

# MONMOUTH UNIVERSITY POLICIES AND PROCEDURES

**Policy Name:** Institutional Human Research Protection Program (HRPP) Policy

**Original Issue Date:** October 1, 2019

**Revision Date:**

**Page 1 of 3 Pages**

**Issued by:** President and Cabinet

**Approved by:** President and Cabinet

**Reviewed by:** Faculty Council

Monmouth University has an established Human Research Protections Program (HRPP) and is committed to meeting the highest standards and current best practices for human research protections.

This Institutional HRPP Policy (hereinafter referred to as “Policy”) supersedes and replaces in its entirety Monmouth University’s Human Participant Research Policies and Procedures issued by the Vice President for Academic Affairs/Provost and approved by the President and Cabinet on October 3, 2001 (revised December 4, 2002, February 23, 2010, and September 27, 2013). The prior Monmouth University Human Participant Research Policies and Procedures shall be null and void and of no further force and effect.

Monmouth University (hereinafter referred to as “MU” or “Institution”) fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of MU. In the review and conduct of research, actions by MU will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (often referred to as the Belmont Report). The actions of MU will also conform to all applicable federal, state, and local laws and regulations, (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe).

In order to fulfill this mission, MU has established a human research protection program (HRPP). The mission of the HRPP is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety and well-being are protected;
- Provide guidance and support to the research community in the conduct of research with human subjects;
- Assist the research community in ensuring compliance with relevant regulations;
- Provide timely and high-quality education, review and monitoring of human research projects; and
- Facilitate excellence in human subjects research.

MU has designated its Provost & Senior Vice President of Academic Affairs as its Institutional Official who has overall responsibility for MU’s HRPP. The duties of the Institutional Official are as follows:

- Fostering, supporting and maintaining an organizational culture that supports the ethical conduct of all research involving human subjects and the adherence to regulations and organizational policies;
- Ensuring that the IRBs function independently by, among other mechanisms, being directly accessible to the IRB Chair(s) and members if they experience undue influence or if they have concerns about the function of the IRBs;
- Oversight of the Institutional Review Board;
- Oversight over the conduct of research conducted by all MU investigators;
- Ensuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations;
- Ensuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations;
- Oversight of the development and implementation of an educational plan for IRB members, staff and investigators;
- Ensuring compliance with institutional policies and all applicable regulations for the protection of human subjects;
- Serving as the signatory authority and ensuring compliance with the terms of the Federal-wide Assurance to the Office of Human Research Protections; and
- Providing support to the human research protections program, by ensuring that the HRPP has the sufficient staff and resources to fulfill its mission and obligations.

In the performance of these duties, the Institutional Official has the authority to delegate such activities as may be necessary in order to fulfill these duties.

To conduct its responsibility effectively, MU maintains an Institutional Review Board to review research protocols involving human subjects. The IRB is an autonomous body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of MU. The IRB has the following authority:

- To approve, require modifications to secure approval, or disapprove human subjects research activities, including exempt research activities under 45 CFR 46.104 for which limited IRB review is a condition of exemption, overseen and conducted under the auspices of MU, regardless of location of the research activities;
- To require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects;
- To conduct continuing review of research requiring such review (e.g., including research subject to the Common Rule that is reviewed by the convened IRB, FDA-regulated research, etc.) at intervals appropriate to the degree of risk of the research, but not less than once per year;

- To render determinations concerning unanticipated problems involving risks to subjects or others, serious noncompliance, and/or continuing noncompliance.
- To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects;
- To observe, or have a third party observe, the consent process;
- To observe, or have a third party observe, the conduct of the research; and
- To determine whether data or information gathered without IRB approval or in association with serious noncompliance may be published or used for research purposes.

All IRB-approved research studies that require continuing review must undergo such review at least once annually by the IRB. If approval by the IRB lapses, all research activity must stop unless it is determined to be in the best interest of already enrolled subjects to continue participating in the research. The investigator can petition the IRB to continue an individual subject's research intervention/interaction during a period of lapsed IRB approval if the investigator believes there is a safety concern or ethical issue such that it is in the best interests of the individual participant to do so.

The IRB has jurisdiction over all human subject research conducted under the auspices of MU, regardless of funding source or performance site. Research under the auspices of the institution includes research:

- Conducted at this institution;
- Conducted by or under the direction of any employee or agent of this institution (including students) in connection with his or her institution responsibilities;
- Conducted by or under the direction of any employee or agent (including students) of this institution using any property or facility of this organization; or
- Involving the use of this organization's non-public information to identify, contact, or study human subjects.

No research involving human subjects may be conducted without IRB approval and no research may commence until all required Institutional approvals (including IRB) are obtained. Exempt research is subject to review for determination of exemption status, and limited IRB review and approval where required. At MU, exemptions are reviewed and granted by the IRB Chair, a designated member, or IRB Office staff.

MU may review any human subjects research protocol and has the right to disapprove or terminate approval of a research protocol that has been approved by the IRB. However, no one at MU shall approve the implementation of human subjects research that has not been approved by the IRB nor may anyone override a decision of the IRB.

All institutional and non-institutional performance sites for MU, domestic or foreign, will be obligated by this policy to conform to ethical principles which are at least equivalent to those of this institution or as may be determined by the Department of Health and Human Services (DHHS) Secretary.

The Institutional Official and the IRB shall adopt operating Standard Operating Procedures for Human Research Protections (SOPs) which shall be approved by Cabinet and Faculty Council. These procedures shall serve as the governing procedures for the conduct and review of all human research conducted under the auspices of MU.