
8. **DOE Employee Research**: Research involving DOE Federal and/or contractor employees must be reviewed and approved by the appropriate DOE IRB or another suitable IRB, in accordance with an IAA or MOU negotiated between the DOE site or Headquarters and the IRB.
9. **Strategic Intelligence Partnership Program (SIPP):** Classified and unclassified human subjects research funded through the SIPP must be reviewed and approved by the Central DOE IRB-Classified.
10. **Paperwork Reduction Act:** Federally funded HSR must comply with the Paperwork Reduction Act, if applicable.

7.8 Department of Justice (DOJ) Research

7.8.1 DOJ Research conducted in the Federal Bureau of Prisons

https://www.bop.gov/policy/progstat/1070_007.pdf

1. **Exclusions and Compatibility:** Implementation of Bureau programmatic or operational initiatives through pilot projects is not considered research. The research must avoid medical experimentation, cosmetic research, or pharmaceutical testing and must be compatible with the operation of prison facilities and the protection of human participants.
2. **Institutional Rules and Agreements:** Investigators must adhere to the rules of the institution or office where the research is conducted. Non-employees of the Bureau of Prisons must sign a statement agreeing to comply with the requirements of 28 CFR §512.
3. **Review and Approval:** The research must be reviewed and approved by the Bureau Research Review Board. Incentives cannot be offered to persuade inmate participants, though soft drinks and snacks may be provided at the test setting. Nominal monetary recompense for time and effort may be offered to non-confined participants involved in authorized research conducted by Bureau employees or contractors.
4. **Use and Disclosure of Records:** Non-employees of the Bureau may receive records in a non-individually identifiable form if advance written assurance is provided that the records will be used solely for statistical research or reporting. Research information identifying participants cannot be released without the participant's prior written consent. Research records containing non-disclosable information directly traceable to a specific person may not be stored in or introduced into an electronic retrieval system, except for computerized data records maintained at an official DOJ site.
5. **Data Handling for Special Interest Studies:** If conducting a study of special interest to the Office of Research and Evaluation that is not a joint project, researchers may be required to provide non-identifiable computerized research data and detailed documentation. These arrangements must be negotiated before data collection begins.
6. **Required Elements of Disclosure:** Required disclosures must include several key components. The identification of the investigators and the anticipated uses of the research results must be clearly stated. Participants should be informed that their involvement is voluntary, with the option to withdraw at any time without facing any penalty or prejudice. The confidentiality of research information must be addressed, noting any exceptions to confidentiality guarantees required by federal or state law. Participants should be assured that their participation will not influence their release date or parole eligibility.
7. **Academic Preparation:** Researchers must have appropriate academic preparation or experience related to the proposed study.
8. **IRB Application Requirements:** The IRB application must contain a comprehensive summary of the study, including the names and current affiliations of the investigators, the title and purpose of the study, the location where the research will be conducted, the methods to be used, and the anticipated results. It should also outline the duration of the study, the number of participants required, the amount of time needed from each participant, and any risks or discomforts involved. In addition, the application must include a detailed description of the research method, a review of related literature, the significance of the results, the resources required from the Bureau of Prisons, and a discussion of the risks, benefits, and steps taken to minimize risks. It should describe physical or administrative procedures to ensure data security and the destruction of records when the research is complete, as well as any anticipated effects of the study on institutional programs and operations. Relevant research materials such as vitae, endorsements, consent statements, questionnaires, and interview schedules must also be included.
9. **Assurances and Certification:** The IRB application must include a statement regarding assurances and certifications required by federal regulations, if applicable.
10. **Responsibility and Reporting:** Researchers are responsible for the actions of associates, assistants, or subcontractors. At least once a year, researchers must provide the Chief, Office of Research and Evaluation, with a progress report. At least 12 working days before releasing findings, researchers must distribute a copy of the report to the Bureau Research Review Board chairperson, regional director, and warden of each institution that provided data or assistance. An abstract must be included in the report.
11. **Publication and Disclosure:** In any publication of results, the Bureau's participation must be acknowledged, but the publication should explicitly disclaim approval or endorsement of the material as reflecting the Bureau's policies or views. Prior to publication, researchers must provide two copies of the material to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons for informational purposes only.

7.8.2 DOJ Research Funded by the National Institute of Justice

https://nij.ojp.gov/funding/human-subjects-protection#:~:text=To%20ensure%20that%20human%20subjects,46%20(Protection%20of%20Human%20Subjects)

1. **Privacy Certificate:** The project must have a Privacy Certificate approved by the National Institute of Justice (NIJ) Human Participants Protection Officer. This ensures compliance with confidentiality and data protection standards.
2. **Confidentiality Statements**: All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator. These statements affirm their commitment to safeguarding participant information. The confidentiality statement in the consent document must specify that confidentiality can only be breached if there is an immediate risk of harm to participants or others. This ensures participants are aware of the limits to confidentiality. Under the Privacy Certificate, investigators and research staff are not required to report child abuse unless the participant has signed an additional consent document permitting such reporting. This provision aligns with specific confidentiality agreements.
3. **Data Management**: A copy of all data must be de-identified and submitted to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, and other relevant research materials. This practice ensures that sensitive information is handled appropriately and maintains participant anonymity.

7.9 Department of Education (ED) Research

https://www2.ed.gov/about/offices/list/ocfo/humansub.html

1. **Compliance Assurance**
   Each school where research is conducted must provide assurance that it complies with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA). This ensures adherence to federal privacy and rights standards.
2. **Materials Inspection**
   Researchers must provide copies of all surveys and instructional materials used in the research. Upon request, parents of children involved in the research must be able to inspect these materials, ensuring transparency and parental oversight.
3. **School Policies**
   The school where the research is being conducted must have established policies regarding the administration of physical examinations or screenings that may be administered to students. This ensures that all procedures align with institutional and regulatory standards.

7.10 Environmental Protection Agency (EPA) Research

https://www.epa.gov/osa/about-human-subjects-research#:~:text=The%20primary%20regulation%20that%20governs,this%20regulation%20%22in%20common.%22

1. **EPA Regulations:** Research conducted, supported, or intended for submission to the EPA is subject to Environmental Protection Agency Regulations. Compliance with these regulations is mandatory to ensure environmental safety and protection.
2. **Prohibition on Exposure:** Intentional exposure of pregnant women or children to any substance is strictly prohibited. This measure protects vulnerable populations from potential harm.
3. **Additional DHHS Requirements:** Observational research involving pregnant women and fetuses must comply with additional Department of Health and Human Services (DHHS) requirements for research involving pregnant women (45 CFR §46 Subpart B) and children (45 CFR §46 Subpart D). This includes adherence to stricter ethical guidelines.
4. **Research Categories:** Research involving children must meet the criteria specified in category #1 or #2, ensuring appropriate ethical standards are applied.

7.11 Massachusetts Law Involving Fetuses in Research

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12J#:~:text=Section%2012J.,laboratory%2C%20research%20or%20other%20experimentation.

1. Regulations on Live Fetuses: Massachusetts law, MGL Chapter 112C, § 12J(a), regulates the use of live human fetuses in scientific research and experimentation. According to this statute, no person shall use any live human fetus, whether before or after expulsion from its mother's womb, for scientific, laboratory, research, or other kinds of experimentation. However, procedures that are incidental to studying a human fetus while it is still in the mother's womb are permitted, provided that these procedures do not substantially jeopardize the life or health of the fetus. Additionally, the fetus must not be the subject of a planned abortion. The law also permits diagnostic or remedial procedures designed to determine or preserve the life or health of the fetus or mother, as long as they adhere to these conditions.
2. Regulations on Dead Fetuses: The statute prohibits experimentation on a dead fetus unless the mother has provided consent. However, consent is not required for routine pathological studies. This provision ensures that any research involving deceased fetuses is conducted with the appropriate consent, except in cases where standard pathological examination is conducted.
3. Prohibition on Consideration for Abortion: Massachusetts law explicitly forbids the performance or offer of performance of an abortion if part or all of the consideration involves the use of fetal remains for experimentation or research. This provision prevents any research or scientific gain from being the motive behind an abortion, ensuring that the procedure is performed solely for the health and welfare of the mother.
4. Prohibition on Selling or Distributing Fetal Remains: The statute also prohibits the sale, transfer, distribution, or giveaway of any fetus for uses that violate its provisions. This clause aims to prevent the commercial exploitation of fetal remains and ensures that any use of fetal tissue is strictly regulated and lawful.
5. Definition and Exclusions: For the purposes of this statute, a fetus is considered live if it shows evidence of life based on the medical standards used to determine life in spontaneously aborted fetuses at the same stage of gestation. The term "fetus" includes both neonates and embryos but excludes pre-implantation embryos or parthenotes as defined in section 2 of chapter 111L, provided they are obtained in accordance with that chapter.
6. IRB Approval and Liability: Individuals performing procedures that might violate this statute are protected from liability if the procedure received written approval from a duly appointed Institutional Review Board (IRB). The IRB's written approval must confirm that the procedure does not breach the statute and must include a reasonable basis for this conclusion. This approval must be maintained as a permanent record by the IRB or the institution and filed with the District Attorney's office for public inspection.
7. IRB Member Immunity: IRB members are granted immunity from liability under this statute if they acted in good faith when determining the lawfulness of a procedure. This provision ensures that IRB members are protected from legal repercussions as long as their decisions were made with the intention of adhering to the legal and ethical standards set forth in the statute.

Section 8: Appendices:

8.1 Available Public Datasets
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8.1 Appendix: Available Public Datasets

Health Data
Agency for Healthcare Research and Quality (AHRQ)
European Social Survey (ESS)
Framingham Heart Study

Centers for Disease Control and Prevention (CDC)
- Behavioral Risk Factor Surveillance System (BRFSS)
- National Health and Nutrition Examination Survey (NHANES)
- Hispanic Health and Nutrition Examination Survey (HHANES)
- National Health Interview Survey (NHIS)
- National Immunization Survey (NIS)
- National Mortality Followback Survey (NMFS)
- National Nursing Home Survey (NNHS)
- National Youth Tobacco Survey (NYTS)
- Pregnancy Risk Assessment Monitoring System (PRAMS)
- Youth Risk Behavior Surveillance System (YRBSS)

Healthcare Cost and Utilization Project (H-CUP)
- The Nationwide Inpatient Sample (NIS)
- The Kids' Inpatient Database (KID)
- The State Inpatient Databases (SID)
- The State Ambulatory Surgery Databases (SASD)
- The State Emergency Department Databases (SEDD)

Health & Retirement Study (HRS)
Longitudinal Studies of Aging (LSOA)
Medicare Current Beneficiary Survey (MCBS)
National Ambulatory Medical Care Survey (NAMCS)
National Immunization Survey (NIS)
National Survey of Family Growth (NSFG)
National Hospital Ambulatory Medical Care Survey (NHAMCS)
National Hospital Care Survey

National Center for Health Statistics (NCHS)
- Mortality
- CMS Medicare Enrollment and Claims Files
- CMS Medicaid Enrollment and Claims Files
- United States Renal Data System (USRDS)
- Social Security Administration (SSA)
- Department of Housing and Urban Development (HUD)
- National Survey of Family Growth (NSFG)
- National Health Care Survey (NHCS)
- National Survey of Children's Health (NSCH)
- National Survey of Children with Special Health Care Needs (CSHCN)

National Health Care Surveys (NHCS)
- National Ambulatory Medical Care Survey (NAMCS)
- National Hospital Ambulatory Medical Care Survey (NHAMCS)
- National Hospital Discharge Survey (NHDS)
- National Survey of Ambulatory Surgery (NSAS)
- National Home and Hospice Care Survey (NHHCS)
- National Nursing Home Survey (NNHS)
- National Nursing Assistant Survey (NNAS)

National Vital Statistics System (NVSS)
- Vital Statistics Online – Access to downloadable datasets
- Natality (Births)
- Mortality (Deaths)
- Linked Birth/Infant Death
- Fetal Death
- National Mortality Followback Survey (NMFS)
- Matched Multiple Birth Data Set
- Mortality Component – Instruction Manuals
- MICAR Data Dictionary

National Institutes of Health (NIH)
- National Health and Aging Trends Study (NHATS)
- National Addiction & HIV Data Archive Program (NAHDAP)
- National Cancer Institute Public Datasets
  - Family Life, Activity, Sun, Health, and Eating (FLASHE)
  - Health Information National Trends Survey (HINTS)
  - Surveillance, Epidemiology, and End Results Program (SEER)

Research and Development Survey (RANDS)
Stochastic Population Analysis for Complex Events (SPACE Program)

State and Local Area Integrated Telephone Survey (SLAITS)
- National Survey of Children's Health
- National Survey of Children with Special Health Care Needs
- Other Survey Modules

UK Biobank

Social and Behavioral Data
General Social Survey (GSS)
Substance Abuse and Mental Health Services Administration (SAMHSA)
Inter-University Consortium for Political and Social Research (ICPSR)
Pew Research Center Datasets

Educational Data
National Center for Education Statistics (NCES)
School Survey on Crime and Safety (SSOCS)
Institute of Education Sciences (IES)
National Assessment of Educational Progress (NAEP)

Economic Data
Survey of Consumer Finances (SCF)
Bureau of Economic Analysis (BEA)
World Bank Open Data
U.S. Bureau of Labor Statistics (BLS)
USDA Food and Nutrition Database
National Longitudinal Surveys (NLS)
- National Longitudinal Survey of Youth 1979 (NLSY79)
- National Longitudinal Survey of Youth 1997 (NLSY97)

Genetic and Genomic Data
dbGaP (Database of Genotypes and Phenotypes)
Genomic Data Commons (GDC)

Public Opinion and Survey Data
American National Election Studies (ANES)
Roper Center for Public Opinion Research
Qualitative Data Repository (QDR)

National Data Archives and Repositories
Inter-University Consortium for Political and Social Research (ICPSR)
National Addiction & HIV Data Archive Program (NAHDAP)
Data Resource Center for Child & Adolescent Health
The National Longitudinal Study of Adolescent to Adult Health (Add Health)
U.S. Census Bureau

8.2 Appendix: OHRP Exemption Review Categories

Although the HHS IRB regulations list eight exemption categories, UMassD has opted to implement six of those categories at this time, see the list below.

Category 1
Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
Examples:

- Evaluating the use of accepted or revised standardized tests.
- Testing or comparing a curriculum or lesson.
- A program evaluation of pharmacy continuing education.

Category 2
Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

1. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot be readily ascertained, directly or indirectly through identifiers linked to the subjects; **OR**
2. Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **OR**
3. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review.

Examples:

- Surveying teachers, nurses, or doctors about a technique or an outcome.
- Interviewing managers about a management style or best practice.
- Conducting a focus group about an experience or an opinion of a community program.

Category 3
(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

A. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly, through identifiers linked to the subjects; **OR**
B. Any disclosure of the Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **OR**
C. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, **AND** an IRB conducts limited IRB review.

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Example:

- Healthy adult subjects are asked to take part in two two-hour-long assessments of memory, attention, and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software. The procedures are conducted during a single visit, and subjects are encouraged to take breaks when desired.

Category 4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

1. The identifiable private information or identifiable biospecimens are publicly available; **OR**
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; **OR**
3. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (HIPAA), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); **OR**
4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Note: Exemption Category 4 only applies to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records, or existing repositories of clinical specimens. No contact between investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another IRB review path will be required. Exemption Category 4(iii) only applies to the use of data (when HIPAA applies) and not to biospecimens.

Example:

- A researcher is given two datasets that contain private, identifiable information. The researcher uses the identifiers to merge the two datasets but strips the resulting (merged) data of identifiers immediately after the merge and before conducting data analysis. The resulting data used for the analysis is completely de-identified with no link to identifiers.

Category 5

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Category 6

Taste and food quality evaluation and consumer acceptance studies,
(i) if wholesome foods without additives are consumed **OR**
(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Dept. of Agriculture

8.3 Appendix: OHRP And FDA Expedited Categories:

Expedited Review categories are outlined below, including examples. Information is also provided through the OHRP and FDA website, included here: Expedited Review categories. Note: Categories one (1) through seven (7) pertain to both initial and continuing IRB review. Categories eight (8) and nine (9) pertain only to continuing IRB review.

Category 1
Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
2. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3
Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

- hair and nail clippings in a nondisfiguring manner;
- deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- permanent teeth if routine patient care indicates a need for extraction;
- excreta and external secretions (including sweat);
- un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- placenta removed at delivery;
- amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- sputum collected after saline mist nebulization.

Note: On October 4, 2010, OHRP clarified that it agrees with the FDA's position that the following procedures are considered noninvasive:

- Vaginal swabs that do not go beyond the cervical os;
- Rectal swabs that do not go beyond the rectum; and
- Nasal swabs that do not go beyond the nares.

Category 4
Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

- physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy;
- weighing or testing sensory acuity;
- magnetic resonance imaging;
- electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

- Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4).
- This category includes materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.
- The phrase "…or will be collected solely for non-research purposes" pertains to the origin of the materials. For example, blood samples that were collected for a clinical test or the results of a course driven exam given in a history class.
-

Category 6

Collection of data from voice, video, digital, or image recordings made for research purposes.
Expedited Review does not apply if identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Category 7

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3).

Category 8

Continuing review of research previously approved by the convened IRB as follows:

1. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
2. where no subjects have been enrolled and no additional risks have been identified; or
3. where the remaining research activities are limited to data analysis.

Clarifiers regarding category (a):

- Closure of enrollment only has to apply to the local site, not to all sites,
- Long-term follow-up may include research interactions (as opposed to intervention) that involve no more than minimal risk to subjects (e.g., quality of life surveys);
- Long-term follow-up may include collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.

Clarifiers regarding category (b):

- "no subjects have been enrolled" means no subjects enrolled at the local site

- "no additional risks have been identified" means no additional risks identified at the local site or any other institution engaged in the research project or from any other relevant source since the IRB's most recent prior review.

Clarifiers regarding category (c):

- The only remaining human subjects research activity is the analysis of data that includes identifiable private information and the IRB reviewer has determined that this activity involves no more than minimal risk.
- Simply maintaining individually identifiable private information without using, studying, or analyzing such information is not human subjects research and thus does not require continuing review.

Category 9

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

8.4 Appendix: Consent Form Builder Sample ICF Language. Situation or Procedure-Specific Template Consent Form Language

Instructions: ***Bolded*** *text within brackets [] or parentheses () include guidance for investigators to replace with details which pertain to the study. Italicized text is guidance language for each section and should not be used within a consent.*

Blood Draw

You will have (***amount***) of blood taken (***number of times drawn, and frequency***). The blood will be taken from (***name the location, i.e., arm***). The total amount of blood taken for the whole study will be (***amount in teaspoons or tablespoons***) The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein, and infection, and a rare risk of fainting.

Caliper (Body Fat) Test

Caliper Test. A tool called a caliper (like a pincher) grasps a small fold of flesh on the back of the arm, shoulder blade, or waist to measure the amount of body fat. Risks from Caliper Test might include a little pain or discomfort from a pinch.

Illegal Behavior or Personal Questions

Select whichever is appropriate:

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.
- Some of the questions asked may make you angry, emotionally upset or stressed out now or at a later time. If this occurs, you can contact the following person for help (***insert appropriate person's name and contact information***). If you do not wish to answer a question, you may skip it and go to the next question.
- There could be a risk of discomfort and harm (to the psyche, reputation, employability, insurability, social status, criminal or civil liability) that may occur as a result of participation. If you do not wish to answer a question, you may skip it and go to the next question.
- If the study staff finds evidence that suggests that you have been physically or sexually abused, they are required by law to report this to local law authorities.
- If the study staff finds evidence of child abuse or neglect, they are required by law to report this to local law authorities.
- We will not ask you about child abuse, but if you tell the interviewer about child abuse, they are required by law to report your name to the state authorities
- The study staff may be required by law to report to appropriate authorities any information you provide that indicates sexual misconduct, including sexual assault, sexual exploitation, dating violence, domestic violence, stalking, and sexual harassment. Therefore, we cannot promise you complete confidentiality of any information you share about experiences of sexual misconduct.

Incomplete Disclosure and/or Deception

For scientific reasons, this consent form does not include complete information about the research questions or topics being tested. You will be fully debriefed following your participation in the research.

OR

We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these conditions, we will explain the procedure to you fully after your participation.

IAPS Research

If you decide to take part in this study, you will be asked to view a variety of pictures categorized as pleasant, neutral, or unpleasant. If any of the media presented makes you feel too uncomfortable to continue, you are free to withdraw from the study at any time without losing credit or payment. The images may include descriptions such as [***insert specific description here***]. You may end your participation at any time if any aspect of the research makes you uncomfortable. If you experience discomfort or have concerns after viewing the images, please contact the principal investigator at [***insert contact information***] or reach out to [***list psychological services with contact information***].

Prisoners

Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

Psychological Risk

This study involves asking sensitive questions relating to **XXXXX** (***describe).***

Select whichever is appropriate:

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

- Some of the questions asked may make you angry, emotionally upset or stressed out now or at a later time. If this occurs, you can contact the following person for help (insert appropriate person's name and contact information). If you do not wish to answer a question, you may skip it and go to the next question.
- There could be a risk of discomfort and harm (to psyche, reputation, employability, insurability, social status, criminal or civil liability) that may occur as a result of participation. If you do not wish to answer a question, you may skip it and go to the next question.

Double-Blind
This is a double-blinded study, which means that neither you or the investigator or the study staff will know which treatment you are receiving. However, in an emergency, the investigator may become unblinded and get this information.

Randomization
Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group. (***OR if the randomization is not equal; then state the odds***)

Focus Groups
Although we ask everyone in the group to respect the privacy and confidentiality of participants, and to keep the discussion in the group confidential, we cannot guarantee this. We will ask you and other participants in the group to use only first names during the session. Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of their fellow participants and not repeat what is said in the focus group to others outside of the group. However, the researchers cannot guarantee that everyone will keep the discussions private. As a study participant you agree to maintain the confidentiality of the information discussed by all participants and researchers during the focus group session. If you cannot agree, please consult with the researcher(s) as you may be ineligible to participate in this study.

Clinical trials registered on ClinicalTrials.gov
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Certificate of Confidentiality.
A Certificate of Confidentiality helps protect the privacy of human research participants enrolled in biomedical, behavioral, and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. For additional information about Certificates of Confidentiality see https://grants.nih.gov/policy/humansubjects/coc.htm

If a Certificate of Confidentiality will not be obtained, use the following language:
In this study, you will be asked about (illegal activities, sensitive information) (***specify these***). We will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, courts have subpoenaed (required release) research records.

NIH funded studies and/or studies with a Certificate of Confidentiality, use the following language:
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Template Conflict of Interest Consent Form Language

Instructions: ***Bolded*** *text within brackets [] or parentheses () include guidance for investigators to replace with details which pertain to the study. Italicized text is guidance language for each section and should not be used within a consent.*

Institutional Conflict of Interest Statement

Dr/Mr/Ms/Mx (insert name here), the person responsible for the conduct of this research study works for the University of Massachusetts – Dartmouth (UMassD). UMassD has a financial interest in the device being used in this research study. You may choose to seek the opinion of another doctor not related to UMassD before enrolling in this research study. More importantly, you are not under any obligation to participate in this research study.

Investigator has been compensated by the Sponsor

Dr/Mr/Ms/Mx (insert investigator name), the person responsible for the conduct of this research study has been compensated for (**insert nature of compensation**) by the sponsor during the past (**insert time frame**).

Investigator is a member of the sponsor's advisory board

Dr/Mr/Ms/Mx (insert investigator name), the person responsible for the conduct of this study is a paid or unpaid member of the Scientific Advisory Board of the company that is sponsoring this research.

Investigator is the Treating Physician

Your doctor, who is also the person responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Investigator owns stock in the Sponsoring Company

Dr/Mr/Ms/Mx (insert name of investigator), the person responsible for the conduct of this study owns stock in the same company that is paying for this research.

Investigator owns the device patent

Dr/Mr/Ms/Mx (insert investigator name), the person responsible for the conduct of this study has a personal interest in the device that is being used in this study.

Investigator receives payment for role in a think tank funded by the study sponsor

The (**insert name of item here**) used in this research study is donated by (**insert sponsor name(s)**). Although **Dr/Mr/Ms/Mx (insert investigator nam**e), the lead investigator for this multi-site research study receives significant financial benefit for participating in a think tank that is funded by the sponsors listed above, **Dr/Mr/Ms/Mx (insert investigator name**) does not control the conduct of the study nor its outcome. **He/she/they** does, however, control the publications related to this study.

Manufacturer is donating device

(Insert name of company), the manufacturer of the device being used in this study is donating the device **to Dr/Mr/Ms/Mx (insert investigator name**), the person conducting this study.

Sponsor is providing device and paying the investigator

In addition to providing the medical device for this study, the sponsor of this research study pays **Dr/Mr/Ms/Mx (insert investigator name(s))**, the person(s) responsible for this research study to (**insert applicable language here**).

Sponsor provides financial support and pays a member of the research team

In addition to providing financial support for this research study, the sponsor of this research study pays **Dr/Mr/Ms/Mx (insert study staff name**), a member of the research staff to (**insert applicable language here**).

Sponsor provides financial support and pays the investigator

In addition to providing financial support for this study, the sponsor of this study pays **Dr/Mr/Ms/Mx (insert investigator name**), the person responsible for this research study to (**insert applicable language here**).

Sample Consent Form Language by Consent Sections

Instructions: ***Bolded*** *text within brackets [] or parentheses () include guidance for investigators to replace with details which pertain to the study. Italicized text is guidance language for each section and should not be used within a consent.*

Introduction:

The purpose of this consent form is to provide you with information to help you decide whether to participate in this research study. This form includes details about:

- Why the study is being conducted.
- The activities you will be asked to complete if you participate.
- Any known risks involved.
- Potential benefits of participating.
- Alternatives to participating in this study.
- How your health information will be used and shared for research purposes.
- The expected duration of your participation in the study.

Participation in this study is voluntary, and you can withdraw at any time without penalty.
The principal investigator (the lead researcher for this project) [**INSERT OTHER APPROPRIATE TITLE IF THE PI WILL NOT CONDUCT THE DISCUSSION**] will discuss the study with you. If you have any questions, please feel free to ask any member of the study team. For questions about the study or in the case of a research-related injury, you can contact [**INSERT CONTACT INFORMATION**].

Take all the time you need to make an informed decision about your participation.

The specific details of this research are described in the 'What is Involved in This Study?' [OR OTHER, AS APPLICABLE] section of this consent form.

This consent [**and HIPAA authorization**] form is directed at research subjects. If you are providing permission as [**INSERT, AS APPLICABLE**] the parent or legal guardian of a minor [**OR**] a legally authorized representative, please read 'you' and 'your' as [**INSERT, AS APPLICABLE**] 'your child' [**OR**] 'the research subject'.

What Information is on This Form?

We are asking [**INSERT, AS APPLICABLE: (A) YOU, (B) YOUR CHILD, (C) A MINOR FOR WHOM YOU ARE THE PARENT OR LEGAL GUARDIAN, OR (D) THE PERSON FOR WHOM YOU ARE A LEGALLY AUTHORIZED REPRESENTATIVE**] to participate in a research study.

Permission for Participation:

This consent form is primarily directed at the research participant. However, if you are providing permission as [**INSERT, AS APPLICABLE: (A) A PARENT, (B) A LEGAL GUARDIAN OF A MINOR, OR (C) A LEGALLY AUTHORIZED REPRESENTATIVE**], please understand that the terms 'you' and 'your' should be interpreted as [**INSERT, AS APPLICABLE: (A) 'YOUR CHILD' OR (B) 'THE RESEARCH PARTICIPANT**'].

Assent for Minors:

- A participant aged 13-17 will [**INSERT, AS APPLICABLE: (A) ALSO BE ASKED TO READ AND SIGN THIS FORM OR (B) WILL BE ASKED TO SIGN A SEPARATE ASSENT FORM**] to indicate their willingness to participate in this study.
- A participant aged 12 or under will also be asked to [**INSERT, AS APPLICABLE: (A) READ AND SIGN AN ASSENT FORM OR (B) PROVIDE VERBAL AGREEMENT**] to indicate their willingness to participate.

This form outlines the purpose of the study, what you will be asked to do if you choose to participate, and how we plan to use your information and/or samples obtained from you.

If you have any questions about this form or the research study at any time, please feel free to ask a member of the study team. You have the right to take all the time you need to decide whether to participate in the study. Participation is entirely voluntary; you do not have to participate if you do not wish to.

Do I need to take part in this research study?

No. Taking part in research is voluntary. If you do not want to participate, there will be no penalty, and you will not lose your current benefits. The Principal Investigator or another member of the study team will explain the study to you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your health.

Why Is This Study Being Done?

We are conducting this research study to find out [**INSERT PURPOSE OF THE STUDY IN LAY TERMS**]. You are being asked to take part in this study because [**INSERT GENERAL INCLUSION CRITERIA**]. About [**INSERT TOTAL NUMBER OF SUBJECTS**] people are expected to be enrolled in this study [**EXPLAIN WHETHER THIS IS AT THIS SITE OR AT ALL SITES**].

We aim to [INSERT SPECIFICS, such as investigate the effectiveness of a device or better understand a particular condition].

You are being invited to participate in this study because [**CHOOSE ONE OF THE FOLLOWING OPTIONS AS APPROPRIATE**]:

- You have [**INSERT CONDITION**].
- You are scheduled to have [**A ROUTINE MEDICAL CARE PROCEDURE**].
- You are part of [**SOME ORGANIZATION/EVENT**], and we would like information about people in this group.

Additionally, we want to find out if [INSERT SPECIFICS, if applicable].

The purpose of this study is to gain a better understanding of the cause of [**DESCRIBE THE MEDICAL CONDITION BEING STUDIED**] (the "Study Medical Condition"). You have been asked to participate in the study because [**INSERT, AS APPLICABLE: (A) YOU HAVE THE STUDY MEDICAL CONDITION, (B) YOU ARE AN UNAFFECTED FAMILY MEMBER OF A SUBJECT WHO HAS THE STUDY MEDICAL CONDITION, OR (C) YOU ARE AN INDIVIDUAL WHOSE INFORMATION WILL BE COMPARED TO THE INFORMATION OF INDIVIDUALS WHO HAVE THE STUDY MEDICAL CONDITION].**

We will study the results of the tests being performed to find and possibly confirm associations between the Study Medical Condition and specific variants.

How long would I be in this study? How many study visits are there?

Guidance: *This brief statement should include the following information:*

1. *How long participation lasts*
2. *How many study visits there are*
3. *If it's a drug study, how long they will be on the drug*
4. *If there's long term follow-up, for how long will it be and how will contact occur*

Examples:

[Example 1] You would be in this study for about [***insert number of days, weeks, months or years]*** and visit the research site about [***insert number]*** times.

[Example 2] You would be in this study for about [***insert number of days, weeks, months or years]*** and visit the research site about [***insert number]*** times. During this time, you would be asked to take the study drug for about [***insert number of days, weeks, months or*** *years].* After you stop taking the drug, you will be in follow-up for [***insert months or years]***.

[If the study involves long-term follow-up] We would like to keep track of your medical condition for ***[insert length of time]***. We would do this by ***[insert method of contacting the participation, e.g., calling on the phone, emailing, etc.] [insert how often, e.g., once a year]*** to see how you are doing. Checking up on you over time helps us look at the long-term effects of the study.

Investigational Use of Devices

Unapproved Devices: [**INSERT DEVICE NAME**] is an investigational device. This means that [**INSERT DEVICE NAME**] has not been approved by the Food and Drug Administration (FDA) for medical use in patients but has only been approved for use in research.

Approved Devices being used Off-Label: **INSERT DEVICE NAME]** is being used in an investigational manner (not for the purpose that it is approved for) in this research study. This means that [**INSERT DEVICE NAME**] has been approved by the FDA for [**INSERT CONDITION AND/OR POPULATION OF SUBJECTS IT IS APPROVED FOR**] but has not been approved for [**INSERT USE RELATED TO THIS RESEARCH**].

Why Are We Interested in Talking with You?

We want to tell you about a research study we are doing. Research helps us learn more about things, including whether medicines or other treatments are safe and effective.

We are asking you to participate in this study because you have [**INSERT SIMPLE/LAYPERSON NAME OF MEDICAL CONDITION OR OTHER REASONS FOR INCLUSION. USE VERY SIMPLE LANGUAGE].** We aim to **[FIND**

OUT/LEARN MORE ABOUT — I.E., PROVIDE A SIMPLIFIED EXPLANATION OF THE HOW OR WHY YOU ARE DOING THE RESEARCH. USE VERY SIMPLE LANGUAGE].

Before agreeing to participate, it's important that you read this form and talk with the research staff. You should only take part if you want to. This form will explain why we are doing the research and what will happen to you if you join the study. You can ask questions at any time before, during, or after our discussion. If you don't understand something, just ask us. We want you to feel comfortable asking questions whenever you think of them. At the end of our discussion, if you agree to participate, we will ask you to sign this form.

What Is This Research Study About?

Guidance: *This section should describe procedures that are being done for research purposes. If clinical procedures are being altered, extended, or performed more frequently for research purposes, or if data from clinical procedures are being used for research, describe the portion that is being done for research.*

In this research study, we want to [**FIND OUT/LEARN MORE ABOUT—I.E. PROVIDE A SIMPLIFIED EXPLANATION OF THE HOW OR WHY YOU ARE DOING THE RESEARCH. USE SIMPLE LANGUAGE**]. There will be about [**INSERT NUMBER**] participants in this study.

What Will Happen If You Are in This Study?

If you choose to participate in this research study, here's what will happen:

1. We will ask you to answer some questions about your health and experiences.
2. We may have you do some specific activities related to the study.
3. We will look at your medical records to gather information.

Your involvement will take approximately [INSERT TOTAL LENGTH OF PARTICIPATION] and will include [INSERT NUMBER OF VISITS] visits, each lasting about [INSERT AMOUNT OF TIME OF VISIT(S)].

During the visits, we may perform the following procedures:

- Take a three-generation family history.
- Conduct a detailed physical exam.
- Take photographs and video recordings of the exam.
- [**LIST SPECIFIC PROCEDURES]**

[*Include if your study has a screening phase]*

This study has a screening portion to see if you qualify for the main part of the study. You will need to have the following exams, tests or procedures to find out if you can be in the main part of the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- ***[List exams, tests and procedures as appropriate. Use bulleted format.]***

Study procedures

If you qualify for the study, you will need to have the following exams, tests or procedures.

- ***[List exams, tests and procedures as appropriate. Use bulleted format.]***

Follow-up procedures

The study team will follow up with you to see how you are doing.

- ***[List follow-up procedures and how often]***

OR

The study team will continue to review your medical records for *[insert length of time]* to see how you are doing.

IRB-approved definitions and descriptions of common study designs and procedures:

Randomization: This study has different groups. You will be put into a group by chance. How your group is chosen is like flipping a coin or rolling dice. Your chance of being put into one group might be higher depending on the design of the study.

- **If you are in group 1** … ***[Explain what will happen for this group with clear indication of which interventions depart from routine care.]***
- **If you are in group 2** … ***[Explain what will happen for this group with clear indication of which interventions depart from routine care.]***
- ***[For studies with more than two groups, explain each group using format above]***

Guidance Optional Study Chart: *In addition to the mandatory narrative explanation of study procedures as above, a simplified calendar (study chart) or schema (study plan) may be inserted here. The schema from the protocol is too complex, but use of a simplified version of the schema is encouraged. Instructions for reading the calendar or schema should be included.*

Risks of Participation

General Risks: Participation may involve physical, psychological, social, or financial risks arising from study procedures, confidentiality breaches, or incidental findings. Specific risks include [**DESCRIBE ANY REASONABLY FORESEEABLE RISKS, DISCOMFORTS, OR SIDE EFFECTS AND THE LIKELIHOOD OF OCCURRENCE**].

Loss of Confidentiality: A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Their plans for keeping your information private are described in the 'confidentiality' section of this consent form.

Blood Draw Risks: If blood is drawn, you may experience soreness, bruising, lightheadedness, or a small risk of infection at the injection site.

Inconvenience: Your participation may require a commitment of approximately [**INSERT AMOUNT OF TIME**] to complete activities such as [**INDICATE WHAT THEY WILL SPEND THEIR TIME DOING**].

Deception: As part of this experiment, you will not be told about some of the study details. If you were told these details at the beginning of the study, it could change the research results. If you decide to be part of the study, you will be given an explanation of what information was withheld from you at the end of your study participation.

Psychological Testing/Sensitive Topics/Emotional Distress: This research study involves psychological testing. The questions being asked may be sensitive and personal in nature. It is possible discussing certain topics or answering some questions may cause some stress or lead to emotional discomfort. If you feel distressed at any point, you are encouraged to seek support. Support resources will be available to you, and you have the option to skip any questions that make you uncomfortable.

Criminal or Civic Liability: We are legally required to report any disclosures regarding child abuse or illegal activities, which may result in legal action. Additionally, threats of self-harm or harm to others must also be reported to the appropriate authorities. If you give us information which suggests that your child or any other child is being abused, we are required by law to report that information to the Department of Children aand Families (DCF). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities. Telling us about your involvement in illegal activities involves the risk of criminal penalties and/or prosecution if your identity were to be revealed. In some cases, we may be required to report such information. If you give us information that you may hurt yourself or someone else, we must report this information to the authorities.

Unexpected Findings: Participation may yield findings affecting your health or well-being. We will discuss how these findings will be communicated to you.

Study Outcome: You may experience disappointment if the study outcomes do not align with your expectations. Participation in this study may change your self-perception or understanding of your circumstances. You may gain new insights or perspectives that could impact how you view yourself. It is important to keep in mind that results may vary and may not provide the insights you hope for.

Perception of Researcher Bias: Concerns may arise regarding the influence of researcher biases on your responses. We strive for objectivity, but you should be aware of this potential concern. We ask you to bring to the investigator or IRB's attention any circumstances which appear to present researcher bias.

Physical Discomfort: Some procedures may lead to mild physical discomfort. If at any point you experience discomfort, please notify the study staff.

No Foreseeable Risks: To the best of our knowledge, there are no foreseeable risks that could significantly affect your well-being.

Randomization Risks: You might be put into a group that receives something that is not as effective as another group. You might have more side effects than people in another group or people who don't join this study.

Placebo Risks: If you are in a group that receives placebo, you will not receive the study drug.

Reproductive Risks: The procedures in this study can harm a fetus or an infant. You should not become pregnant, breastfeed, or cause a pregnancy while on this study. If you become pregnant, you will have a pregnancy test at set times during the study. If sexual activity could lead to a pregnancy, you and your partner must use contraception while you are in the study. You may also need to use contraception for a period of time after the study. Acceptable methods of contraception may include:

- An intrauterine device (IUD)
- Hormonal contraceptives (birth control pill, patch, ring, injectable, or implant)
- Condoms (internal or external) used with another acceptable method
- Complete abstinence (no sexual activity that could lead to a pregnancy)

The study team will describe which of these methods are acceptable for this study. If you think you may be pregnant, or may have caused a pregnancy, at any time during the study, tell the study staff right away. They will talk with you about your options.

Sample Formatting for Risk of Experimental Procedures:

Common, Some May be Serious
(Out of 100 people, more than 20 and up to 100 may have:)

- *Enter risk/side effect (list most serious risks first)*
- *Enter risk/side effect*
- *Enter risk/side effect*

Occasional, Some May be Serious
(Out of 100 people, from 4-20 may have:)

- *Enter risk/side effect (list most serious risks first)*
- *Enter risk/side effect*
- *Enter risk/side effect*

Rare, And Serious
(Out of 100 people, 3 or fewer may have:)

- *Enter risk/side effect (list most serious risks first)*
- *Enter risk/side effect*
- *Enter risk/side effect*

Guidance Notes on these categories:

- *In all categories, list the most serious risks first. "Serious" is defined as side effects that may require hospitalization or may be irreversible, long-term, life threatening or fatal.*
- *Physical and non-physical risks and side effects should include such things as the inability to work. Whenever possible, describe side effects by how they make a patient feel.*
- *Use lay language to describe side effects. For example, instead of syncope, use "fainting"; instead of dyspnea, "shortness of breath."*
- *If there may be side effects that have been noted during treatment, not enough data is available to determine if the side effect is related to the intervention. Inclusion of this information in the informed consent document is not mandatory, but it may be prudent to mention the most serious effects. If included, these side effects should be listed under a separate category titled "Side effects reported by patients, but not proven to be caused by intervention." Side effects in this category do not have to be labeled as "Common," "Occasional," or "Rare and Serious" and should not be repeated here if they appear in a previous category.*

Are There Benefits to Taking Part in the Study?

Potential Direct Benefits

You may or may not receive personal (direct) benefits from taking part in this study. However, the possible benefits of participating in this research may include:

- [**DESCRIBE ANY BENEFITS TO THE PARTICIPANT WHICH MAY REASONABLY BE EXPECTED FROM THE RESEARCH, such as improved understanding of a condition, access to new treatments, educational insights, or psychological support**].
- Participation may provide you with [**specific services, assessments, or support**] that could enhance your well-being.

No Direct Benefits

You may not receive personal (direct) benefits from participating in this research study. However, the information collected from this research may contribute to the advancement of knowledge in [**FIELD/AREA OF STUDY**] and help others in the future. By participating, you may be contributing valuable insights that could lead to improved interventions, treatment options, or understanding of [**DESCRIBE TARGET POPULATION OR ISSUE**].

What Other Options Are There?

No Alternatives

You may choose not to take part in this research study. Your decision will not affect your current or future care.

Alternatives for Non-Treatment Studies

If you decide not to participate in this study, several alternatives are available to you. You do not have to take part in this study to receive treatment for your condition. Alternatives to participating in this study may include:

- **Standard Medical Interventions**: You can seek traditional treatments available for your condition without enrolling in this study, such as [**INSERT SPECIFIC TREATMENTS OR PROCEDURES**].
- **Psychological Support**: If applicable, you may opt for psychological counseling or therapy sessions that are outside the scope of this research.
- **Other Clinical Trials**: You may consider enrolling in other clinical trials that address your condition. Research centers or healthcare providers can provide information about ongoing studies that may be suitable for you.
- **Self-Management Options**: Engaging in self-care practices or support groups related to your condition may provide alternative forms of support and management.

It is important to note that participation in this study will not delay or withhold any standard diagnostic procedures or treatments that are recommended for your condition.

Alternatives for Treatment Studies

If you choose not to participate in this treatment study, you may still have access to various standard treatment options that do not require participation in research. These options may include:

- **Standard Treatment Protocols**: You can receive the usual standard of care for your condition, which may involve [**INSERT SPECIFIC TREATMENTS AND PROCEDURES**].
- **Ongoing Medical Care**: Regular follow-up appointments with your healthcare provider for monitoring and management of your condition.
- **Other Therapeutic Interventions**: Alternative therapeutic approaches, including [**INSERT SPECIFIC ALTERNATIVE THERAPIES OR INTERVENTIONS**], which may not be part of this study.
- **Consultation with Specialists**: Seeking evaluation and treatment from specialists in your condition, which may offer alternative diagnostic or therapeutic options.

Please discuss any questions or concerns you may have about your treatment options with your healthcare provider. They can help you understand the best choices for your specific situation.

Who is paying for this study?

Guidance*: The IRB requires that all consent forms disclose which agencies or institutions (e.g., National Institutes of Health, Department of Defense, National Science Foundation, Center for Disease Control, State agencies), cooperative groups, foundations or industry sponsors are funding the research or providing study drugs or equipment for the study. If the study is not being funded by an external agency, then the internal funding source, i.e., Department funds, personal funds, should be identified.*

Compensation

In return for your time and effort, you will be paid ***[$XXX]*** for taking part in this study. ***[Describe any pro-rating or bonuses and specify method and timing of payment.]***

[Include the following statement if you are using a third-party payment method. Amend as necessary so it is accurate regarding the system being used.]

A company called [***company name***] is working on behalf of the study to pay participants. [***Company name***] will need to collect certain personal information about you to set up your payment account.

[If the company has a separate informational document or consent sheet about how the payment system works, include the following sentence in this consent form*.]*

You will be given a separate document from *[company name]* with detailed information about the payment process.

[Include the following if participants will be paid more than $599.99 in a calendar year]

The Internal Revenue Service (IRS) must be notified when a participant is paid $600 or more in a year, so your payment will be reported to the IRS. You must give the researchers your address and Social Security number for IRS reporting purposes.

Will I be reimbursed for expenses if I take part in this study?

"Reimbursement" refers to money that participants are paid for specific costs they incur in order to participate in the study, e.g., transportation, meals, lodging, and parking.

Choose 1 of the 3 following options.
[Option 1 -Reimbursement]
You will be reimbursed for expenses if you take part in this study. ***[Describe what expenses, e.g., travel, meals, lodging, parking, and specify method and timing of reimbursement.]***

[Option 2- if there may be expenses but they will not be reimbursed:]
You will not be reimbursed for expenses if you take part in this study.

[Option 3- if participants will not incur any expenses (e.g., travel, meals, parking, etc.)]
This study does not involve any expenses to research participants.

Are there any costs to me for taking part in this study?
Choose 1 of the 2 options below.
[Option 1, for clinical studies with Sponsor]
No. There is no cost to you if you take part in this study. However, you may need to pay for items such as parking and transportation. You will be billed for the costs of any usual medical care you receive outside of this study. You will also be responsible for any deductibles or co-payments for these usual medical care costs.

[Option 2, for studies with no costs]
There will be no costs to you for being in this study.

[For clinical studies] Can I stop being in the study if I want to?
If you stop being in the study, any data we have already collected will remain part of the study records. The study team may still get information from your medical records if it is important to the study. This information may include information like laboratory results, treatment courses, or health outcomes. If you do not want this information to be collected after you decide to stop being in the study, you must tell the study team.

Can I Select Someone to Act for Me in the Future if I Cannot Act for Myself?
You have the option to designate someone to act on your behalf if you lose the capacity to consent for yourself or in the event of your death. This designated individual will have the authority to make decisions regarding your data and/or biological samples collected during the study.

Designating a Representative
If you choose to designate someone, please consider the following:

- **Who to Choose**: You may select a family member, close friend, or legal representative whom you trust to make decisions in your best interest. This person should be familiar with your values, preferences, and any specific wishes you may have regarding your data and biological samples.
- **Scope of Authority**: The person you designate will have the authority to make decisions about the use, storage, and sharing of your data and biological samples as per the guidelines set forth in this study.
- **Revocation**: You can revoke this designation at any time while you are still capable of making decisions. If you wish to change or revoke your choice, please inform the study team in writing.
- **Documentation**: It may be necessary to complete a formal document to designate your representative, and you will be provided with guidance on this process if you decide to proceed.

If you have any questions about designating a representative or need assistance in making this decision, please feel free to reach out to the study team.

Can I be removed from the study by the Principal Investigator?
Yes. The Principal Investigator may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest if you did not follow the study rules, or the study has been stopped.

How will my information be used?
Guidance*: The options vary according to the following study characteristics:*

- *Whether the study analyzes data only (no specimens) versus data and specimens*
- *Whether the study is subject to the* NIH Data Management & Sharing (DMS) *policy**

** "Subject to NIH's DMS policy" means all three conditions apply: (1) this study receives funding from NIH, (2) the grant application was submitted to NIH on or after January 25, 2023, and (3) the* Data Management and Sharing plan *approved by the NIH includes a plan to share scientific data from this study.*

If de-identified study information will never be shared, choose option 5 or 6. This should be very rare.

Options: *Choose 1 statement from the options below.*

[Option 1— For studies that use data only (no specimens), and are not subject to NIH's DMS policy*:]
Researchers will use your information to do this study. Once the study is done, we may use your information for other research studies in the future. We may share it with other researchers to be used in their studies. We will not share your name or other information that could identify you. We cannot promise that this will prevent future researchers from figuring out who you are. We will not ask you for additional permission to share this de-identified information.

[Option 2— For studies that use data AND specimens, and are not subject to NIH's DMS policy*:]
Researchers will use your information and specimens to do this study. Once the study is done, we may use your information and specimens for other research studies in the future. We may share them with other researchers to be used in their studies. We will not share your name or other information that could identify you. We cannot promise that this will prevent future researchers from figuring out who you are. We will not ask you for additional permission to share this de-identified information.

***[Option 3*— For studies that use data only (no specimens), and which are subject to NIH's DMS policy*:]**
Researchers will use your information to do this study. Once the study is done, we may use your information for other research studies in the future. We will share it with other researchers to be used in their studies. We will not share your name or other information that could identify you. We cannot promise that this will prevent future researchers from figuring out who you are. We will not ask you for additional permission to share this de-identified information. Your research data will be stored in a computer database. Other researchers and companies can use the database to do their own research. There are different types of databases. Some are available to the public. This is called "unrestricted access." Others require special permission to use. This is called "restricted access."

[Option 4— For studies that use data AND specimens, and are subject to NIH's DMS policy*:]
Researchers will use your information and specimens to do this study. Once the study is done, we may use your information and specimens for other research studies in the future. We will share them with other researchers to be used in their studies. We will not share your name or other information that could identify you. We cannot promise that this will prevent future researchers from figuring out who you are. We will not ask you for additional permission to share this de-identified information. Your research data will be stored in a computer database. Other researchers and companies can use the database to do their own research. There are different types of databases. Some are available to the public. This is called "unrestricted access." Others require special permission to use. This is called "restricted access."

[Option 5— For studies using data only. Only use if you are 100% sure that de-identified data will never be shared or used outside of this study:]
We will use your information to conduct this study. Information gathered during this research study will only be used for this study. They will not be shared with other researchers.

[Option 6—For studies using data and specimens. Only use if you are 100% sure that de-identified data will never be shared or used outside of this study:]
We will use your specimens and information to conduct this study. Specimens and information gathered during this research study will only be used for this study. They will not be shared with other researchers.

Will I share in any profits from this study?
No. Your specimens or information obtained from your specimens may be used for commercial use. If this happens, you will not share in any profits.

What Are My Rights If I Take Part in This Study?
Taking part in this study is entirely your choice. You can decide not to take part or to stop participating at any time, without penalty. Your choice will not affect the treatment you receive from the doctors and staff at the University of Massachusetts-Dartmouth. If you decide to leave the study before it is finished, please inform one of the researchers listed at the beginning of this consent form. Your participation will also end if the researchers or the study sponsor stop the study earlier than expected or if you do not follow the study procedures.

Who Can I Call If I Have Questions?
You may call [**INSERT NAME OF PRINCIPAL INVESTIGATOR OR STUDY CONTACT]** at [**INSERT PHONE NUMBER**] if you have any questions or concerns about this research study. If you have any questions about your rights as a research participant or if you have concerns about this study, please contact:

Office of Institutional Ethics & Compliance
University of Massachusetts-Dartmouth
285 Old Westport Road, Foster 008E
Dartmouth, MA 02747

Withdrawal from Study

Guidance: *Participation in any study must be voluntary. Subjects must be informed they may withdraw from the study at any time before it is completed, without facing negative consequences. The exact wording can vary depending on the nature of the study, but it should ensure participants feel safe in making the decision to stop.*

Your participation in this study is completely voluntary. You may withdraw at any time before the study is completed, without any penalty or loss of benefits to which you are otherwise entitled. Choosing to withdraw will not result in any negative consequences.

Use of Data

We would like to store the data that you agreed to provide as part of this study and possibly use it for future research. The data will be stored at University of Massachusetts - Dartmouth (UMassD) either with the researchers on this study or in a central storage facility. With your permission, your data will be stored at UMassD indefinitely in identifiable form. Your data will be labeled with a code number that the researchers on this study or the people managing the storage facility will be able to link to you. Also, with your permission, your data may be used by other researchers at UMassD or at other institutions, including commercial companies, for research on your [***SELECT: medical condition(s), symptom(s)]*** or other conditions. If your data is shared with researchers who are not part of this study, it will be provided in deidentified form. This means that your name and other identifying information have been permanently removed from your data or that your data is coded, and the researchers who will use it will not have access to the key for the code. Any future research using your data may lead to the development of information, products, tests, and treatments that could have commercial value. You will not receive any compensation that may result from this research.

[___ I agree] [___ I do not agree] to the storage of my data at UMassD in identifiable form after the completion of this study.

[___ I agree] [___ I do not agree] to the use of my data for future research and/or testing, including for commercial purposes, that may or may not be related to this study. I understand that my data will only be provided to researchers in deidentified form or coded.

You can change your mind regarding the storage and future use of your data at any time. If you wish to withdraw your consent, please contact [**INSERT CONTACT INFORMATION**] for further information. UMassD is committed to ensuring the security and confidentiality of your data. All data will be stored securely and handled in accordance with applicable laws and regulations.

Use of Data Collected in This Study for Future Research

We would like to store the data that you agreed to provide as part of this study and possibly use it for future research. The data will be stored at the University of Massachusetts - Dartmouth (UMassD), either with the researchers on this study or in a central storage facility. With your permission, your data will be stored at UMassD indefinitely in identifiable form, labeled with a code number that the researchers or the storage facility staff can link to you. Your data may also be used by other researchers at UMassD or at other institutions, including commercial companies, for research on your [***SELECT: medical condition(s), symptom(s)]*** or other conditions. If shared with outside researchers, your data will be provided in deidentified form, meaning your identifying information will be permanently removed or coded, with no access to the key for the code. Any future research using your data may lead to the development of information, products, tests, and treatments that could have commercial value. You will not receive any compensation from this research. You can change your mind regarding the storage and future use of your data at any time. If you wish to withdraw your consent, please contact [**INSERT CONTACT INFORMATION**] for further information.

Please select only one option for each statement:

1. **[___ I agree] [___ I do not agree]** to the use of my data for future research and/or testing, including for commercial purposes, that may or may not be related to this study. I understand that my data will only be given to researchers in deidentified form or coded.
2. **[___ I agree] [___ I do not agree]** to the storage of my data in identifiable form after the completion of this study.
3. **[___ I agree] [___ I do not agree]** to have my data stored for future research by the investigators who are conducting this study.
4. **[___ I agree] [___ I do not agree]** to have my data stored and shared with other investigators who are doing research that is related to this study or my condition.
5. **[___ I agree] [___ I do not agree]** to have my data stored and shared with other investigators who are doing research that is or is not related to this study or my condition.

Why Might Researchers Want to Contact Me in the Future?
We may want to contact you for additional information or to learn more about the research findings from this study.

If requested, you may be asked to provide additional information, participate in other research studies, or allow us to use your data in identifiable form for future studies. If participation in future research or the use of your data in identifiable form is requested, you may be asked to sign an additional form to agree to this.

Additionally, in the future, we may want to contact you if we learn more about the basis for the study's condition or other related conditions. This may include opportunities for treatment or improved treatment options related to such conditions.

Permission for Future Contact
The researchers may wish to contact you in the future for various reasons, such as:

- To provide you with updates on the study results.
- To invite you to participate in follow-up studies related to your condition or treatment.
- To gather additional information that may enhance the understanding of the study outcomes.

Future contact may occur on an as-needed basis, depending on the researchers' requirements and developments in the research field.

Please initial below to indicate whether or not you give permission for future contact:
_____ **(initial)** I give permission to be contacted in the future for research purposes.
_____ **(initial)** I give permission to be contacted in the future for information relating to this study.
_____ **(initial)** I give permission to be contracted in the future by the study sponsor for further information.

Statement of Consent [and HIPAA Authorization]

I have read the consent [**and HIPAA authorization]** form and discussed this research study, including the purpose, procedures, risks, benefits, and alternatives, with the investigator or study staff. Any questions I had were answered to my satisfaction. I confirm that I am 18 years of age or older and understand that I am free to not participate in the study or to withdraw at any time without jeopardizing my future care or status with this investigator.

By signing below, I agree to take part in this research study and give my authorization for the use of my protected health information and information collected during the research. I understand that this information will be used for [insert specific purposes], and I will receive a copy of this signed and dated consent and HIPAA authorization form to keep for my records. By signing this consent and HIPAA authorization form, I have not given up any of the legal rights that I would have if I were not a participant in the study. If I have questions later about the research or my rights as a participant, I can contact [**insert investigator's name and contact information**].

[WHEN FINALIZING DOCUMENT, MAKE SURE THE STATEMENT OF CONSENT AND SIGNATURES ARE ON THE SAME PAGE. OMIT SIGNATURE LINES THAT DO NOT APPLY TO YOUR STUDY. IF THE SIGNATURE LINE REMAINS, THE EXPECTATION IS THAT IT WILL BE USED AT THE TIME OF EACH ENROLLMENT.]

Signatures

_____

Print Name of Research Participant Date

_____

Research Participant Signature Date

If this consent also serves as the parental permission, please include a parent/Guardian signature line.

_____

Print name of Parent/Legal Guardian Date

_____

Parent/Guardian Signature Date

[IF THIS CONSENT ALSO SERVES AS THE PERMISSION FROM A SURROGATE, PLEASE INCLUDE A "LEGALLY-AUTHORIZED REPRESENTATIVE" SIGNATURE LINE.]

_____

Print name of Legally Authorized Representative Date

_____

Legally Authorized Representative Signature Date

_____

Print Name of Person Obtaining Consent Date

_____

Person Obtaining Consent Signature Date

_____

Print name of Witness Date

_____

Witness Signature Date

[THE SIGNATURE OF A WITNESS IS ONLY REQUIRED WHEN OBTAINING CONSENT FROM:

- **A NON-ENGLISH SPEAKING RESEARCH PARTICIPANT USING THE SHORT FORM PROCESS, OR**
- **A PERSON WHO IS PHYSICALLY NOT ABLE TO READ, TALK OR WRITE.]**

8.5 Appendix: Federal Agencies that issue Certificates of Confidentiality:

1. **National Institutes of Health (NIH):** NIH issues Certificates of Confidentiality (CoCs) to protect the privacy of research participants by preventing the disclosure of sensitive information even in response to legal demands. CoCs are automatically issued for applicable NIH awards. Researchers can use the NIH award itself as confirmation of CoC protections. For more information, visit the NIH Certificates of Confidentiality website or contact the NIH CoC Coordinator at **coc@nih.gov**.
2. **National Institute of Justice (NIJ):** NIJ provides CoCs for research related to criminal justice and law enforcement, ensuring that sensitive research data related to these fields is protected from legal disclosure. Request CoCs as part of the grant application process. CoCs are typically issued along with grant awards. For more information, visit the NIJ website or contact the NIJ grants office at **nij@ojp.usdoj.gov**.
3. **Office for Victims of Crime (OVC):** OVC issues CoCs for research involving victims of crime, protecting sensitive victim information from legal disclosure. Apply for CoCs through the grant application process. CoCs are often included with grant awards. For details, visit the OVC website or email the OVC grants office at **OVCGrants@ojp.usdoj.gov**.
4. **Substance Abuse and Mental Health Services Administration (SAMHSA):** SAMHSA provides CoCs for research involving substance abuse and mental health services, ensuring confidentiality of sensitive participant data. Request CoCs through the grant application process. CoCs are typically issued with grant awards. For more information, visit the SAMHSA website or contact SAMHSA at **SAMHSA_grants@samhsa.hhs.gov**.
5. **Department of Justice (DOJ):** The DOJ may provide CoCs for research related to legal, criminal justice, and law enforcement topics, protecting sensitive information from disclosure. Request CoCs as part of the research grant application process. CoCs are generally included with grant awards. For more information, visit the DOJ website or contact the DOJ Office of Justice Programs at **ojp@ojp.usdoj.gov**.

8.6 Appendix: Data and Safety Monitoring Plan (DSMP) Template

A comprehensive Data and Safety Monitoring Plan (DSMP) must be developed and approved prior to the initiation of a trial involving more than minimal risk. Below is a detailed checklist outlining the essential components of a DSMP. This plan ensures that adequate provisions are made for monitoring the safety of participants and the integrity of the data throughout the study.

1. Summary of the Protocol:

- **Study Design:** Provide a brief description of the study design, including key features and methodology.
- **Objectives and Outcome Measures:** Outline primary and secondary objectives and specify the outcome measures.
- **Inclusion/Exclusion Criteria:** Define criteria for participant eligibility and exclusion.
- **Sample Size and Power Calculation:** Include details of power calculations and the rationale for the sample size.

2. Trial Management:

- **Participating Sites:** List all clinics or data collection centers involved in the study.
- **Enrollment Timetable:** Present a graphical representation of the enrollment timeline, showing projected vs. actual enrollment.
- **Target Population Distribution:** Provide details on the demographic distribution of the target population (e.g., gender, minorities).

3. Data Management and Analysis:

- **Data Acquisition and Transmission:** Describe methods for data collection and transmission, including technology and processes used.
- **Data Entry Methods:** Outline procedures for data entry and verification.
- **Data Security:** Explain measures in place to ensure the protection of confidentiality and data security.
- **Data Analysis Plan:** Detail the plan for data analysis, including statistical methods and handling of missing data.

4. Quality Assurance:

- **Validity and Integrity:** Describe procedures to ensure the validity and integrity of the data.
- **Accuracy and Completeness:** Outline methods to guarantee data accuracy and completeness throughout the data collection, entry, and analysis phases.

5. Regulatory Issues:

- **Reporting of Serious Adverse Events (SAEs):** Specify reporting procedures for SAEs. Include reporting requirements to the IRB, NIDA (or other relevant bodies), and FDA if applicable.
- **Protocol Changes:** Detail the process for reporting changes or amendments to the protocol. All protocol modifications must be pre-approved by the appropriate regulatory bodies.

6. Trial Safety:

- **Risk Mitigation Plan:** Describe the plan for managing risks associated with the study, including SAEs.
- **Trial Stopping Rules:** Outline conditions under which the study will be modified or terminated and specify who makes these decisions.
- **AE/SAE Collection and Reporting:** Define the process for collecting, assessing, and reporting adverse events (AEs) and SAEs.
- **Follow-Up Plan:** Describe procedures for following up on AEs and SAEs.

7. Trial Efficacy:

- **Interim Analysis:** Provide plans for interim analysis of efficacy data, if applicable. Describe how interim findings will be used to inform study continuation or modification.

8. DSMP Administration:

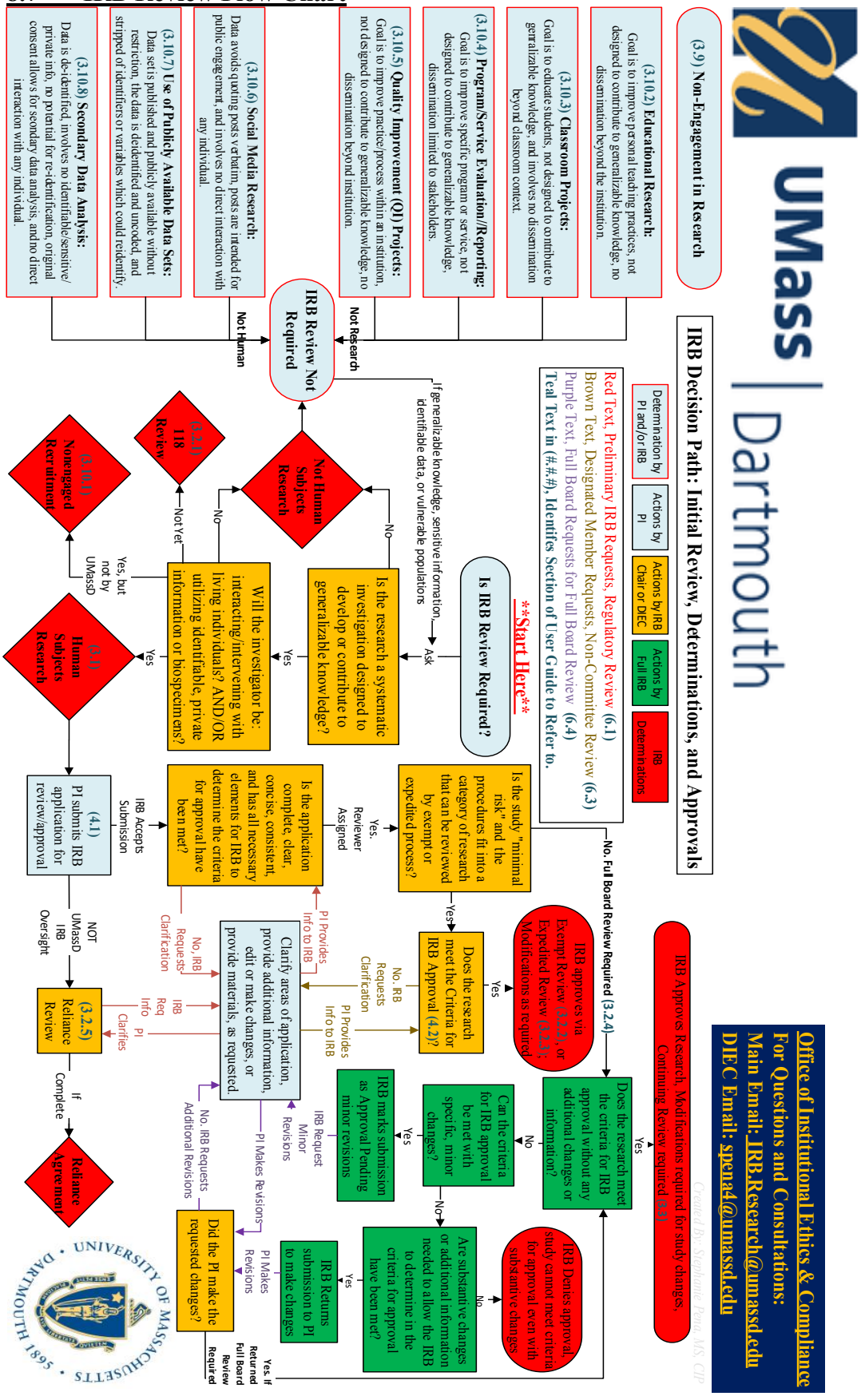
- **Responsibilities:** Identify individuals or teams responsible for implementing and overseeing the DSMP.
- **Conflict of Interest:** Disclose any conflicts of interest related to the DSMB members or monitoring entities.
- **Frequency of Monitoring:** Specify how often data and safety monitoring will occur and how often reports will be generated and reviewed.
- **DSM Report Content:** Detail the contents of the DSM reports to be submitted to regulatory bodies. Reports should include:
    - Description of trial progress

    - Enrollment updates and baseline sociodemographic characteristics
    - Participant retention and disposition (active, completed, terminated/withdrawn)
    - Regulatory issues, amendments, deviations, and QA issues
    - Listings of AEs and SAEs
    - Efficacy data (if applicable)

9. Data and Safety Monitoring Board (DSMB) Plan (if applicable):

- **DSMB Composition:** List DSMB members and their affiliations.
- **Conflict of Interest:** Disclose any conflicts of interest among DSMB members.
- **Meeting Frequency:** Specify how often the DSMB will meet.
- **Confidentiality Protection:** Ensure measures are in place to protect the confidentiality of DSMB discussions and findings.
- **Monitoring Activities:** Describe initial and ongoing monitoring activities, including how the DSMB will review study data and communicate findings.
- **Communication Plan:** Outline how DSMB findings and recommendations will be communicated to the IRB, NIDA, and FDA (as applicable).

8.7 IRB Review Flow Chart



Section 9: References:

Adopted with gratitude from:

1. UMass Amherst. Office of Research and Engagement. IRB Guidance.
2. UMass Lowell. Office of Research Integrity. IRB Policies & Procedures.
3. Harvard University. Office of Regulatory Affairs and Research Compliance. Investigator Manual
4. Dana Farber/Harvard Cancer Center. Office for Human Research Studies. OHRS Information Sheet Library.
5. Northwestern University. IRB Office. Resources & Guidance.
6. Northeastern University. Department of Human Research. Investigator Manual & Policies.
7. University of Connecticut. Research Integrity & Compliance. HRPP Policies & Standard Operating Procedures.
8. Penn State University. Office for Research Protections. Polices and Guidelines.
9. Boston Children's Hospital. Research. IRB Guidelines & Policies.