



Human Subjects Protection Program Plan

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Scope

Throughout this document “Institution” refers to Rutgers, The State University of New Jersey.

Purpose

This Institution is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this Institution’s plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This Institution’s Human Subjects Protection Program (HSPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Subjects Protection Program is based on all individuals in this Institution along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

Definitions

Agent

An individual who is an employee is considered an agent of this Institution for purposes of engagement in Human Research when that individual is on-duty in any capacity as an employee of this Institution.

An individual who is not an employee is considered an agent of this Institution for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of this Institution.

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this Institution.

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Engaged in Human Research

In general, this Institution is considered engaged in Human Research when this Institution’s employees or agents for the purposes of the Human Research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. This Institution follows The Office for Human Research Protections (OHRP) guidance on “Engagement of Institutions in Research¹” to apply this definition and exceptions to this definition.

Human Research

Any activity that either:

¹ <http://www.hhs.gov/ohrp/policy/engage08.html>

- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
- Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

Human Subject as Defined by DHHS

A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition (45 CFR 46.102(e)):

Intervention

means both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction

means communication or interpersonal contact between investigator and subject.

Private Information

means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable Private Information

means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable Biospecimen

means a Biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the Biospecimen.

Human Subject as Defined by FDA

An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Investigator

The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Research as Defined by DHHS

A systematic investigation, including research development, testing and evaluation, designed to

develop or contribute to generalizable knowledge (45 CFR 46.102(l))².

The following activities are **not** considered Research as Defined by DHHS:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
 - Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
 - Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
 - Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.
- Secondary research involving non-identifiable newborn screening blood spots.

Research as Defined by FDA

Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; or
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Mission

The mission of this Institution's Human Subjects Protection Program plan is to protect the rights and

² For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

welfare of subjects involved in Human Research that is overseen by this Institution.

Ethical Requirements

In the oversight of all Human Research, this Institution (including its investigators, research staff, students involved with the conduct of Human Research, the Institution’s institutional review boards (IRBs), IRB members and chairs, IRB staff, the Institutional official, and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report”:

- Respect for Persons
- Beneficence
- Justice

Legal Requirements

This Institution commits to apply its ethical standards to all Human Research regardless of funding.

All non-exempt Human Research must undergo review by one of the Institutionally designated IRBs. Activities that do not meet the definition of Human Research do not require review and approval by one of the Institution’s IRBs and do not need to be submitted to one of the Institution’s IRBs unless there is a question regarding whether the activity is Human Research.

When this Institution is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the Institution commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When this Institution is engaged in FDA Human Research, this Institution commits to apply the FDA regulations relevant to the protection of Human Subjects.

The Institution will employ equivalent protections for human research not covered by laws, regulations, codes, or guidance.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the IRB Office who will provide a determination.

Other Requirements

When reviewing research that involves community-based research, the IRB obtains consultation or training.

All policies and procedures are applied identically to all research regardless of whether the research is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Identifying and complying with local laws
- Conducting initial review, continuing review, and review of modifications to previously approved research

- Post-approval monitoring
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process and other language issues
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs

For clinical trials, this Institution commits to apply the “International Conference on Harmonization – Good Clinical Practice E6” (ICH-GCP) to the extent such guidelines have been adopted by/are consistent with the FDA regulations.

This Institution prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)

This Institution utilizes the IRB to review and approve the use of a Humanitarian Use Device (HUD) before it can be used at a facility for clinical care (with the exception of emergency use).

When Human Research is conducted or funded by the Department of Justice (DOJ), this Institution commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the Institution commits to comply with 28 CFR §512.

When Human Research is conducted or funded by the Department of Defense (DOD), this Institution commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D. This Institution will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects.

Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

When Human Research is conducted or funded by the Department of Education (ED), this Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

When Human Research is conducted or funded by the Department of Energy (DOE), this Institution commits to applying the Department of Energy (DOE) O 443.1B and to use “DOE Institutional Review Board Template for Reviewing Human Subjects Research Protocol that Utilize Personally Identifiable Information (PII).”

When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this Institution commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

When Human Research is subject to the European Union General Data Protection Regulations (GDPR), this Institution coordinates with the Institution's Privacy Officer or legal counsel to ensure that the research activities conform to broader institutional policies related to GDPR, where applicable, as well as legal counsel's interpretation of study-specific GDPR requirements.

Sponsored Human Research

For both sponsored and non-sponsored Human Research this Institution abides by its ethical principles, regulatory requirements and its policies and procedures.

Scope of Human Subjects Protection Program

The categories of Human Research overseen include:

- International research
- Research conducted or funded by the Department of Defense (DOD)
- Research conducted or funded by the Department of Justice (DOJ)
- Research conducted or funded by the Department of Education (ED)
- Research conducted or funded by the Department of Energy (DOE)
- Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA)
- Federally funded research.
- Research involving fetuses.
- Research involving in vitro fertilization.
- FDA-regulated research.
- Research involving drugs that require an IND.
- Research involving devices that require an abbreviated IDE.
- Research involving devices that require an IDE issued by FDA.
- Investigator held abbreviated IDE.
- Investigator held IND or IDE.
- Research involving pregnant women as subjects.
- Research involving non-viable neonates.
- Research involving neonates of uncertain viability.
- Research that plans to or is likely to involve prisoners as subjects.
- Research involving children as subjects.
- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.
- Research involving a waiver of consent for planned emergency research.
- Emergency use of a test article in a life-threatening situation.
- Activities involving humanitarian use devices.
- Research using the short form of consent documentation.

The categories of Human Research not overseen include:

- Research conducted or funded by the Veteran Administration (VA)
- Classified Research.

Human Subjects Protection Program Policies and Procedures

Policies and procedures for the Human Subjects Protection Program are available on the following public Web site: <https://research.rutgers.edu/researcher-support/research-compliance>.

Human Subjects Protection Program Components

Institutional Official

The Senior Vice President for Research is designated as the Institutional Official.

The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the Human Subjects Protection Program budget.
- Allocate resources within the Human Subjects Protection Program budget.
- Appoint and remove IRB members and IRB chairs.
- Hire and fire research review staff.
- Determine what IRBs the Institution will rely upon.
- Approve and rescind authorization agreements for IRBs.
- Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research.
- Create policies and procedures related to the Human Subjects Protection Program that are binding on the Institution.
- Suspend or terminate research approved by one of the Institution's authorized IRBs.
- Disapprove research approved by one of the Institution's authorized IRBs.

The Institutional Official has the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Subjects Protection Program.
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirement.
- Institute regular, effective, educational and training programs for all individuals involved with the Human Subjects Protection Program.
- Ensure that the research review process is independent and free of coercion or undue influence and ensure that officials of the Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
- Ensure that the IRB Chair(s) and members have direct access to the Institutional Official or University Ethics and Compliance for appeal if they experience undue influence or if they have concerns about the function of the IRB.
- Implement a process to receive and act on complaints and allegations regarding the Human Subjects Protection Program.
- Follow-up on findings of serious or continuing non-compliance of IRB staff and IRB members.

- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas, and where necessary removal of individuals from involvement in the Human Subjects Protection Program.
- Ensure that the Human Subjects Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Review and sign federal assurances (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.

All Members of The Institution

All individuals within the Institution have the responsibility to:

- Be aware of the definition of Human Research.
- Comply with the ethical standards of the Belmont Report, federal regulations and other laws governing human research activities, as well as, institutional policy, HSPP policies and IRB determinations.
- Consult the IRB when there is uncertainty about whether an activity is Human Research.
- Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the Institutional Official.
- Report allegations of undue influence regarding the oversight of the Human Subjects Protection Program or concerns about the Human Subjects Protection Program to the Institutional Official or University Ethics and Compliance.
- Report allegations or finding of non-compliance defined as a failure to follow the laws or regulations that govern human research, the organization's policies or procedures, or the requirements or determinations of the IRB, including protocol deviations with the requirements of the Human Subjects Protection Program to the IRB.

Individuals who are responsible for business development are prohibited from carrying out day-to-day operations of the review process.

IRBs

The list of IRBs designated by the Institution Official to be the IRBs relied upon by the Human Subjects Protection Program and the scope of review of these IRBs is listed in the IRB rosters available from the IRB Office.

Relying on an External IRB

This Institution may rely upon IRBs of another Institution provided one of the following is true:

- The IRBs are part of an AAHRPP accredited institution or organization.
- The IRBs are not part of an AAHRPP accredited institution or organization, but where reasonable steps have been taken to ensure that subjects are adequately protected. For example, for research that is no greater than Minimal Risk, there may be an assurance that the IRBs will adhere to applicable ethical standards and regulations. For research that

is greater than Minimal Risk, the institutions may agree on more extensive oversight.

- The IRBs are part of an established reliance network (e.g. Smart IRB) that has established contractual and SOP level procedures to clarify the roles and responsibilities associated with IRB reliance and to establish mechanisms to ensure quality and consistency in the review process among institutions.
- The sIRB has been pre-determined by study sponsor or grant or established by prior arrangement.
- This Institution's investigator is a collaborator on Human Research that is primarily conducted at another institution or organization and the investigator's role does not include interaction or intervention with subjects.
- The Institution is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

Reliance on an external IRB requires an Authorization Agreement and an active Institutional Profile, as well as a local review for compliance with local policies of the Institution. When Human Research carried out at this institution or by its agents is reviewed by an IRB at another institution or organization, this HRPP will follow established policies and procedures that specify which studies are eligible for reliance, how reliance is determined, and will provide information to researchers about reliance criteria and the process for seeking IRB reliance.

The IRBs relied upon by this Institution have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. All Human Research must be approved by one of the IRBs designated by the Institutional Official. Officials of this Institution may not approve Human Research that has not been approved by one of the Institution's IRBs.
- Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs' requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research.
- Determine whether an activity is Human Research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.
- Serve as the Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.

Serving as the IRB of Record

When this institution provides IRB review for other institutions, this HRPP will follow established policies and procedures to ensure that the composition of the IRB is appropriate to review the research and will comply with applicable laws of the relying site. This includes ensuring the IRB is appropriately constituted, members are appropriately qualified, members will not participate in the review of research in which they have a conflict of interest; and that the IRB separates business functions from ethical review.

The IRB will review the research in accordance with established policies and procedures to determine that research is ethically justifiable, according to all applicable laws, including initial review, continuing review, review of modifications to previously approved research and unanticipated problems involving risks to subjects or others. The IRB will also have the ability to suspend or terminate IRB approval; as well as have the final authority to decide whether researcher or research staff conflict of interest and its management, if any, allows the research to be approved and request audits of research reviewed.

The IRB will notify the researcher (and organization) of its decisions, make relevant IRB policies and records available to the relying institution or organization and specify an IRB contact for communication.

Investigators, Research Staff and Students involved in the conduct of Human Research

Investigators, research staff and students involved in the conduct of human research have the responsibility to:

- Comply with the ethical standards of the Belmont Report, federal regulations and other laws governing human research activities, as well as, institutional policy, HSPP policies and IRB determinations.
- Follow the Human Subjects Protection Program requirements described in the HRP-103 - INVESTIGATOR MANUAL
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the IO.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the Institutional Official, IRB, and other individuals involved with the Human Subjects Protection Program.
- Determine whether someone is acting as an agent of the Institution.
- Determine who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.
- Determine whether any Human Research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland conforms with EU General Data Protection Regulations (GDPR).

Deans/Department Chairs

Deans and Department Chairs have the responsibility to:

- Oversee the review and conduct of Human Research in their department or school.
- Forward complaints and allegations regarding the Human Subjects Protection Program to the Institutional Official or Office of Ethics and Compliance.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

Grants and Contracts Offices

The Office of Research and Sponsored Programs and the Office of Corporate Contracts have the responsibility to review contracts and funding agreements for compliance with Human Subjects Protection Program policies and procedures.

Education and Training

This plan is made available to all employees and students at the Institution via the Human Subjects Protection Program website. To maintain awareness of HRPP policies and procedures, new information, revised materials and opportunities for continuing education are communicated to the research community by way of various email list-serve groups targeted to appropriate audiences.

IRB members, IRB staff, and others involved in the review of Human Research, including the IO, must complete initial CITI training and renewal at 3-year intervals. IRB members and staff are restricted from reviewing or processing research without current CITI training.

Investigators and research staff and students involved in the conduct of Human Research must complete the initial and continuing training described in HRP-103 – INVESTIGATOR MANUAL

Questions and Additional Information for the HSPP

The Human Subjects Protection Program wants your questions, information, and feedback. Contact and location information for the Human Subjects Protection Program is:

Human Subjects Protection Program
335 George Street
Liberty Plaza / 3rd Floor / Suite 3200
New Brunswick, NJ 08901
732-235-9806 or 973-972-3608
irboffice@research.rutgers.edu

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Subjects Protection Program or ethics review process may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the Executive Director of the Human Subjects Protection Program, the Office of Ethics and Compliance, or any other designee of the Institutional Official.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The Institutional Official has the responsibility to investigate all other reports and take corrective or disciplinary actions as needed, per Rutgers Policy. Legal penalties may apply, as appropriate.

Employees who report in good faith possible compliance issues will not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Institutional Official or The Office of Ethics and Compliance.

To make such reports, contact the Compliance hot-line at 833-RU ETHICS.

Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and Institutional requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state, or institutional. Random audits may also be conducted.

Disciplinary Actions

The Institutional Official may place limitations or conditions on an investigator's, research staff's, or student's privilege to conduct Human Research whenever in the opinion of the Institutional Official such actions are required to maintain the Human Subjects Protection Program.

Approval and Revisions to the Plan

This Human Subjects Protection Program Plan is to be approved by the Institutional Official or designee. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official or designee has the responsibility to review this plan annually to assess whether it is providing the desired results.