

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 involves humans, human tissue or human data must be submitted for IRB review. This includes research involving (a) non-living individuals or (b) anonymized/coded data or tissue with no direct interaction with the subjects.

2.1.4. Activities that may not be Human Research as described in [IRB REGULATORY GUIDANCE: Engagement \(HRP-422\)](#) should obtain IRB review to confirm the activity is not Human Research.

2.1.5. 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 IRB provides written determinations in response to written requests.

2.1.6. Direct questions about whether an Institution is engaged in Human Research to the IRB. The IRB provides written determinations in response to written requests.

2.1.7. After a study is completed, the Institution does not consider the return of results to former subjects to be Human Research.

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 and HRPP staff members

2.2.3.6. Institutional Official

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.

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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 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 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 Institution 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 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.
 - 2.3.1.6. 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. For Human Research as Defined FDA, the Institution applies 21 CFR §50 and §56.
 - 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.
- 2.3.3. 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.

2.4. Components of the HRPP

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

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- 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. 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. Sign IRB authorization agreements
- 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
- 2.4.2. 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.

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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.

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 AAHRPP's IRB Evaluation Checklist: https://admin.share.aahrpp.org/Website%20Documents/IRB_Evaluation_Checklist.DOC 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.

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- 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. The following individuals are authorized to suspend, terminate, or prohibit research that has been approved by the IRB:
 - 2.4.4.4.1. Institutional Official
 - 2.4.4.4.2. 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. Grants and Contracts Office works with the Institutional Official on HRPP issues.
 - 2.4.7.1. To review contracts for compliance with HRPP requirements.
- 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. Questions, Concerns, and Feedback
 - 2.6.1. 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.
 - 2.6.2. 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:

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(352) 294-2744

UF Compliance Hotline: 1-877-556-5356

- 2.6.3. 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

- 2.6.4. 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>)