

POLICY: Human Research Protection Program

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1. PURPOSE

- 1.1. This policy establishes the Institution'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 Institution as references in "[IRB REGULATORY GUIDANCE: 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 approved by a UF IRB or an external IRB with which UF has entered into a reliance agreement.

2.1.3. Any research activity that engages UF and its personnel in non-exempt human subject research, where engagement is defined [per UF REGULATORY GUIDANCE: ENGAGEMENT\(HRP-422\)](#) must be submitted for IRB review.

2.1.4. Activities that may not be Human Research as described in [IRB REGULATORY GUIDANCE: Engagement \(HRP-422\)](#) should obtain automatic determination of non-human status by using UF Research Non-Human auto-determination tool.

2.1.5. Whether an activity (such as classroom research, quality improvement, program evaluation) constitutes research can be determined by the UF Research auto-determination tool. Direct question whether an activity constitutes research will be answered by the IRB by providing written determinations in response to written requests.

2.1.6. Direct questions about whether an activity (such as case reports, public surveillance activities) constitute human research will be answered by the IRB by providing written determinations in response to written requests.

2.1.7. Exempt determinations under §46.104 will be made either by IRB or by using UF Research auto-determination exempt tool for qualifying categories of exempt research. ([HRP 134](#))

2.2. Ethical Principles

2.2.1. The Institution 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 Institution 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. All faculty, staff, and students engaged as investigators or research staff.

2.2.3.2. All unaffiliated investigators engaged in research via an unaffiliated investigators agreement.

2.2.3.3. All volunteers or other agents.

2.2.3.4. IRB members, IRB chairs, and IRB Vice Chairs

2.2.3.5. IRB vice-chairs

2.2.3.6. IRB and HRPP staff members

2.2.3.7. Institutional Official

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- 2.3. 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. Review and Oversight 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 Institution applies 45 CFR §46 Subpart A and all other regulations of that agency relevant to the protection of human subjects.
 - 2.3.1.1. The Institution 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 Institution 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 Institution applies 28 CFR §22 and 28 CFR §512 to Human Research as Defined by HHS conducted or supported by DOJ.
 - 2.3.1.4. The Institution 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.
 - 2.3.1.5. The Institution 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. The Institution applies FDA regulations, the Original Rule, the Revised Rule and 45 CFR §46 B,C, and D as described in the tables within the Reference section.
 - 2.3.2.1. If an IND or IDE is required, the IRB will not grant final IRB approval until such is obtained from the FDA and provided to the IRB.
 - 2.3.2.2. For International Research, country specific regulations and laws will be followed.
 - 2.3.3. When following ICH-GCP, clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and the applicable regulatory requirements.
 - 2.3.4. For research conducted in other countries, the Institution 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
 - 2.3.5. When activities are covered under other laws, the definition encompasses activities that are “research involving human subjects” as defined by those laws.
 - 2.3.6. This Institution 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.

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2.4. Components of the HRPP

2.4.1. Institutional Official

2.4.1.1. The Institutional Official is the leader of the HRPP.

2.4.1.2. The Institutional Official is authorized to:

2.4.1.2.1. Allocate HRPP resources

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 Institution

2.4.1.2.4. Determine what IRBs the Institution will rely upon

2.4.1.2.5. Disapprove, suspend, or terminate 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. 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

2.4.1.2.9. Act against employees related to serious noncompliance or continuing noncompliance

2.4.1.2.10. Sign IRB authorization agreements

2.4.1.2.11. Suspend or terminate Human Research

2.4.1.3. The Institutional 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 federalwide assurances (FWA) and addenda

2.4.1.3.11. Report to AAHRPP as soon as possible but generally within 48 hours of becoming aware of:

2.4.1.3.11.1. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators,

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and corresponding compliance actions taken under non-US authorities related to human research protections

2.4.1.3.11.2.

Any litigation, arbitration, or settlements initiated related to human research protections.

2.4.1.3.11.3.

Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP

2.4.2. All employees and agents of the Institution:

2.4.2.1. All employees and agents of the Institution ultimately report to the Institutional Official for HRPP issues.

2.4.2.2. All employees and agents of the Institution are responsible to:

2.4.2.2.1. Be aware of all applicable HRPP policies.

2.4.2.2.2. Be aware of the definition of Human Research.

2.4.2.2.3. Consult the IRB when there is uncertainty about whether an activity is Human Research.

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 to the IRB or other appropriate institutional agents.

2.4.3. IRB members and IRB staff members

2.4.3.1. IRB members, IRB chairs, IRB vice-chairs, and IRB 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

2.4.3.1.4. Respond to contacts from participants or others

2.4.3.1.5. Ensure contacts from participants or others are reported to the IRB when required by the IRB's written procedures

2.4.3.1.6. Ensure research submitted to an external IRB meets local requirements

2.4.3.1.7. Ensure research approved by an external IRB has all local approvals before being conducted

2.4.3.1.8. Make "[BROCHURE: Should I Take Part in Research \(HRP-900\)](#)" available to research staff to provide to subjects

2.4.3.2. IRB members and IRB staff members ultimately report to the Institutional Official for HRPP issues.

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2.4.4. IRB

2.4.4.1. The Institution may rely upon the IRB of another institution provided an IRB Authorization Agreement (IAA) is in place and one of the following is true:

- 2.4.4.1.1. The IRB is part of an AAHRPP-accredited Institution.
- 2.4.4.1.2. All Interventions and Interactions occur at another Institution.
- 2.4.4.1.3. The Institution is engaged in Human Research solely because it receives funding directly from a Federal department or agency.
- 2.4.4.1.4. The Institution is engaged in Human Research which does not meet one of the terms above, as part of executing an IAA with the outside IRB, the Institution will request that they complete the UF External IRB Evaluation Checklist to confirm that they comply with high performance standards and regulatory and legal requirements.

2.4.4.2. The IRB has the authority:

- 2.4.4.2.1. To approve, require modifications to secure approval, and disapprove all Human Research activities overseen and conducted by the Institution
- 2.4.4.2.2. To establish policies and procedure to guide investigators on compliance with IRB, University, State and Federal requirements.
- 2.4.4.2.3. 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
- 2.4.4.2.4. To observe, or have a third party observe, the consent process and the conduct of the Human Research.
- 2.4.4.2.5. Determine whether an activity is Human Research.
- 2.4.4.2.6. Determine whether the Institution is engaged in Human Research.
- 2.4.4.2.7. To decide whether financial interests Related to the Research and the management, if any, allow approval of the Human Research.

2.4.4.3. The Institution cannot approve Human Research that the IRB has not approved.

2.4.4.4. External organizations that rely on the Institutions' IRB can expect the Institution's IRB to follow the requirements outlined in POLICY: UF sIRB (HRP-194).

- 2.4.4.4.1. Should the relying organization terminate reliance on the IRB, the IRB will continue oversight of active studies until closure or a mutually agreed-upon transfer of the studies.

2.4.4.5. Upon request or when required by law, the institution will execute an Authorization Agreement with the relying organization, which documents respective authorities, roles, responsibilities, and communication between this Institution and the relying organization.

2.4.4.6. The following individuals are authorized to suspend, terminate, or prohibit research that has been approved by the IRB:

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- 2.4.4.6.1. Institutional Official
- 2.4.4.6.2. University President

- 2.4.5. Investigators and research staff ultimately report to the Institutional Official for HRPP issues and are to follow the obligations described in [“INVESTIGATOR GUIDELINE: Investigator Obligations \(HRP-800\).”](#)
- 2.4.6. Legal counsel works with the Institutional Official as needed on HRPP issues 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 Institutional 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. UF Research Contracting works with the Institutional Official on HRPP Contract related issues.
 - 2.4.7.1. Purpose: UF Research is responsible for ensuring that provisions in contracts and funding agreements contribute to the protection of research participants in sponsored research. Contracts and funding agreements must address important elements such as medical care for research-related injury, prompt reporting of safety related findings, and disclosure of research results.
 - 2.4.7.2. Determination and Application: AAHRPP Element I-8 applies when the scope of work for a contract or funding agreement is determined to be greater than Minimal Risk (45 CFR 46.102(i); 21 CFR 56.110).
 - 2.4.7.3. Related Accreditation Elements:
 - 2.4.7.3.1. Element I.8.A. UF requires that a written contract or funding agreement with the sponsor address medical care for research participants with a research-related injury, when appropriate. The contract or funding agreement must indicate who will provide care and who is responsible to pay for it.
 - 2.4.7.3.2. Element I.8.B. When sponsors conduct research site monitoring visits or conduct monitoring activities remotely, UF requires that a written contract or funding agreement state that the sponsor will promptly report to UF any findings that could affect the safety of participants or influence the conduct of the study.
 - 2.4.7.3.3. Element I.8.C. When the sponsor has the responsibility to conduct data and safety monitoring, UF requires that a written contract or funding agreement address provisions for monitoring data to ensure the safety of participants and for providing data and safety monitoring reports to UF.
 - 2.4.7.3.4. Element I.8.D. UF requires a written contract or funding agreement that addresses plans for disseminating findings from the research and the roles that the researchers and sponsors will play in the publication or disclosure of results.
 - 2.4.7.3.5. Element I.8.E. When participant safety could be directly affected by study results after the study has ended, UF requires that a written contract or funding agreement include the provision that the sponsor will notify UF of the results in order to consider informing participants.

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2.4.7.4. Procedure: The UF Research Division of Sponsored Programs is responsible for the review, negotiation, and execution of written contracts and funding agreements that are determined to be within the scope of the HRPP program's oversight. Executed contracts and funding agreements must include all appropriate elements as required by the HRPP. The exclusion of any required elements must be approved by the Director of the Division of Sponsored Programs or the Institutional Official. UF has issued institutionally approved template research-related injury language that must be included verbatim in the consent document approved by the applicable Institutional Review Board "IRB". The UF Research Division of Sponsored Programs responsible for confirming that the terms specified in the contract or funding agreement are consistent with the institutionally approved template research-related injury language.

2.5. Written Procedures

- 2.5.1. The Institution makes written materials describing the HRPP available to all members of the Institution through its Web site at <http://research.ufl.edu/hrpp.html>.
- 2.5.2. When written materials are changed, the Institution 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 Institutional meetings
 - 2.5.2.4. Training
 - 2.5.2.5. Mentoring

2.6. Reliance Agreements

- 2.6.1. For federally funded research that must follow the Revised Rule(with the exception of exempt research for which IRB review is not required by regulation) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB must document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy

2.7. Questions, Concerns, and Feedback

- 2.7.1. The Institution solicits questions, concerns, and feedback by making the document "[BROCHURE: Should I Take Part in Research \(HRP-900\)](#)" available on its Web site and available to investigators to provide to the public.
- 2.7.2. 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:

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Michael P. Mahoney
 Director of Research Operations and Services
 106 Broad Building, PO Box 100137
 Gainesville, FL 32610 mmahoney@ufl.edu
 (352) 294-2744

UF Compliance Hotline: 1-877-556-5356

- 2.7.3. Individuals may also contact the Institutional Official at:

David Norton, Ph.D.
 Vice President for Research
 223 Grinter Hall
 PO Box 115500
 Gainesville, FL 32611-6550
dpnorton@ufl.edu
 (352)392-9271

- 2.7.4. The Institution takes steps to protect employees and agents who report in good faith from retaliation and harassment. Immediately reports such concerns to the Institutional 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>)
- 3.2. Table of Applicability of Regulatory and Policy Requirements by Category of Research

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Category of Research	Before Jan 21, 2019	On or after Jan 21, 2019
FDA regulated research that is NOT emergency use ¹ , compassion use, or device research on anonymous tissue specimens ²	<ul style="list-style-type: none"> FDA regulations Original Rule Subparts B, C, D 	<ul style="list-style-type: none"> FDA regulations Revised Rule Subparts B, C, D
Emergency use, compassion use, and device research on anonymous tissue specimens ³	<ul style="list-style-type: none"> FDA regulations 	<ul style="list-style-type: none"> FDA regulations
Research regulated by federal department or agency other than DOJ	<ul style="list-style-type: none"> Original Rule⁴ Subparts B, C, D 	<ul style="list-style-type: none"> Revised Rule Subparts B, C, D
Research regulated by DOJ	<ul style="list-style-type: none"> Original Rule Subparts B, C, D 	<ul style="list-style-type: none"> Original Rule Subparts B, C, D

¹ This includes emergency use as defined in 21 CFR 56.102(d) and described in 21 CFR 50.23(a) and (b). This does not include waiver of consent for planned emergency research.

² Research Involving Human Subjects as Defined by FDA that is also Research Involving Human Subjects as Defined by HHS

³ Research Involving Human Subjects as Defined by FDA that is NOT Research Involving Human Subjects as Defined by HHS

⁴ On or after January 21, 2019, sponsors can request that the research in this category initially reviewed, determined exempt, or waived before January 21, 2019 be re-reviewed under the Revised Rule