

**INVESTIGATOR MANUAL:  
A GUIDE TO HUMAN SUBJECTS' PROTECTION IN RESEARCH  
HRP-103**

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Unless indicated otherwise, all documents referenced in the document are available on the HSPP website <https://research.rutgers.edu/researcher-support/research-compliance>.

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

## 1. Introduction to the Investigator's Manual

Rutgers University, The State University of New Jersey, is legally and ethically bound to protect the rights and welfare of Humans participating in research conducted by its faculty, staff and students. Federal regulation, state law, University policy and professional standards of the investigator's academic discipline demand compliant, ethical and responsible conduct of social, behavioral and biomedical research involving Humans. We offer this manual **HRP-103 SOP: Investigator Manual** to help you meet your responsibilities by guiding you through relevant regulations, laws, and policies related to Human Research.

## 2. What Is Human Research?

The University follows the regulatory definitions of "Human Subjects Research", which are described in Toolkit item **HRP-101 SOP: The Human Subjects Protection Program Plan**. An algorithm for determining whether an activity is Human Research can be found at Toolkit item **HRP-310 WORKSHEET: Human Research Determination**. Use this document for guidance as to whether a research activity meets either the Department of Health and Human Services (DHHS) or Food and Drug Administration (FDA) definition of Human Subject Research, keeping in mind that the IRB makes the ultimate determination in questionable cases as to whether an activity constitutes research subject to IRB oversight. See Section 12 of this document for more information about what qualifies as Human Research. To request an IRB determination for your project, go to <https://research.rutgers.edu/researcher-support/research-compliance/irb-submission-process> and follow the instructions, or consider using HSPP's *online Non-Human Research Self-Certification Tool (HRP-310b)* found at <https://research.rutgers.edu/node/1426>.

Investigators cannot conduct Human Research without prior IRB review and approval, or a determination that the research is not Human Research or is exempt from further IRB review.

## 3. What Is An Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is a committee designated by an institution to review, approve, and conduct periodic post-approval review of Human Research studies that fall within its scope of authority, as required by federal or state regulation and university policy. The primary purpose of IRB review is to protect the rights and welfare of Humans participating in the research. This University supports a number of IRBs. Each committee is composed of respected scientists, non-scientists, community members, staff and a variety of specialists from diverse fields of study. To contact the IRB, go to <https://go.rutgers.edu/ContactUs>.

## 4. What Is The Human Subjects Protection Program (HSPP)?

Toolkit item **HRP-101 SOP: HUMAN RESEARCH PROTECTION PROGRAM PLAN** describes this institution's overall plan to protect subjects in Human Research.

- The mission of the Human Research Protection Program.
- The ethical principles that the institution follows governing the conduct of Human Research.
- The applicable laws that govern Human Research.
- When the institution becomes "engaged in Human Research" and when someone is acting as an agent of the institution conducting Human Research.

- The types of Human Research that may not be conducted.
- The roles and responsibilities of individuals within the institution.

## 5. What Training Do Investigators and Study Staff Need to Conduct Human Research?

All persons planning to conduct Human Research—faculty, staff, students and faculty advisors of students—must complete an online research ethics and compliance education program prior to IRB approval of proposed Human Research, including research that may be deemed exempt. The online program is called **Collaborative Institutional Training Initiative (CITI Training)**. Proof of CITI Training completion by all members of the research team must be submitted with the application for IRB review. Study staff may not participate in Human Research until their CITI Training is completed. CITI Certification is valid for a three-year period, after which time the training must be repeated. See <https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/hspirb-educational>, for more information or go directly to <https://www.citiprogram.org/> to enroll and gain access to the online program.

You may have additional training required by other federal, state, organizational or funding agencies, as applicable. Your Department/School may also have additional training requirements.

## 6. When Am I “Engaged” In Research?

You are considered “engaged” in Human Research when you 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information about them for research purposes. Further, an institution is considered to be “engaged” in Human Research when it receives a direct Federal award to support the research. For more information, review **Toolkit item HRP-311 WORKSHEET Engagement Determinations**.

## 7. Who Is Qualified to Conduct Human Research And What Responsibilities Do They Have?

All individuals planning to conduct Human Research must be qualified by training and experience to perform the various role responsibilities of the Research outlined below:

- A **Principal Investigator** is the individual who assumes full responsibility for a research project, including the supervision of any co-investigators, research assistants, house staff and students and assuring all study personnel adhere to federal regulations, state and local laws, institutional policies, IRB policies and procedures regarding the safety and protection of human subjects, and good clinical practice guidelines (GCP). [See **A3 GCP** within Toolkit item **HRP-103a SOP: Investigator Manual – All Appendices** to learn more.]
- An **Investigator** is an individual, qualified by training and experience, to perform various tasks related to the conduct of human subjects’ research activities such as obtaining informed consent from subjects, interacting with subjects and communicating with the IRB and adhering to federal regulations, state and local laws, and University and IRB policies and procedures regarding the safety and protection of Humans in the research, and good clinical practice guidelines (GCP). [See **A3 GCP** within Toolkit item **HRP-103a SOP: Investigator Manual – All Appendices** to learn more.]
- FDA outlines additional responsibilities when conducting a clinical investigation of a drug, biological product, or medical device. [See **A2 FDA** within Toolkit item **HRP-103a SOP: Investigator**

**Manual—All Appendices** to learn more.]

The University requires investigators to possess additional specific qualifications to serve in one of the two key Human Research roles outlined above. Additional qualifications may apply depending on the Department or School. [Go to <https://research.rutgers.edu/node/1366> to learn more.

- **Key Study Personnel** - listed in the IRB application, are individuals, qualified by training and experience, and who are directly involved in conducting the research with human subjects by interacting or intervening for research purposes, including participating in the consent process by either leading it or contributing to it; or who are directly involved with recording or handling identifiable private information, related to those subjects for the purpose of conducting the research.
- **Faculty Advisor** and **Student Research** – Research conducted by students should be appropriate to their educational level and commensurate with their training. Undergraduates may serve on a research project, but not as the principal investigator. Graduate students may serve as principal investigators if the Department/School permits them to do so (and the IRB approves). If a graduate student is designated as the PI, additional responsibilities accrue to them, including obtaining a fulltime Rutgers faculty member to serve as their advisor and co-investigator on the proposed Human Research. For more information about student responsibilities in Human Research or the role and responsibilities of the Faculty Advisor at <https://research.rutgers.edu/node/1366>.

All research personnel must complete CITI training [**See Section 5**] and comply with all applicable federal, state and local laws and regulations, as well as university policies and guidance.

Please note that funding agencies may have their own definitions and additional role responsibilities of investigators and study personnel as it applies to grant or other funding applications. The IRB will work with you to coordinate compliance if any discrepancies exist between university and funding agency policies.

## **8. What Financial Interests Must Investigators and Study Staff Disclose?**

Federal guidelines require that an actual, perceived, or potential conflict of interest (COI) in research be eliminated or mitigated. Individuals involved in the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards are considered to have an institution responsibility.

All individuals that are involved in the design, conduct, or reporting of research must complete an eCOI certification when the following occur:

- On submission of an initial IRB application for proposed human subject research;
- On an annual basis during the duration of the research;
- At the time of a funded research project; and
- Within 30 days of discovering or acquiring new interests with respect to COI;

In addition, individuals with reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center are required to disclose the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration of the travel.

Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:

- Joining the institution
- Financial conflicts policies are revised in a manner that changes investigator requirements
- Non-compliant with financial conflicts policies and procedures

Additional details can be found at Toolkit item **HRP-055 SOP: Financial Conflicts of Interest**.

### **9. How Do I Submit An Application For IRB Review Of My Research?**

The HSPS website offers information and detailed instructions about how and what to submit for IRB review at <https://research.rutgers.edu/researcher-support/research-compliance/irb-submission-process>. Prior to submission, upon investigator request, an IRB professional, will pre-review proposed research—including COVID-19 and pandemic-related studies—to provide feedback on additional things to consider, revise or add to the research plan to facilitate a timely review by the IRB. For more information or to schedule a pre-review of your proposed research before submission, email the IRB office at [human-subjects@research.rutgers.edu](mailto:human-subjects@research.rutgers.edu).

### **10. How Do I Request to Rely on An External IRB?**

Confirm if Rutgers University is willing to rely on an external IRB by contacting the Rutgers IRB Administrator by email at: [IRBRelianceAdmin@research.rutgers.edu](mailto:IRBRelianceAdmin@research.rutgers.edu).

### **11. How Do I Request That This IRB Serve as The IRB Of Record (SIRB) For My Collaborative Or Multi-Site Research Study?**

Confirm if Rutgers University is willing to be the IRB of Record by contacting the Rutgers IRB Reliance Administrator at: [IRBRelianceAdmin@research.rutgers.edu](mailto:IRBRelianceAdmin@research.rutgers.edu).

### **12. How do I submit a request to use a Humanitarian Use Device (HUD) for clinical use?**

The Institution utilizes the IRB to review and approve the use of a HUD before it can be used at a facility for clinical care. You can refer to Toolkit Item **HRP-323 WORKSHEET: Criteria for Approval-HUD** for additional information regarding the criteria that the IRB uses to review and approve HUD uses. The clinical use of a HUD is not considered Human Research but must still be submitted for review and approval by the IRB prior to clinical use (with the exception of emergency use). The IRB will inform you whether or not a consent document is required for HUD use.

Complete and submit the application in the electronic IRB system and upload the following supplements: protocol, copy of the Humanitarian Device Exemption approval order issued by FDA, Product Labelling provided by the manufacturer, any Patient Information Packets, and Institutional approval for use of HUD as a clinical service. The IRB may ask for additional information.

### 13. How Do I Write an Investigator Protocol?

A protocol is an investigator's plan detailing how the PI and study personnel, if any, will conduct research—its chief aims and significance, its design and time frame, recruitment and enrollment, the data collection methodologies, analysis, and study closure, as well as, highlighting design features to safeguard the rights and welfare of humans or their private information in the study.

The HSPP website offers protocol templates to help investigators develop Human Research protocols that reflect good science, scholarship, and ethical merit <https://go.rutgers.edu/HSPP-Toolkit>.

As you write your protocol be mindful that the IRB reviews proposed protocols to determine, among other things, if the research plan holds scientific or scholarly merit and ethical safeguards. To learn more about how IRBs evaluate protocols for scientific or scholarly merit and ethical safeguards, see Toolkit items **HRP-320 WORKSHEET: Scientific or Scholarly Review** and **HRP-314 WORKSHEET: Criteria for Review**, respectively.

**NOTE:** If you believe your research does not qualify as Human Research requiring IRB review, you may submit your IRB application for a non-human subjects' determination prior to drafting a full research protocol. To learn more about non-human subjects' determinations, go to Toolkit item **HRP-310 – WORKSHEET – Human Research Determination Algorithm** or consider using HSPP's *online Non-Human Research Self-Certification Tool (HRP-310b)* found at <https://research.rutgers.edu/node/1426>.

### 14. How Do I Compose A Consent Document?

Consent to participate in research is one of the cornerstones of the ethical conduct of research involving Humans. Investigators must assure the consent document provides adequate information about the research and is written in a way comprehensible to the potential subject. The HSPP website offers a variety of templates to assist investigators developing assent documents (children under 18), consent documents (adults, including surrogacy) and parental permission documents. Go to <https://go.rutgers.edu/HSPP-Toolkit> to choose the template that best meets the needs of your study. Templates include suggested consent language and documentation requirements.

Investigators must also assure that the consent *process*—from recruitment to enrollment, and through participation to the end of participation—is conducted in a way that lends itself to voluntariness of enrollment, as well as, continuation in or withdrawal from the study by the adequate, accurate and timely exchange of information between investigator and subject. Note that the consent *process* is distinct from the consent *document*. Describe the *process* of consent in the protocol. The IRB will review both the document(s) and the process to assess adequacy of information, comprehensibility of document(s) provided, and voluntariness of the process of consent.

There may be circumstances when consent or documentation of consent is not indicated for the research. For more information about consent or consent documentation waivers, review Toolkit items **HRP-090 SOP: Informed Consent Process** and **HRP-091 SOP: Written Documentation of Consent**.

If your research plans include enrolling persons who do not speak English, go to <https://go.rutgers.edu/HSPP-Guidance> for guidance and <https://go.rutgers.edu/HSPP-Toolkit> for applicable templates to ensure clear communication with persons who have limited or no English language proficiency, as well as, the documentation requirements for same.

If your research study meets the requirements for an exemption and there are interactions with subjects, you may use an abbreviated process for obtaining consent. Consent can be verbal, but you must provide the following information to subjects through an information sheet or written script:

- The subject is being asked to participate in a research study;
- A description of the procedure(s) the subject will be asked to complete;
- Provisions to protect the subject's privacy, if applicable;
- Participation is voluntary; and
- The investigator's name and contact information.

Date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

## 15. What Are the Different Regulatory Classifications That Research Activities May Fall Under?

Proposed research submitted to the IRB may fall under one of the following regulatory classifications:

- **Not Human Research:** Activities must meet the definition of *human subjects research* to require IRB oversight. Activities that do not meet this definition are not subject to IRB oversight or review. The investigator is responsible for the initial assessment as to whether an activity constitutes Human Research based on the federal criteria. If one or more of the criteria is not met, the project does not require IRB review. However, since the University holds investigators responsible if the determination is not correct, investigators are encouraged to submit their proposed research to the IRB to determine whether it constitutes human subjects' research requiring IRB review and approval. If a change in study plans occurs after an IRB determination of Not Human Subjects Research, you *may* need to request another determination from the IRB. Call your IRB for more information.

NOTE: When you submit your project for an IRB determination of non-human subjects research: (1) be sure to provide sufficient information about your proposed project in the application so that a determination can be made accurately and swiftly (such as, study purpose and design, what data will be collected, how it will be collected and from whom); and (2) state that you believe the project does not qualify as Human Research. To learn more about the criteria an IRB uses to determine Human versus not Human subjects' research, review Toolkit item **HRP-310 WORKSHEET: Human Research.**

- **Exempt:** Certain categories of Human Research may qualify to be exempt from federal regulation. The research must pose minimal risk of harm to subjects and fit into one or more of the detailed categories of research. It is the responsibility of the institution, not the investigator, to determine whether proposed Human Research is exempt from review. If a change in study plans occurs after a determination of exemption, you *may* need to request another determination of exemption. Call



your IRB for more information. To learn more about exemption qualifications, review Toolkit item **HRP-312 WORKSHEET: Exemptions**. When your study is complete, submit a final report to the IRB.

- **Review Using the Expedited Review** – Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated reviewer, rather than the convened board. New proposed research must pose minimal risk of harm to subjects and fit in one the detailed categories to qualify for expedited review. (Some research originally reviewed by the full board may qualify for expedited review at time of continuing review as well if certain conditions are met.) For more information about expedited review, review Toolkit item **HRP-313 WORKSHEET: Expedited Review**.
- **Review by A Convened IRB**: Non-exempt human subjects research that does not qualify for expedited review must be reviewed by the convened IRB (aka a 'Full Board' meeting).

## 16. How Does an IRB Decide Whether to Approve Research?

When the IRB reviews proposed Human Research, it must determine that the research meets regulation, state law and University policy, and appropriately applies the ethical principles of respect for persons, beneficence and justice.

The **Common Rule**, DHHS regulated research [45 CFR 46], lists eight criteria that must be satisfied before IRB approval may be granted. The list can be found in Toolkit item **HRP-314 WORKSHEET: Criteria for Approval**. For proposed exempt research, see Toolkit item **HRP-312 WORKSHEET: Exemption** and for proposed expedited research, see Toolkit item **HRP-313 WORKSHEET: Expedited Review**. The checklists are used for initial review, continuing review, and review of modifications to previously approved Human Research. You are encouraged to use the checklists as a guide as you craft your Investigator Protocol to assure you address the criteria for approval as you design your study elements. To learn about DHHS-regulated research requirements, see **A1 DHHS** within Toolkit item **HRP-103a SOP: Investigator Manual—All Appendices**. To read the Common Rule, go to <https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/policies-and>.

The **Food and Drug Administration (FDA)** requires satisfaction of the same criteria, and more, when conducting clinical research leading to the development of drugs and devices [21 CFR 50, 21 CFR 56]. To learn more about FDA-regulated research requirements, see **A2 FDA** within Toolkit item **HRP-103a SOP: Investigator Manual—All Appendices**. To read the FDA regulations, go to <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/fda/index.html>.

Special regulatory and ethical considerations apply when research involves vulnerable persons. Vulnerability in research means that, due to contextual and/or relational circumstances, persons lack the freedom or capability to protect their self-interests when deciding whether to enroll, decline to enroll, or withdraw from research. The Common Rule and FDA regulations identify and require additional protections for vulnerable persons in research—such as pregnant women, human fetuses, neonates, prisoners, children, persons with physical handicaps or mental disabilities, persons disadvantaged economically or educationally, racial minorities, the very sick and the institutionalized. It may also be

necessary to afford additional protections to individuals who are situationally vulnerable due to real or perceived differences in role relationships—such as, between students and teachers or patients and their caregivers, etc. To learn about regulatory protections for vulnerable populations, go to <https://go.research.rutgers/HSPG-Guidance>. There you will find links to the applicable federal regulations, NJ State laws, and University policy regarding safeguards for vulnerable populations.

The **HIPAA Privacy Rule** establishes the conditions under which electronic health information, such as electronic medical records, may be used or disclosed for research purposes. The Rule strives to protect the privacy of health information, while at the same time ensuring investigators have access to the medical information necessary to conduct vital research. Among other things, the Privacy Rule also defines the means by which individuals participating in human studies research are informed of uses and disclosures of their medical information for research purposes and how researchers must obtain their authorization (permission) to use it. To learn what qualifies as protected health information and under what circumstances investigators may access it for research purposes, go to <https://go.rutgers.edu/HSPG-Guidance>. This site also outlines under what circumstances an investigator may request a waiver of the HIPAA Authorization (Permission to use protected health information for research without obtaining a patient’s authorization.).

To view a HIPAA Authorization, go to <https://go.rutgers.edu/HSPG-Toolkit> and click on Consent Templates. The HIPAA Authorization is found in the Section labelled ‘Special Consent Passages’.

**Other Applicable laws and regulations:** To learn about other laws and regulations that may apply to your research, go to <https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/policies-and>.

## 17. What Are the Decisions the IRB Can Make When Reviewing Proposed Human Research?

The IRB may approve research, approve with conditions or modifications, approve with stipulations, table or defer research, or disapprove research, for newly proposed research, as well as, at continuing review, or when the investigator proposes modifications to existing IRB-approved research:

- Not Human Research: [See Section 15 above].
- Approved: The IRB deems the proposed research activity, as submitted, meets all the criteria for approval as defined by regulation. To review what regulatory criteria must be met before IRB approval is granted, see Toolkit item **HRP-314 WORKSHEET: Criteria for Approval**. Depending on the funder, Toolkit item **HRP-318 WORKSHEET: Additional Federal Agency Criteria** may also apply.
- Modifications Required to Secure Approval/Approved with Conditions: To secure approval, the IRB requires specific changes to newly proposed research, modifications to existing IRB-approved research, or other action(s) to be taken by the investigator. The IRB will include in its written notification a statement of the reasons for the decision and recommendations on what study

elements must be changed or modified in order to secure IRB approval. **NOTE:** Research activities cannot begin until the IRB approves the research activity with conditions.

- **Approved with Stipulations:** The IRB approves the proposed research as submitted, however, there are stipulations limiting the conduct or initiation of some research activities until additional information or documentation is provided (e.g., such as a site approval, limited data set use agreement, etc.).
- **Tabled/Deferred:** An IRB may table/defer review of proposed research for a variety of reasons (e.g., insufficient meeting time to conduct a thorough review of the proposed research, loss of quorum, insufficient detail provided in the application to make a determination, etc.) The investigator may not initiate proposed research activities or implement proposed changes to previously approved research until the IRB completes its review and approves the research.
- **Disapproved:** The IRB has determined that the research activity, as submitted, does not meet the criteria for approval as required by regulation and/or the IRB requires substantial revisions in order to approve the research. The IRB will explain the reasons for disapproval and the investigator has the opportunity to request a meeting with the IRB to review the study. The investigator cannot conduct research activities that have been disapproved by the IRB.

## 18. What Will Happen After IRB Review?

The IRB Office will provide the Principal Investigator with a written decision indicating that the IRB has approved the Human Research, requires changes or modifications to secure approval, has approved but placed stipulations on certain research activities or has disapproved the research.

- **If the IRB approves the research:** The research activities may begin once all other University and Department/School approvals have been met. IRB approval is usually good for a limited period of time, the length of which is noted in the approval letter.
- **If the IRB requires changes or modifications to the research:** Make the requested changes/modifications and submit them to the IRB. If all requested changes/modifications are made, the IRB will issue an approval. Research cannot begin until approval is received. If you do not accept the requested changes/modifications, write up your justifications for why the changes/modifications should not be made to the proposed research and submit it to the IRB for their consideration.
- **If the IRB tables or defers the research:** The IRB will provide a written narrative explaining the reason(s) for their action to delay or defer. If applicable, they will suggest ways to make the study approvable and give you an opportunity to respond in writing.
- **If the IRB disapproves the research:** The IRB will provide a written narrative explaining the reason(s) the study cannot be approved and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting.

### **19. What Are My Obligations as an Investigator?**

Investigators must conduct research in an appropriate manner, consistent with ethical standards for their discipline and in accordance with federal requirements, state law and University Policy. Investigators must also:

- Be knowledgeable about and comply with laws, regulations, policies, and standards, domestic and international, when they apply to the research.
- Ensure experimental test articles have appropriate regulatory approval or meet exemption requirements for such approvals, when applicable to the research.
- Do not start Human Research activities until you have the final IRB approval letter.
- Do not start Human Research activities until you have obtained all other required institutional approvals, including School/Department approvals and approvals unique to the demands of the research, if applicable. For industry-supported clinical trials, do not start Human Research activities until you have received a copy of the executed Clinical Trials Agreement from the Clinical Trials Office.
- Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, and space through the completion of the study.
- Ensure that study personnel are qualified (e.g., including, but not limited to, appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
- Update the IRB office with any changes to the lists of study personnel or research sites.
- Personally, conduct or supervise the Human Research in a manner that ensures the ethical conduct of the research, and the integrity of the study, including analysis of data and publication of results. Recognize that the investigator is accountable for the research performance failures of any study team member.
- Conduct the Human Research in accordance with the protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
- When required by the IRB, ensure that assent, consent, or permission is obtained in accordance with federal regulations for the protection of human subjects and the protocol as approved by the IRB.
- Do not change or modify Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects. Go to <https://go.rutgers.edu/HSPG-Guidance> to find Guidance on procedural and reporting requirements if this occurs.
- Submit proposed modifications to approved study plans for IRB review and approval *before* making changes to study plans. Protect the rights, safety and welfare of subjects involved in the research.
- Conduct safety monitoring of human subjects to ensure that potential risks to subjects are eliminated or minimized to the extent possible.

- Maintaining confidentiality of human subject data in accordance with the IRB-approved protocol. When the research involves Protected Health Information (PHI) or highly sensitive data (e.g., social security numbers, illicit drug use or other criminal activity), ensuring data security of the information to prevent a breach of confidentiality.
- Notify the IRB when certain events or milestones occur in the research.
- Submit a Continuing Review application or Status Report in a timely manner as requested in the IRB approval letter.
- Submit an Unanticipated Problem involving risks to subjects or others (including Unanticipated Adverse Device Effects), or a death in an interventional study for which a Rutgers IRB is the IRB of record that occurred within 30 days of the intervention or interaction. Unanticipated problems or a death should be reported in accordance with the following timeframes:
  - Within 24 hours of discovery – a death in an interventional study for which a Rutgers IRB is the IRB of Record.
  - Within five business days of discovery – an unanticipated problem which is a serious adverse event.
  - Within five business days of discovery – all other unanticipated problems.
- Submit a Reportable Event report within in five business days from date of discovery for any of the following:
  - Information that indicates a new or increased risk, or a new safety issue (physical, psychological, economic, or social harm). For example:
    - New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
    - An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
    - Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
    - Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
    - Potential or actual breach of confidentiality of identifiable information [such as a loss of a laptop w/ PHI], psychological stress, financial loss, loss of employment, etc.
    - Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
    - Any changes significantly affecting the conduct of the research
  - Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
  - Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483.)
  - Written reports of study monitors.
  - Failure to follow the protocol due to the action or inaction of the investigator or research staff.

- Breach of confidentiality.
  - Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
  - Incarceration of a subject in a study not approved by the IRB to involve prisoners.
  - Complaint of a subject other than concerns regarding minor payments for study participation that cannot be resolved by the research team.
  - Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
- Submit a Final report for study closure when the study has concluded.
  - Report suspected research noncompliance or misconduct by others to the appropriate University Authorities. Guidance on what constitutes research noncompliance and reporting requirements for same is found at <https://go.rutgers.edu/HSPG-Guidance>. For guidance on what constitutes research misconduct and how to report it, go to <https://research.rutgers.edu/researcher-support/research-compliance/research-integrity>.
  - Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
  - Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees”).
  - Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of subject enrollment (“bonus payments”).
  - See additional requirements of various federal agencies in the Appendices. These represent additional requirements and do not override the baseline requirements of this section.
  - If the study is a clinical trial and supported by a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. Please contact the study sponsor with any questions.
    - If certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), the supporting Federal department or agency may permit or require redactions to the information posted. Contact the Federal department or agency supporting the clinical trial for a formal determination.
    - Contact the supporting Federal department or agency sponsor with any other questions regarding consent form posting obligations.

The PI has additional responsibilities if she/he serves as a sponsor-investigator. In such situations, the PI must adhere to all FDA regulatory requirements (i.e., 21 CFR 50, 54, 56, 312, 600, and 812), state regulations, Rutgers policies, and compliance with ICH-E6 (R2) version of Good Clinical Practice Guidelines, and must:

- Complete a Good Clinical Practice course that includes ICH-E6 (R2) GCP guidelines. If the study is sponsored/supported by the National Institutes of Health.
- Submit an Investigational New Drug (IND) application for any new investigational drug or biologic

in accordance with 21 CFR 312 or 21 CFR 600, respectively; or an Investigational Drug Exemption (IDE) for investigational devices in accordance with 21 CFR 812.

- Comply with the investigator agreement and any Clinical Trial Agreement (CTA) between Rutgers and the sponsor;
- Comply with the sponsor and investigator responsibilities of 21 CFR 312 when conducting a clinical trial involving an investigational drug and 21 CFR 812 when conducting a clinical trial involving a significant risk device.
- Maintain an Investigator Site File (commonly called a Regulatory Binder) that includes all regulatory documentation for the study.
- Maintain appropriate drug/device/biologic accountability records to ensure accurate documentation of all dispensations and receipt of investigational product. It is recommended that all investigational drugs are managed and stored by the appropriate Pharmacy (e.g., CINJ, RWJ, University Hospital). If kept by the investigator, the PI must ensure appropriate storage and security of the investigational product to ensure its integrity and safety.

## **20. What Are My Responsibilities To Communicate With The IRB After Study Approval?**

You are responsible to communicate with the IRB through the electronic IRB system when certain events or milestones occur in the conduct of IRB-approved Human Research:

- Continuing Review/Status Report – In the Notice of IRB approval, the IRB will advise you when and often your study must be re-reviewed by the IRB during the course of its conduct. Follow their instructions. Note: The PI is responsible to submit a continuing review application in sufficient time for IRB to review and approve the continuing review before study expiration.]. Study activities must cease during periods of lapsed IRB approval.
- Modifications to the Research Plan – You must notify the IRB of any modifications you wish to make to an IRB-approved study. This includes any request to add to, revise, or remove elements from any document previously approved by the IRB. For example, if a member of study team changes, you wish to change a protocol design element, or add/delete a study site, to name a few, you must submit a Modification Request to the IRB and receive their approval before you make any changes.].
- Unanticipated Events or Protocol Deviations – If an unexpected or adverse event occurs (e.g., adverse event, loss of data, stolen laptop, etc.) or you identify someone has deviated from the protocol plan (e.g., failing to secure consent from a subject, omitting a step in the protocol plan, etc.), you must submit a report to the IRB that outlines the details of the event or deviation as soon as possible after it occurs. The report must also outline what corrective action(s) you took and any changes you propose to the protocol plan to assure the problem(s) does not happen again. [For Submission Instructions see <https://go.rutgers.edu/HSPP-Guidance>.] If research documents containing subjects' identifiers or your laptop storing research data are misplaced or stolen, follow the reporting requirements as outlined at [University Policy 70.1.3 Incident

Management found at <https://policies.rutgers.edu/> )

- **Study Closure** – You must submit a request for study closure to the IRB when you wish to close the study: (1) because you have completed data gathering and will no longer interact with subjects or hold their private information, or (2) determine you are unable to complete the research once activities have commenced. Note: Obligations to communicate with the IRB do not end until the IRB approves your request for study closure.
- **Study Withdrawal** – Submit a request to withdraw your IRB-approved study if, for whatever reason, you change your mind about conducting the research before any research activities were initiated (such as recruitment, consent, specimen or data collection).

## **21. What Are My Obligations as The Overall Study PI for a Single IRB (sIRB) study?**

- Coordinating with HRPP personnel to determine whether this institution's IRB can act as the single IRB for all or some institutions participating in the study or if an external IRB will assume oversight.
- Identifying all sites that will be engaged in the human research and requiring oversight by the IRB.
- Ensure that all sites receive a request to rely on the reviewing IRB and that all institutional requirements are satisfied before a study is activated at a relying site.
- Collaborate with the reviewing IRB to document roles and responsibilities for communicating and coordinating key information from study teams and the IRB or HRPP at relying sites.
- Respond to questions or information requests from study teams or the IRB or HRPP staff at relying sites.
- Provide relying site investigators with the policies of the reviewing IRB.
- Provide relying site investigators with the IRB-approved versions of all study documents.
- Preparation and submission of IRB applications on behalf of all sites. This includes initial review, modifications, personnel updates, reportable new information and continuing review information for all sites.
- Establishing a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB. This includes site-specific variations in study conduct, such as the local consent process and language, subject identification and recruitment processes and local variations in study conduct.
- Ensuring that consent forms used by relying sites follow the consent template approved by the reviewing IRB and include required language as specified by the relying sites.
- Providing site investigators with all determinations and communications from the reviewing IRB.
- Submitting reportable new information from relying sites to the reviewing IRB in accordance with the terms outlined in the authorization agreement or communication plan.
- Reporting the absence of continuing review information from relying sites if they do not provide the required information prior to submission of the continuing review materials to the reviewing IRB. Notifying the relying site of their lapse in approval and applicable corrective actions.
- Providing study records to the relying institution, reviewing IRB or regulatory agencies upon request.

## **22. What are my obligations as investigator when relying on an external IRB?**

- Obtain appropriate approvals from this institution prior to seeking review by another IRB.



- Comply with determinations and requirements of the reviewing IRB.
- Provide the reviewing IRB with requested information about local requirements or local research context issues relevant to the IRB's determination prior to IRB review.
- Notifying the reviewing IRB when local policies that impact IRB review are updated.
- Cooperating in the reviewing IRB's responsibility for initial and continuing review, record keeping and reporting and providing all information requested by the reviewing IRB in a timely manner.
- Disclosing conflicts of interest as required by the reviewing IRB and complying with management plans that may result.
- Promptly reporting to the reviewing IRB any proposed changes to the research and not implementing those changes to the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
- When enrolling participants, obtain, document and maintain records of consent for each participant or each participant's legally authorized representative.
- Promptly reporting to the reviewing IRB any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement.
- Providing the reviewing IRB with data safety monitoring reports in accordance with the reviewing IRB's reporting policy.
- Reporting non-compliance, participant complaints, protocol deviations or other events according to the requirements specified in the reliance agreement.

### **23. How do I document consent?**

Use the signature block approved by the IRB. Complete all items in the signature block, including dates and applicable checklists.

The following are the requirements for long form consent documents:

- The subject or representative signs and dates the consent document.
- The individual obtaining consent signs and dates the consent document.
- Whenever the IRB or the sponsor require a witness to the oral presentation, the witness signs and dates the consent document.
- For subjects who cannot read and whenever required by the IRB or the sponsor, a witness, conversant in both English and the language spoken by the prospective subject, to the oral presentation signs and dates the consent document.
- A copy of the consent document is to be provided to the subject.

The following are the requirements for short form consent documents:

- The subject or representative signs and dates the short form consent document.
- The individual obtaining consent signs and dates the summary.
- The witness to the oral presentation signs and dates the short form consent document and the summary.
- Copies of the signed and dated consent document and summary are provided to the person(s) signing those documents.

#### **24. How do I submit a modification?**

Complete the Modification Smart Form in the electronic IRB system and attach all requested supplements, have the Modification submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted without inclusion of the modification until IRB approval is received. Updates to the list of study personnel will be acknowledged unless the update represents a modification to the research.

#### **25. How do I submit a Continuing Review or Status Report?**

Complete the Continuing Review/Status Report Smart Form in the electronic IRB system and attach all requested supplements, and have the Smart Form submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If the continuing review involves modifications to previously approved research, submit those modifications either as a combined Modification and Continuing Review or as a separate request for modification using the Modification Smart Form the electronic system.

If the continuing review application is not received by the date requested in the approval letter, you will be restricted from submitting new Human Research until the completed application has been received. If the approval of Human Research expires all Human Research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing Human Research procedures is a violation of institutional policy. If current subjects will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current subjects. If current subjects will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB chair and provide a written list of the currently enrolled subjects and why they will be harmed by stopping Human Research procedures.

#### **26. How do I close out a study?**

Complete the Continuing Review Smart Form in the electronic IRB system and attach all requested supplements, and have the Smart Form submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If you fail to submit a continuing review form to close out Human Research, you will be restricted from submitting new Human Research until the completed application has been received.

#### **27. How Long Do I Keep Research Records?**

Data retention is an important part of the research process. Research data must be preserved for a set period of time in order to comply with federal law, University policy and funding agency requirements. The data must be well-organized and accessible.

Your project’s data retention requirements depend on the type of data involved. At a minimum, the University requires research data to be retained for 3 years after study closure. If you collected Protected

Health Information (PHI), the HIPAA Privacy Rule requires research data to be retained for six years after study closure. Your School/Department and/or the grant/funding agency, if any, may require data to be retained even longer.

Comply with the longest data retention time period that applies to your research. You may keep your data even longer, but not shorter, than required.

Some federal (such as FDA) and funding agencies require investigators to retain subject identifiers for long periods of time for safety reason. Some studies may retain subject identifiers because, by design, they need long term follow-up or future contact with subjects. If there is no regulatory or funding agency requirement or study justification to retain identifiers, it affords greater protections to destroy identifiers and/or links to identifiers as soon as possible after the data is collected and any quality check for accuracy is completed.

If you leave the University, for any reason, you must arrange to leave a copy of the research data with your School/Department; they will also retain your research records for the required period of time. If you conducted your research at a non-Rutgers facility and your data is being stored there, you must ensure that Rutgers can have access to the data upon request. For more information about research record retention, refer to Toolkit item **HRP-072 SOP: IRB Records and Retention**.

## 28. What are IRB Review Fees?

Under certain circumstances, the IRB may charge a fee to review and oversee the conduct of Human Research. To learn more about when fees apply, go to <https://research.rutgers.edu/node/1356>.

## 29. What Other Things Are There To Consider?

- **Emergency use of an unapproved drug, biologic or device** – Contact the IRB Office immediately to discuss the situation. If there is no time to make this contact, see Toolkit item **HRP-322 WORKSHEET: Emergency Use** for the regulatory criteria allowing such a use and make sure these are followed. Use the consent template HRP-506 TEMPLATE: Emergency Use Consent found at <https://go.rutgers.edu/HSP-Toolkit> to prepare your consent document. You will need to submit a report of the emergency use to the IRB within five days of the use of unapproved devices, drugs and biologics, and an IRB application for initial review within 30 days. If you fail to submit the report within five days or the IRB application for initial review within 30 days you will be restricted from submitting new Human Research until the report and IRB application for initial review have been received.

Emergency use of an unapproved drug or biologic in a life-threatening situation without prior IRB review is “research” as defined by the FDA, the individual getting the test article is a “subject” as defined by the FDA, and therefore is governed by FDA regulations for IRB review and informed consent. FDA may require data from an emergency use to be reported in a marketing application. Emergency use of an unapproved device without prior IRB review is not “research” as defined by the FDA and the individual getting the test article is not a “subject” as defined by the FDA. However, FDA guidance recommends following similar rules as for emergency use of an

unapproved drug or biologic.

Individuals getting an unapproved drug, biologic, or device without prior IRB review cannot be considered a “subject” as defined by US Department of Health and Human Services (DHHS) and their results cannot be included in prospective “research” as that term is defined by DHHS.

- **Other Required Reviews and Approvals:** Depending on the elements of study design outlined in the proposed Human Research, an investigator may be required to obtain other approvals, in addition to IRB approval. For example, the study may need to be reviewed by a Scientific Review Board depending on the type of research or if required by their department, Institutional Biosafety Committee approval may be necessary if the techniques or materials proposed to be used in the research require such review, Performance Site Approvals or Letters of Cooperation (Permission) from University affiliated or non-affiliated research sites prior to research on the property, or a signed Data Use Agreement to access/use data held in a non-University database, to name a few. The IRB cannot issue final approval for studies that lack necessary approvals. To learn about required approvals that may apply to your research, go to <https://research.rutgers.edu/researcher-support/research-compliance/irb-submission-process>.
- **International Research:** If Human Research will take place outside of the United States, there are a number of ethical and compliance matters to consider:
  - Investigators must have sufficient knowledge of the General Data Protection Regulation (GDPR) when research proposes to involve individuals residing in the European Economic Area. In addition to other human subject protections that apply, the research must be designed and conducted in ways that protect subjects to control any personal data collected about or from them. To learn more about GDPR, see **A10 GDPR** within Toolkit item **HRP-103a SOP: Investigator Manual—All Appendices** and **HRP-335 WORKSHEET GDPR Compliance**.
  - The investigator must have sufficient knowledge of country laws, regulations and the local research context to be able to design and conduct research in a way that protects the rights and welfare of the subjects and respects their customs and practices. [A compilation of international laws, regulations and guidelines is found here <http://www.hhs.gov/ohrp/international/compilation-human-research-standards/>].
  - Depending on research design, FDA regulations, the funding agency, or research activities occurring at non-U.S. study sites, research may need to comply with the International Council of Harmonization Good Clinical Practices <http://www.ich.org/products/guidelines.html>.
  - Investigators who conduct international research must comply with the University’s information technologies policies on travel with electronic devices. For information on how to protect devices and the data stored on them, go to <https://it.rutgers.edu/it-risk-policy-and-compliance/>.
  - Investigators may be subject to federal export control laws and regulations. For example, movement of equipment and data stored on laptops and other electronic devices used in the research, as well as, shipping materials to/from the international site are regulated by federal export control laws. Visit the Rutgers Export Control website to learn more about

research rules and responsibilities around export control

<https://research.rutgers.edu/researcher-support/research-compliance/export-control>.

- **Clinical Trial Registration:** ClinicalTrials.gov [<http://clinicaltrials.gov/>] is a federal database that offers up-to-date information to improve public access to and study data/results of federally and privately supported studies for a wide range of diseases and conditions. Researchers conducting interventional studies that meet certain federal requirements must register their clinical trial at this site. The responsibility to register rests with the principal investigator. For more information about registration requirements, go to <https://research.rutgers.edu/node/1571>.

### 30. Will HSPP Conduct a QA Audit my Research?

Consistent with its mission to create a culture of research integrity and compliance, the HSPP Analysts conduct random, periodic quality assurance audits of University research involving human subjects. Before study closure, your research may be randomly selected for an in-person quality audit or a desk review based on a Quality Improvement Self-Assessment you complete and return.

### 31. How Do I Get Additional Information and Answers to My Questions?

We all share responsibility for assuring that the rights and welfare of the individuals involved in University research. The Human Subjects Protection Program and the IRBs and support staff stand ready to help you navigate the IRB process. This document, policies and procedures of the Human Subjects Protection Program, forms and templates, and guidance documents relevant to Human Research are available on the HSPP website at <https://orra.rutgers.edu/hssp>.

- If you have any questions or concerns about or for the Human Subjects Protection Program, contact: HSPP, 335 George Street, Liberty Plaza, Suite 3200, New Brunswick, NJ 08901, (732) 235-9806 or (973) 972-3608 or [human-subjects@research.rutgers.edu](mailto:human-subjects@research.rutgers.edu).
- If you have questions or concerns about or for the IRB, go to <https://go.rutgers.edu/ContactUs>.
- If you wish to express a concern about research non-compliance, go to <https://go.rutgers.edu/ContactUs>.

Our collaborative efforts to work as partners in Human Research serve to minimize the burdens to subjects and maximize the benefits to science and society. Best wishes in your human research endeavors.

### 32. How Can I Report A Concern About The IRB or HSPP?

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 actions as needed.

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.

### 33. For Further Information, Toolkit Documents, and Guidance

To find Toolkit items and Guidance referenced in this Manual, go to <https://go.rutgers.edu/HSP-Toolkit> to obtain referenced Toolkit Forms & Templates and <https://go.rutgers.edu/HSP-Guidance> to obtain referenced Guidance documents. Contact your IRB Office at <https://go.rutgers.edu/ContactUs> if you need further assistance.

### 34. Appendices

The Appendices highlight additional requirements that must be satisfied for different types of research. Go to Toolkit item **HRP-103a SOP: Investigator Manual—All Appendices** to view the collection in its entirety <https://go.rutgers.edu/HSP-Toolkit>.

- Appendix A-1: Additional Requirements for DHHS-Regulated Research
- Appendix A-2: Additional Requirements for FDA-Regulated Research
- Appendix A-3: Additional Requirements for Clinical Trials (ICH-GCP)
- Appendix A-4: Additional Requirements for Department of Defense (DOD) research
- Appendix A-5: Additional Requirements for Department of Energy (DOE) Research
- Appendix A-6: Additional Requirements for Department of Justice (DOJ) Research
  - Additional Requirements for DOJ Research conducted in the Federal Bureau of Prisons
  - Additional Requirements for DOJ Research Funded by the National Institute of Justice
- Appendix A-7: Additional Requirements for Department of Education (ED) Research
- Appendix A-8: Additional Requirements for Environmental Protection Agency (EPA) Research
- Appendix A-10: Single IRB Studies
- Appendix A-11: Additional Requirements for Research Subject to EU General Data Protection Regulations (GDPR)