



SUBJECT: Human Research Protections Program: Governing Principles, Policy, & Organizational Structure	Effective Date: November 20, 2018	Policy Number: 10.3.1
	Supersedes: November 20, 2015 October 21, 2011 June 10, 2011 April 9, 2011 March 2007 Revision, Parts I and III, "The Protection of the Rights and Welfare of Human Subjects of Research at FAU"	Page 1 of 10
	Responsible Authorities: Vice President, Research Institutional Review Board Associate Director, Research Integrity	

I. Background

The Human Research Protections Program (HRPP) at Florida Atlantic University is governed by several guiding principles and laws.

a. Ethical Principles. The primary ethical principles applied to research governed by the HRPP are those stated in the *Belmont Report*. The three main principles are:

- Respect for persons (including obtaining informed consent, giving consideration to privacy and confidentiality and adding protections for vulnerable populations);
- Beneficence (applied by weighing risks and benefits); and
- Justice (applied by the equitable selection of subjects).

Other appropriate ethical standards may be applied to research governed by the HRPP in certain circumstances if they are recognized by the federal or other funding source or the state or country where the research will occur.

b. Legal Principles. The basic legal principles governing research governed by the HRPP are:

- The federal policy for protection of human subjects ("Common Rule") in 45 CFR Part 46;
- FDA regulations for the protection of human subjects in 21 CFR Parts 50 and 56;
- Federal regulations under 32 CFR Part 219 and 34 CFR Part 97 (Department of Defense and Department of Education, respectively);
- Standards for privacy of individually identifiable health care information ("HIPAA Privacy Rule") in 45 CFR Parts 160 and 164 (FAU is a hybrid covered entity under HIPAA); and
- Applicable Florida state laws.

II. Purpose

The purpose of this policy is to ensure the protection and welfare of human subjects participating in research engaged in by FAU.

III. General Statement

Florida Atlantic University promotes the highest code of conduct for research involving human subjects to adequately protect the rights and welfare of human subjects participating in that research. FAU is committed to developing, implementing and maintaining a systematic and comprehensive HRPP with appropriate leadership and monitoring. The President of the University and the Vice President of Research have overall responsibility for FAU's HRPP. The Vice President of Research is the designated "institutional official" (hereafter referred to as "IO") who delegates shared responsibility for the HRPP to the Director of Research Integrity. Additionally, the IRB has oversight of all policies, procedures and practices relating to institutional review of proposed new protocols, informed consent, protocol data and safety monitoring, management of financial conflicts and financial disclosure. This policy describes the essential elements of FAU's plan for implementing, maintaining and monitoring the HRPP.

Activities to which the HRPP Applies

FAU's HRPP applies to all research involving human subjects engaged in by the University (Note: this includes student projects that meet the definition of research, but does not apply to student projects designed exclusively for instructional purposes).

Research shall be considered “human subjects research” if it satisfies any of the following criteria:

- It is a "clinical investigation" involving "human subjects" as defined in United States Food and Drug Administration ("FDA") regulations (21 CFR Section 50.3);
- It is "research" involving "human subjects" as defined in United States Department of Health and Human Services ("DHHS") regulations or other Common Rule regulations (45 CFR Section 46.102);
- It is research subject to Department of Defense (DOD) or Department of Education regulations for the protection of human subjects (32 CFR Part 219 and 34 CFR Part 97).
- It is research involving human subjects under any other applicable state or local laws or regulations.

Human subjects research becomes subject to the HRPP whenever one or more of the following conditions occurs:

- FAU's employees or agents observe, intervene or interact with human subjects for purposes of research under the auspices of the University;
- FAU's employees or agents obtain individually identifiable private information about human subjects for purposes of research under the auspices of the University;
- FAU receives a direct award from any source to conduct research involving human subjects, even where all activities involving human subjects are carried out by a subcontractor or collaborator;
- The research involves human subjects and the researchers recruit those subjects from the University, including using the University's public information to identify and contact potential research subjects, or uses any of its property or facilities;
- There is an emergency use of investigational drug, device or biologic under FDA regulations by an employee or agent of FAU: or
- FAU's IRB is the IRB of record for the research even though conducted or supplied by another institution.

IV. Policy

It is the policy of Florida Atlantic University ("FAU" or "University") that the rights and welfare of human subjects participating in research engaged in by FAU must be adequately protected. All such research, including research projects, theses, or dissertations, whether unfunded or funded by grants, contracts, or other mechanisms, must satisfy each of the following requirements:

- I. It must be guided by applicable ethical principles including respect for persons, beneficence and justice as described in "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research" of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("Belmont Report");
2. It must comply with applicable laws and regulations;
3. It must be conducted by persons with appropriate expertise and training;
4. It must have scientific or scholarly merit;
5. It must be reviewed and approved by a properly constituted institutional review board (IRB) that functions independently of other FAU administrative or scientific units with respect to protecting the rights and welfare of human research subjects. This requirement may be satisfied through an expedited IRB review process if permitted under applicable law and FAU policy.

Research subject to the HRPP may not proceed without IRB approval even if it has been approved by other FAU departments or officials. The ability to effectively protect the rights and welfare of human subjects participating in FAU research depends on the willingness of those involved in such research to personally adhere to the standards described in this policy and to report suspected noncompliance with this policy. It is the obligation of all FAU employees to report any suspected or confirmed noncompliance with the HRPP to FAU's IRB, the Chair of the IRB HRPP, the Director of Research Integrity, or the General Counsel through regular organizational channels.

Principal investigators and others who design, conduct or are engaged in research involving human subjects are expected to be familiar with this policy and FAU's HRPP. PIs and others must be trained and educated with regards to all aspects of research involving human subjects, and accept continuing responsibility for compliance with this policy and the HRPP through all stages of the research process.

V. Definitions

The following definitions and abbreviations apply to terms used in this policy:

- **Belmont Report:** The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- **CFR:** Code of Federal Regulations
- **DHHS:** United States Department of Health and Human Services.
- **OHRP:** The Office of Human Research Protections
- **FDA:** The United States Food and Drug Administration
- **FWA:** Federal Wide Assurance
- **HIPAA:** The Health Insurance Portability and Accountability Act aka Public Law 104-191 (1996)
- **HRPP:** The Human Research Protection Program
- **IRB:** The Institutional Review Board
- **OGC:** The Office of the General Counsel

VI. Accountability

a. The Principal Investigator (PI) will be responsible for:

- Assuming overall responsibility for all aspects of research subject to the HRPP;
- Ensuring the safety of participating human subjects as well as ensuring that such research does not proceed without necessary IRB and regulatory approvals;
- Gaining familiarity with this policy and the HRPP, acquiring appropriate training and education, and continuing to accept continuing responsibility for compliance with this policy and the HRPP through all stages of the research process.

b. The Vice President for Research (aka Institutional Official) will be responsible for:

- Overall responsibility of the University's HRPP;
- Overseeing the creation, implementation and maintenance of the HRPP and ensuring that the importance of protecting human subjects is properly understood within the University research community;
- Acting as the University's Institutional Official and signing the University's Federal Wide Assurance ("FWA");
- Ensuring that there are open channels of communication within the

components of the HRPP with respect to the protection of human subjects participating in research governed by the HRPP;

- Ensuring the independence of the University's IRBs and its ability to act without undue influence; ensuring that no applicable research project may proceed unless it is reviewed and approved by the University 's IRB;
- Ensuring that the HRPP has sufficient resources to function properly;
- Ensuring that there is appropriate review and monitoring of the HRPP and that appropriate disciplinary action is taken with respect to non-compliance with this policy, the HRPP or requirements or determinations of the IRB;
- Participating in the appointment of the Director of Research Integrity and Chair of the IRB;
- Reviewing and approving conflict disclosures and conflict management plans when directly related to the HRPP.

c. The Research Integrity Office (RIO) will be responsible for:

- Managing RI and ensuring that RI is providing appropriate administrative support to the IRB [*RI is managed by the Assistant Vice President, Research Integrity who reports to the IO with respect to the effective operation of the HRPP];
- Developing policies and procedures relating to implementation of the HRPP particularly with regard to the operations of the IRB and for reporting non-compliance with the HRPP or the requirements and determinations of the IRB;
- Developing and implementing training programs for persons engaged in research governed by the HRPP including members of the IRB, IRB staff, investigators and research staff;
- Ensuring that appropriate government agencies are notified of:
 - (a) serious or continuing noncompliance with the requirements or determinations of the IRBs,
 - (b) unanticipated problems involving risks to research participants or others,
 - (c) study terminations or suspensions required by the IRB.

- Ensuring that the IO and other appropriate university officials are advised of:
 - any serious or continuing noncompliance with the HRPP or the requirements or determinations of the IRB;
 - unanticipated problems involving risks to research participants or others, study terminations or suspensions required by the IRB;
 - any concerns about the independent functioning, undue influence or coercion of the IRB or any of their members relating to their role in the HRPP;
 - any other serious concerns about the ability of the IRB to effectively carry out their responsibilities under the HRPP.
- Providing the IO and IRB information pertaining to all IRB meetings;
- Communicating to the IO budget concerns related to the HRPP;
- Acting as a liaison between the IRB, other components of the HRPP, and FAU's affiliated entities to ensure effective operation and communication among components of the HRPP and to ensure that there is appropriate scientific or scholarly review of any research subject to the HRPP such that no applicable research proceeds without the necessary IRB approval;
- Developing policies and procedures for the disclosure and management of financial conflicts of IRB members as required by the university;
- Ensuring that there are appropriate means for research participants to report questions or concerns about research in which they are participating and that any such questions or concerns are responded to promptly and appropriately;
- Assisting with any internal audit process directly related to the HRPP and ensure that the IO, other appropriate university officials or any government or outside agency pertaining to the protection of human subjects, is informed regarding any HRPP infractions that could directly or indirectly impact research participant safety or university operations;
- Assisting in promoting the HRPP so that it is understood within the university;
- Assisting in promoting appropriate communication and cooperation between investigators and research staff;
- Assisting with internal review and approval of conflict disclosures and conflict management plans as required by the HRPP's policy.

d. Institutional Review Board

FAU's IRB has the ultimate responsibility for determining whether the risks to participants have been appropriately minimized through the use of sound research design and whether those risks are reasonable in light of the anticipated benefits to the participants and the importance of the proposed research.

The IRB performs the principal review functions of the HRPP. No research subject to the HRPP may proceed without review and approval by the IRB even if it has been approved by some other university college/division/unit. This requirement may be satisfied through an expedited IRB review process if permitted under applicable law and HRPP policy.

The Institutional Review Board (IRB) will be responsible for:

- Reviewing all research under the auspices of the HRPP, including those research studies identified as exempt from the federal regulations in order to determine if the research meets the applicable ethical standards and other requirements of this policy and the HRPP. Based on its review, the IRB's options include but are not limited to approving, requiring modifications, closing, suspending, terminating or disapproving such research;
- Reviewing serious and continuing noncompliance with the HRPP and the requirements and determinations of the IRB. This includes unanticipated problems that involve risks to human subjects or others. Any research that is not being conducted in accordance with the requirements and determinations of the IRB or the HRPP or which is causing unexpected problems placing subjects or others at risk of harm;
- Ensuring that one or more of the appropriate university officials (i.e. IO, Director of RI) are advised of:
 - any serious or continuing noncompliance with the HRPP or requirements and determinations of the IRB,
 - any concerns about the independent functioning, undue influence or coercion of the IRB or any of their members relating to their role in the HRPP or
 - any other serious concerns about the ability of the IRB to effectively carry out their responsibilities under the HRPP.
- Establishing subcommittees, as needed, to evaluate specific issues of concern and make recommendations to the IRB. The IRB may also observe or have a third party observe the consent process or any part of the conduct of any research subject to the HRPP.

- Reviewing proposed conflict management plans and determining whether the management plan meets applicable ethical standards and requirements of the HRPP.
 - Developing, guiding and implementing the HRPP, inclusive of all relevant policies and procedures at FAU.
 - Securing consultants if the IRB reasonably determines that appropriate expertise is necessary for a protocol review, and that this expertise does not exist within the committee or within the university.
 - Ensuring that none of its members participate in the review of a project if such participation would constitute a conflict of interest or cause the appearance of a conflict of interest. A member with an application under consideration by the IRB may be present to answer questions from the
 - other members of the IRB, however he/she must leave the meeting room for the time during which his/her application is being evaluated and voted upon. In addition, members are strongly cautioned to be especially sensitive in avoiding conflict of interest situations, or the appearance of a conflict, to protect their own, their Department's and the University's reputation. This includes projects from the member's own department, if the member has more than a casual interest in the project.
 - Conducting official business only when a quorum (one more than half the number of current IRB members) is present. At least one member whose primary occupational concerns are not scientific must be present. Actions of the IRB shall be determined by majority vote after proper motions have been made, seconded and discussed.
- e. The University General Counsel (or designee) will be responsible for:**
- Providing legal advice through the OGC or through outside counsel to all components of the HRPP;
 - Ensuring that one or more of the President, Provost, or Vice-President of Research are advised of the following of which the OGC becomes aware:
 - any serious or continuing noncompliance with the HRPP,
 - any concerns about the independent functioning, undue influence or coercion of the IRB or any of their members relating to their role in the HRPP, or
 - any other serious concerns about the ability of the IRB to effectively carry out their responsibilities under the HRPP.
 - Reviewing and approving conflict disclosures and conflict management plans as required by the HRPP Conflict of Interest Policy.

VII. Procedures

Specific standard operating procedures regarding submission, initial evaluation, review, and ongoing management/monitoring of IRB applications will be developed and referenced in a separate document, labeled 1a., "Standard Operating Procedures of the IRB and Research Integrity."

VIII. Policy Renewal Date

NA

IX. References

The Belmont Report
45 CFR Part 46
21 CFR Parts 50 and 56
45 CFR Parts 160 and 164
32 CFR Part 219
34 CFR Part 97

POLICY APPROVAL

Initiating Authority

Signature: 

Date: 10/29/2018

Name: Daniel C. Flynn, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)