

POLICY: Human Research Protection Program

Document No.:	Edition No.:	Effective Date:	Page:
HRP-010	003	18 Oct 2017	Page 1 of 6

1. PURPOSE

- 1.1. This policy establishes the [Organization]'s Human Research Protection Program (HRPP) and its commitment to protect the rights and welfare of human subjects.

2. POLICY

2.1. Scope

2.1.1. The HRPP applies to:

- 2.1.1.1. All <Human Research> in which engages the [Organization] as defined by "WORKSHEET: Engagement (HRP-422)."
- 2.1.1.2. All <Human Research> submitted to the IRB for review.

2.1.2. <Human Research> may not commence until IRB approved.

2.1.3. Activities that are not <Human Research> do not require IRB review unless there is uncertainty whether the activity is <Human Research>.

2.1.4. Direct questions about whether an activity (such as classroom research, quality improvement, case reports, program evaluation, or surveillance activities) represents <Human Research> to the IRB. The [Organization] provides written determinations in response to written requests.

2.1.5. Direct questions about whether an organization is engaged in <Human Research> to the IRB. The [Organization] provides written determinations in response to written requests.

2.1.6. After a study is completed, the [Organization] does not consider the return of results to former subjects to be <Human Research>.

2.2. Ethical Principles

2.2.1. The [Organization] follows the ethical principles described in the report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" also known as "The Belmont Report." (see Reference 1)

2.2.2. The [Organization] applies its ethical principles to all <Human Research> regardless of support or geographic location.

- 2.2.2.1. Policies and procedures applied to research conducted domestically are applied to international research.

2.2.3. The following categories of individuals are expected to abide by these ethical requirements:

- 2.2.3.1. Investigators (whether professional or student)
- 2.2.3.2. Research staff
- 2.2.3.3. IRB members, IRB chairs, and IRB vice-chairs
- 2.2.3.4. HRPP staff members
- 2.2.3.5. The [Organizational Official]
- 2.2.3.6. Employees and agents

2.2.4. Clinical trials should be conducted in accordance with the ethical principles in Reference 1 that have their origin in the Declaration of Helsinki and are consistent with good clinical practice and the applicable regulatory requirements.

2.3. Legal Requirements

- 2.3.1. For <Human Research as Defined by HHS> conducted, supported, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the [Organization] applies 45 CFR §46 Subpart A and all other regulations of that agency relevant to the protection of human subjects.

POLICY: Human Research Protection Program

Document No.:	Edition No.:	Effective Date:	Page:
HRP-010	003	18 Oct 2017	Page 2 of 6

- 2.3.1.1. The [Organization] applies all subparts of 45 CFR §46 to <Human Research as Defined by HHS> conducted or supported by DHS, HHS, or VA.
- 2.3.1.2. The [Organization] applies 10 USC 980, DOD Instruction 3216.02, OPNAVINST 5300.8B, and SECNAVINST 3900.39D to <Human Research as Defined by HHS> conducted or supported by DOD.
- 2.3.1.3. The [Organization] applies DOE Order 443.1A and to use "Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with the Department of Energy (DOE) Requirements" to <Human Research as Defined by HHS> conducted or supported by DOE.
- 2.3.1.4. The [Organization] applies 28 CFR §22 and 28 CFR §512 to <Human Research as Defined by HHS> conducted or supported by DOJ.
- 2.3.1.5. The [Organization] applies 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98, 34 CFR §99, and 34 CFR §356 to <Human Research as Defined by HHS> conducted or supported by ED.
- 2.3.1.6. The [Organization] applies 40 CFR §26 and EPA Order 1000.17 Change A1 to <Human Research as Defined by HHS> conducted or supported by EPA, or where the results of the <Human Research> are to be submitted to EPA.
- 2.3.2. For <Human Research as Defined FDA>, the [Organization] applies 21 CFR §50 and §56.
- 2.3.3. For <Clinical Trials>, the [Organization] commits to apply the "International Conference on Harmonisation – Good Clinical Practice E6." (ICH-GCP)
- 2.3.4. For research conducted in other countries, the [Organization] applies all policies and procedures applied to research conducted domestically, including:
 - 2.3.4.1. Confirming the qualifications of investigators for conducting the research
 - 2.3.4.2. Conducting initial review, continuing review, and review of modifications to previously approved research
 - 2.3.4.3. Post-approval monitoring
 - 2.3.4.4. Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
 - 2.3.4.5. Consent process and other language issues
 - 2.3.4.6. Ensuring all necessary approvals are met
 - 2.3.4.7. Coordination and communication with local IRBs
 - 2.3.4.8. Requiring that research staff are knowledgeable about local laws and procedures
- 2.3.5. When the laws of a local jurisdiction encompass activities not included in the definition of <Human Research>, the [Organization] complies with those laws.
- 2.3.6. This [Organization] prohibits payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- 2.3.7. This IRB reviews payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") and does not allow them unless the possibility of coercion and undue influence is minimized.
- 2.4. Components of the HRPP
 - 2.4.1. [Organizational Official]
 - 2.4.1.1. The [Organizational Official] is the leader of the HRPP.
 - 2.4.1.2. The [Organizational Official] is authorized to:
 - 2.4.1.2.1. Allocate HRPP resources

POLICY: Human Research Protection Program

Document No.:	Edition No.:	Effective Date:	Page:
HRP-010	003	18 Oct 2017	Page 3 of 6

- 2.4.1.2.2. Appoint and remove IRB members, IRB chairs, and IRB vice-chairs
- 2.4.1.2.3. Bind HRPP policies on the [Organization]
- 2.4.1.2.4. Determine what IRBs the [Organization] will rely upon
- 2.4.1.2.5. Disapprove <Human Research>
- 2.4.1.2.6. Hire and fire HRPP staff members
- 2.4.1.2.7. Limit or condition privileges to conduct <Human Research>
- 2.4.1.2.8. Prohibit publication of research
- 2.4.1.2.9. Require destruction of research samples or data
- 2.4.1.2.10. Determine that information represents <Serious Noncompliance>, <Continuing Noncompliance>, an <Unanticipated Problem Involving Risks to Subjects or Others>, a <Suspension of IRB Approval>, or a <Termination of IRB Approval>
- 2.4.1.2.11. Suspend or terminate <Human Research>
- 2.4.1.2.12. Take personnel action against employees related to <Serious Noncompliance> or <Continuing Noncompliance>
- 2.4.1.2.13. Sign IRB authorization agreements
- 2.4.1.3. The [Organizational Official] is responsible to:
 - 2.4.1.3.1. Oversee the HRPP
 - 2.4.1.3.2. Ensure the independence of the review process
 - 2.4.1.3.3. Ensure that complaints and allegations regarding the HRPP are appropriately handled
 - 2.4.1.3.4. Ensure that the HRPP has sufficient resources, including IRBs, appropriate for the volume and types of <Human Research> reviewed, so that reviews are accomplished in a thorough and timely manner
 - 2.4.1.3.5. Establish a culture of compliance with HRPP requirements
 - 2.4.1.3.6. Investigate and correct allegations and findings of undue influence on the <Human Research> review process
 - 2.4.1.3.7. Investigate and correct systemic problems related to the HRPP
 - 2.4.1.3.8. Periodically review HRPP policies and procedures
 - 2.4.1.3.9. Periodically review HRPP resources
 - 2.4.1.3.10. Review and sign federal assurances (FWA) and addenda
- 2.4.2. All individuals of the [Organization]:
 - 2.4.2.1. All individuals of the [Organization] ultimately report to the [Organizational Official] for HRPP issues.
 - 2.4.2.2. All individuals of the [Organization] who are engaged in research are responsible to:
 - 2.4.2.2.1. Be aware of this policy.
 - 2.4.2.2.2. Be aware of the definition of <Human Research>, including local and international practices and laws that pertain to <Human Research>
 - 2.4.2.2.3. Consult the IRB when there is uncertainty about whether an activity is <Human Research>.

POLICY: Human Research Protection Program

Document No.:	Edition No.:	Effective Date:	Page:
HRP-010	003	18 Oct 2017	Page 4 of 6

- 2.4.2.2.4. Not conduct <Human Research> without IRB approval.
- 2.4.2.2.5. Report allegations of undue influence related to the HRPP.
- 2.4.2.2.6. Report <Allegations of Noncompliance> or <Findings of Noncompliance>.
- 2.4.3. IRB members and HRPP staff members
 - 2.4.3.1. IRB members, IRB chairs, IRB vice-chairs, and HRPP staff members are responsible to:
 - 2.4.3.1.1. Follow HRPP policies and procedures
 - 2.4.3.1.2. Undergo initial training, including training on specific federal agency requirements (e.g., DOD) when such research is reviewed
 - 2.4.3.1.3. Participate in continuing education activities at least annually, including training on specific federal agency requirements (e.g., DOD) when such research is reviewed
 - 2.4.3.2. IRB members and HRPP staff members ultimately report to the [Organizational Official] for HRPP issues.
- 2.4.4. IRB
 - 2.4.4.1. The [Organization] may rely upon the IRB of another organization provided an Institutional Agreement for IRB review (IAIR) is in place, the IRB will maintain and comply with institutional policies and standard operating procedures (SOPs) that are consistent with national standards for human research protection programs, such as the Association for the Accreditation of Human Research Protection Programs (AAHRPP)
 - 2.4.4.2. All <Interventions> and <Interactions> occur at another organization.
 - 2.4.4.3. The [Organization] is engaged in <Human Research> solely because it receives funding directly from a federal department or agency.
 - 2.4.4.4. The IRB has the authority:
 - 2.4.4.4.1. To approve, require modifications to secure approval, and disapprove all <Human Research>.activities overseen and conducted by the [Organization]
 - 2.4.4.4.2. To suspend or terminate approval of <Human Research>.not being conducted in accordance with HRPP requirements or that had been associated with unexpected serious harm to participants
 - 2.4.4.4.3. To observe, or have a third party observe, the consent process and the conduct of the <Human Research>.
 - 2.4.4.4.4. Determine whether an activity is <Human Research>.
 - 2.4.4.4.5. Determine whether the [Organization] is engaged in <Human Research>
 - 2.4.4.4.6. To decide whether financial interests <Related to the Research> and the management, if any, allow approval of the <Human Research>.
 - 2.4.4.5. The [Organization] cannot approve <Human Research>.that the IRB has not approved.

POLICY: Human Research Protection Program

Document No.:	Edition No.:	Effective Date:	Page:
HRP-010	003	18 Oct 2017	Page 5 of 6

- 2.4.4.6. The following individuals are authorized to disapprove research that has been approved by the IRB, institute a <Suspension of IRB Approval>, or institute a <Termination of IRB Approval>:
 - 2.4.4.6.1. [Chief Research Officer]
 - 2.4.4.6.2. [Organizational Official]
- 2.4.5. Investigators and research staff ultimately report to the [Organizational Official] for HRPP issues and are to follow the obligations described in "INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)."
- 2.4.6. Legal counsel works with the [Organizational Official] on HRPP issues and is responsible to:
 - 2.4.6.1. Determine who is a <Legally Authorized Representative>, <Child>, and <Guardian>
 - 2.4.6.2. Provide legal advice related to the HRPP to the [Organizational Official], IRB, and investigators
 - 2.4.6.3. Determine who is an agent for purposes of engagement
 - 2.4.6.4. Identify relevant state and international laws
 - 2.4.6.5. Resolve conflicts among applicable laws
- 2.4.7. Grants and Contracts Office works with the [Organizational Official] on HRPP issues.
 - 2.4.7.1. The Grants and Contracts Office is responsible to review contracts for compliance with HRPP requirements.
- 2.5. Written Procedures
 - 2.5.1. The [Organization] makes written materials describing the HRPP available to all members of the [Organization] through its Web sites at:
 - 2.5.1.1. <http://www.umassmed.edu/ccts/irb/policiesops--checklistsworksheets/>
 - 2.5.1.2. http://www.umassmed.edu/ccts/irb/forms_templates/
 - 2.5.1.3. <http://www.umassmed.edu/ccts/irb/>
 - 2.5.2. When written materials are changed, the [Organization] communicates to affected individuals through one or more of the following actions:
 - 2.5.2.1. Email communications
 - 2.5.2.2. Web-site postings
 - 2.5.2.3. Direct outreach at organizational meetings
 - 2.5.2.4. Training
 - 2.5.2.5. Mentoring
- 2.6. Questions, Concerns, and Feedback
 - 2.6.1. The [Organization] solicits questions, concerns, and feedback.
 - 2.6.2. Individuals should address questions, suggestions, concerns, or complaints about the IRB or human research protection program; allegations of undue influence, <Allegations of Noncompliance> or <Findings of Noncompliance> orally or in writing to the [Organizational Official]:

Margaret J. Koziel, MD
 Senior Director of Clinical Research, UMCCTS
 Professor of Medicine, UMass Medical School
 362 Plantation Street
 Worcester, MA 01605
 Email: margaret.koziel@umassmed.edu
 Phone: (508) 856-2319

**POLICY: Human Research Protection
Program**

Document No.:	Edition No.:	Effective Date:	Page:
HRP-010	003	18 Oct 2017	Page 6 of 6

2.6.3. Individuals may also contact the [Institutional Official] at:

Katherine Luzuriaga, MD
Vice Provost, Clinical and Translational Research
UMass Medical School
373 Plantation Street
Worcester MA 01605
Email: Katherine.Luzuriaga@umassmed.edu
Phone: 508-856-6282

2.6.4. The [Organization] takes steps to protect employees who report in good faith from retaliation and harassment. Immediately reports such concerns to the [Organizational Official].

3. REFERENCES

- 3.1. "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979, (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>)