



RUTGERS POLICY

Section: 90.2.11

Section Title: Compliance

Policy Name: Policy for Human Subjects Protection and the Institutional Review Board

Formerly Book: N/A

Approval Authority: President

Responsible Executive: Vice President for Research and Economic Development

Responsible Office: Office of the Vice President for Research and Economic Development

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1. **Policy Statement**

The University is responsible for the protection of the rights and welfare of human subjects involved in all of the research to which this policy applies and for compliance with all applicable laws and regulations for human subjects research. The primary responsibility for enforcing this policy shall vest in the Institutional Official.

2. **Reason for Policy**

This policy reaffirms the University's commitment to the protection of the rights and welfare of human subjects involved in research. The University requires all human subjects research to be conducted in conformance and compliance with all applicable Federal, State and other regulations, and with the terms of the Federal Wide Assurance (FWA) on file with the U.S. Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP). The policy supports the University's mission to pursue excellence in research.

3. **Who Should Read This Policy**

All faculty, staff and other employees, students, volunteers or other individuals conducting research on Rutgers premises, using Rutgers' property or facilities, and Rutgers' Institutional Review Board (IRB) authorization.

4. **Related Documents**

5. **Contacts**

Office of the Vice President for Research and Economic Development

6. The Policy

90.2.11 POLICY FOR HUMAN SUBJECTS PROTECTION AND THE INSTITUTIONAL REVIEW BOARD

I. DEFINITIONS

A. **Research**

For purposes of this policy, the University adheres to the definitions of *research* as provided by DHHS under 45 CFR 46.102(d) and the Food and Drug Administration (FDA) under 21 CFR 50.3(c), 21 CFR 56.102(c).

B. **Human Subject**

The University adheres to the definitions of *human subject* as provided by DHHS under 45 CFR 102(f) and the FDA under 21 CFR 50.3(g), 21 CFR 56.102(g).

II. APPLICABILITY

A. This policy covers human subjects research that is (1) sponsored by Rutgers; (2) directed or performed by Rutgers faculty, staff and other employees, students, volunteers or other agents in connection with their institutional responsibilities or educational programs, whether or not the research is carried out on Rutgers premises; (3) conducted by any individual, regardless of institutional affiliation, using any Rutgers' property or facilities; (4) using Rutgers non-public information to identify or contact human research subjects or prospective subjects, regardless of the affiliation of the investigator or site of the research; (5) otherwise conducted under Rutgers University auspices; and (6) conducted under an IRB authorization, affiliation or other legal agreement.

B. This policy covers all such human subject research, regardless of the source of sponsorship or funding, or if the research is unsponsored or unfunded. Only a University IRB or authorized non-Rutgers IRB has the authority to approve human subjects research under this policy and to make determinations of exemption of human subjects research from further review.

III. ACCOUNTABILITY

Under the direction of the President and such other University officials as designated by the President, the Institutional Official (IO), as named in the University's FWA shall ensure compliance with this policy. The IO is authorized to act for the University, to assume on behalf of the University the obligations imposed by the pertinent federal regulations and to execute the University's FWAs.

The duties of the IO are as follows:

- Be responsible for compliance with institutional policies and all applicable regulations for the protection of human subjects.
- Be the signatory authority for the FWA to OHRP.
- Provide all available institutional support to the IRB.
- Determine who may or may not conduct human subject research activities.

In performance of these duties, the IO may delegate responsibilities to an appropriate IRB official.

The IO shall have the authority to authorize agreements allowing a Rutgers IRB to rely upon the determinations made by a non-Rutgers IRB. The IO shall also have the authority to authorize agreements allowing a non-Rutgers IRB to rely upon a Rutgers IRB determination.

IV. POLICY

- A. The University is responsible for the protection of the rights and welfare of human subjects involved in all of the research to which this policy applies and for compliance with all applicable laws and regulations for human subjects research. The primary responsibility for enforcing this policy shall vest in the IO.
- B. All human subjects research to which this policy applies must be reviewed by a University IRB before research activities may begin. In the event that the IO has executed an authorization agreement with another institution, the other institution's IRB must first review the research. No research involving human subjects may be conducted without IRB approval and no research may commence until all required institutional approvals are obtained. The IRB has the following authority:
- To approve, require modifications to secure approval, defer, or disapprove all research activities overseen and conducted under the auspices of Rutgers, regardless of location of the research activities;
 - 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 participants;
 - 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 may be published or used for research purposes.
- All IRB-approved research studies are subject to ongoing review, which must be conducted at least once annually by the IRB. If IRB approval lapses, all research activity, including data analysis, must stop. The investigator can petition the IRB to continue an individual participant's research intervention/interaction during a period of lapsed IRB approval if the investigator believes that terminating study procedures creates a safety concern or ethical issue.
- C. The IRB officers and staff shall ensure the appropriate training of all individuals proposing and/or performing human subjects research covered by this policy.
- D. Infractions of federal regulations or University policies and procedures for human subjects research may result in suspension or termination of the research. The IRB will investigate and determine the necessary corrective action with regard to any infraction of which it has notice. There may be additional administrative action under other applicable University policies.
- E. University officials may, under exceptional circumstances, independently review any research protocol and if they deem necessary to disapprove the implementation of a research protocol even if it has been approved by the IRB. However, University official or officials may not approve the implementation of any research protocol in lieu of IRB approval, nor may they override IRB decisions disapproving a research protocol.
- F. All institutional and non-institutional performance sites for the University, 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 DHHS Secretary.
- G. All clinical trials which (1) prospectively assign human subjects to interventional and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome, or (2) are phase II-IV drug, biologics and device trials for which FDA approval is sought must be registered at ClinicalTrials.gov within 21 days of enrollment of the first participant.
- H. The IRB shall adopt operating procedures to implement this policy. These procedures shall serve as the governing procedures for the conduct and review of all human research conducted under this policy.