University of Massachusetts Amherst

Research and Engagement

Research Administration and Compliance

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**Policy on Human Subjects in Research**

**and the Institutional Review Board**

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The University of Massachusetts Amherst (the University) is responsible for safeguarding the rights and welfare of persons who participate as human subjects in research. The University is committed to the ethical conduct of research, and strives to adhere to the highest ethical standards for the protection of human subjects consistent with the principles of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission published the *Belmont Report* that articulates the ethical principles that guide the conduct of research with human subjects and serve as the foundation of Title 45 Code of Federal Regulations Part 46, Policy for the Protection of Human Subjects. This regulation (revised July 19, 2018) has been adopted by 20 federal agencies and thus has come to be known as the *Common Rule*.

# **Purpose**

The purpose of this policy is to define the elements of the University Human Research Protection Program including those of the Institutional Review Board (IRB). The IRB is a federally mandated committee responsible for review of all research involving human participants for compliance with the federal regulations. The following information expands on the University’s role in facilitating the application of the regulations related to the protection of human subjects in research.

# **Authority**

The University Vice Chancellor for Research and Engagement, also referred to as the Institutional Official (IO), exercises general executive responsibility for the research programs of the University. The IO is the University official responsible for ensuring that the Human Research Protection Program (HRPP) has the resources and support necessary to comply with federal regulations and guidelines that govern human subject research. As an agent of the institution, the IO is legally authorized to represent the institution in matters regarding human subject research, is the signatory official for all Assurances and assumes the obligations of the University’s Assurance.

# **Assurance and IRB Regulations**

The University maintains a Federal Wide Assurance (FWA) with the Department of Health and Human Services’ Office of Human Research Protections (OHRP). The OHRP is the federal administrative agency that monitors the IRB and associated activities. The Institutional Review Board (IRB) oversees the use of human subject in research and is governed by federal regulations Title 45, Part 46, Protection of Human Subjects, *the Common Rule,* that dictate the scope and purpose of IRB activities.

The Food and Drug Administration (FDA) also protects human research participants through its investigational drug and device regulations. Both OHRP and the FDA (21 CFR 50 and 21 CFR 56) monitor human research protections through educational efforts, site visits, and reporting requirements. Both have the authority to suspend research for failure to adhere to the regulations.

* The University Federal Wide Assurance (FWA) is identified as FWA00003909.
* The IRB registration is identified as IRB00000017.

# **Human Research Protection Program (HRPP)**

In the role as the IO, the Vice Chancellor for Research and Engagement implemented the campus Human Research Protection Program (HRPP). The HRPP is an integrated system including an Institutional Review Board (IRB), Human Research Protection Office (HRPO), other review units, oversight functions, and educational and quality assurance activities that together seek to assure the rights and welfare of human participants in biomedical and social behavioral research.

# **The Institutional Review Board (IRB)**

The University Institutional Review Board (IRB) is responsible for overseeing the use of human subjects in research conducted at the University or conducted by University faculty, staff, or students at locations other than those owned by the University. The IRB collaborates with the University research community to ensure that human subjects are treated with dignity, adequately protected from risk of harm, and voluntarily participate in the research in accordance with the *Belmont Report* principles of Respect for Persons, Beneficence and Justice.

As guided by the *Common Rule*, the University IRB is authorized to:

* Review and approve, require modifications, or deny approval for any research activities covered by this policy
* Conduct continuing review (where applicable) of research covered by this policy at intervals appropriate to the degree of risk but not more than one year
* Observe or have a third-party (internal to the University or from an external organization) observe the consent process and/or the research, and review research documentation
* Suspend or terminate studies that are not being conducted in accordance with the IRB’s requirements or that have been, or appear might be, associated with serious harm to subjects

**Selection and Operation of the Institutional Review Board**

The IRB Chair, Vice Chair, Associate Director, Assist. VCRE and/or the IO, may identify a need for a new or replacement member, or alternate member. Department Chairs and others may also suggest nominations. The Chair, Assist. VCRE and HRPO staff are consulted to determine the appropriateness of nominees, based on qualifications, and needs of the committee.

If there are no nominees, then appropriate Department Chairs or Program Directors will be contacted in writing, concerning the vacancies and solicit nominees from the Department Chairs or Program Director. The final decision in selecting a new member is made by the Institutional Official, or the IRB Chair and the Associate Director of the HRPO.

Appointments are made for a renewable three-year period of service. Members may resign by written notification to the Chair. On an annual basis, the IRB Chair, and the Associate Director of the HRPO reviews the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements.

The IRB must be composed of at least five members with varying backgrounds to promote an adequate review of research protocols. The IRB shall include at least one member whose primary concerns are in a scientific area and at least one member whose primary concerns are nonscientific. The IRB shall include at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University. If research warrants, additional members with experience working with vulnerable populations would also be present. The IRB shall not be composed entirely of members of one profession, and efforts will be made to assure a diverse membership in regard to gender, ethnicity, and culture. No IRB member shall participate in the initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the IRB.

**Project Suspension and Termination**

The IRB has the authority to temporarily suspend or permanently terminate approval of a research protocol that has been determined to not be conducted in accordance with the research protocol approved by the IRB or that has been found to represent unexpected serious harm to research participants. The IRB may also suspend or terminate research activities for which reporting requirements have not been followed.

In the event of project suspension or termination, the investigator will be notified in writing by the IRB immediately upon such action being taken by the IRB. In the case of a suspended project, the investigator will be provided with a list of conditions that must be met in order to continue with the research and a timeframe within which to comply. Research activities shall not resume until the investigator has been notified by the IRB that the suspension has been removed.

**Reporting Problems with Approved Research**

At the time of IRB approval, investigators are informed of their responsibility to immediately notify the IRB of any unexpected problems, injuries, or increased risks to human subjects participating in the research. Additionally, if an individual other than the investigator believes that any research misconduct has taken place in the project, he or she shall immediately notify the institutional official. The institutional official shall form a review committee consisting of the IRB Chair and at least one other IRB member, and HRPO representative to conduct an investigation of the allegations, beginning with an interview with the research team. The results of the investigation shall be reported to the full IRB, who will responsible for prescribing a corrective action plan to address the noncompliance or terminate the project altogether. The IRB has the authority to suspend the project at any point in the investigation following the initial interview with the research team.

# **The University Human Research Protection Office (HRPO)**

The University Human Research Protection Office (HRPO) is the administrative hub for the University’s Human Research Protection Program. HRPO provides professional and administrative support to the IRB as well as the larger University community, including faculty, students, and staff, who engage in human subject research. Investigators can consult with the HRPO to establish the need for human subject review and for questions related to planning or on-going research. The HRPO, along with the IRB, strive to ensure that research complies with all federal, state and local regulations also taking into consideration cultural context and local laws and customs when conducting domestic and transnational research.

# **Vulnerable Populations**

If human subject participants involved in research are likely to be vulnerable to coercion or undue influence or have diminished decision-making capacity, research must include additional safeguards to protect their rights and welfare. The IRB must ensure that all of the regulatory requirements for the protection of vulnerable subjects are met and that appropriate additional protections are in place. In the case of research involving children or prisoners, additional IRB members with expertise are required.

Children - While there are often compelling reasons for including children as research subjects, research involving children should be avoided unless the use of adults in the research would not provide access to the data needed for a particular research protocol. Additional precautions are required for research involving children and adequate provisions must be made for soliciting the permission of the children’s parents or guardians as well as the assent of the children, when in the judgment of the IRB, the children are capable of providing assent. In determining whether children involved in the research are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. An IRB Member specializing in research with children is typically a routine member of the IRB.

Prisoners - Additional precautions are required for research involving prisoners, who because of their incarcerated state, may be under constraints that would prohibit their ability to make a truly voluntary and uncoerced decision of whether to participate in a research project. Research projects involving prisoners generally require full IRB review. A majority of the IRB members shall have no associations with the prison(s) involved. In addition, the IRB composition includes a Prisoner Representative with appropriate background and experience to serve in that capacity.

# **Human Subject Training**

Investigators (including students), key personnel, and faculty advisors (for student projects) shall be required to complete training on the use of human research subjects by completing the CITI Training for Human Subject Research. HRPO Staff and IRB Members also have CITI training requirements specific to their role in the Program. Training is valid for a period of five years, after which time investigators, IRB Members and HRPO staff are required to take a refresher course for re-certification. Current training is required for all investigators, key personnel, and faculty advisors prior to the approval of research protocols submitted for IRB review.

**For additional information:**

Human Research Protection Program - Standard Operating Procedures

(Please contact humansubjects@ora.umass.edu )

DHHS Office of Human Research Protection (OHRP) -

<https://www.hhs.gov/ohrp/>

Campus Human Research Protection Office (HRPO) - <https://www.umass.edu/research/compliance/human-subjects-irb>