



pSite Investigator Manual
(For Single IRB Review of Multi-Site Research)
3/23/2021

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Scope

Throughout this document “institution” refers to Rutgers, the State University of New Jersey.

What is the purpose of this manual?

This manual, **HRP-103p SOP: pSite Investigator Manual**, is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to this institution.

General information regarding Human Research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see below: [“What training does my staff and I need in order to conduct Human Research?”](#)

What is Human Research?

The Toolkit item **HRP-101 SOP: Human Subjects Protection Program Plan** defines the activities that this institution considers to be “Human Research.” An algorithm for determining whether an activity is Human Research can be found in the Toolkit item **HRP-310 WORKSHEET: Human Research**, located at <https://go.rutgers.edu/HSPP-Toolkit>. Use this document for guidance as to whether an activity meets either the Department of Health and Human Services (DHHS) or Food and Drug Administration (FDA) definition of Human Research, keeping in mind that the Institutional Review Board (IRB) makes the ultimate determination in questionable cases as to whether an activity constitutes Human Research subject to IRB oversight.

You are responsible not to conduct Human Research without prior IRB review and approval (or an institutional review and approval of exempt Human Research). If you have questions about whether an activity is Human Research, contact the IRB Office at <https://go.rutgers.edu/ContactUs> who will provide you with a determination. If you wish to have a written determination, provide a written request to the IRB Office.

What training does my staff and I need to conduct Human Research?

This section describes the training requirements imposed by the IRB. You may have additional training imposed by other federal, state, or institutional policies.

Investigators and staff conducting research involving more than minimal risk to subjects must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Investigators and staff conducting research involving no more than minimal risk to subjects must complete either the online CITI program.

The CITI site can be accessed at <http://www.citiprogram.org/>.

Training is valid for a three-year period after which time the training must be repeated.

All members of the research team involved in the design, conduct, or reporting of the research must complete training. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects.

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What financial interests do my staff and I need to disclose conduct Human Research?

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 in Toolkit item **HRP-055 SOP: Financial Conflicts of Interest**.

How do I request to rely on an external IRB?

Create and submit an Administrative Review application in elrb.rutgers.edu if the Principal Investigator will be relying on an External IRB. Reach out the IRB Reliance Administrator for guidance (IRBRelianceAdmin@research.rutgers.edu)

How do I request that this IRB serve as the IRB of record (sIRB) for my collaborative or multi-site research study?

Reach out to the IRB Reliance Administrator at: IRBReliance@research.rutgers.edu at least 5 weeks before the grant deadline to obtain a Letter of Support, if the request pertains to a funded Cooperative Study that is mandated to use a Single IRB. See Toolkit item **HRP-893 SOP: RU as IRB-of-Record**.

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How do I write an Investigator Protocol?

A protocol is an investigator’s plan detailing how the Principal Investigator (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 Human Subjects Protection Program (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 Approval**, 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>.

How do I create 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> page 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.

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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/HSPG-Guidance> for guidance and <https://go.rutgers.edu/HSPG-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 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.

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.

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- 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.

What are my obligations after IRB approval?

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.
- 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.
- 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. 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 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. See <https://orra.rutgers.edu/emergency-use> for procedural and reporting requirements if this occurs.
- Protect the rights, safety and welfare of subjects involved in the research.
- Notify the IRB when certain events or milestones occur in the research
- Submit a Continuing Review application or Status Report as requested in the IRB approval letter.

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- Submit proposed modifications to approved study plans for IRB review and approval *before* making changes to study plans.
- Submit an Unanticipated Problem involving risks to subjects or others, 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 one week of discovery – an unanticipated problem which is a serious adverse event.
 - Within two weeks of discovery – all other unanticipated problems.
- Submit a Reportable Event report within 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
 - Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
 - A harm is “unexpected” when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
 - A harm is “probably related” to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.

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- 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 that cannot be resolved by the research team.
 - Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
 - Unanticipated problems involving risks to subjects or others: any information that is (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm.
 - For research conducted at an Internal Site, the RU investigator will make the determination as to whether an incident, experience, or outcome constitutes an Unanticipated Problem.
 - For research conducted at an External Site, an incident, experience, or outcome generally should be reported to the IRB only if a Monitoring Entity— Data and Safety Monitoring Board (DSMB), Data Monitoring Committee, a coordinating or statistical center, or a sponsor—or an External Site investigator has determined that it constitutes an Unanticipated Problem, which is subsequently reported to the RU Investigator.
 - Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).
- 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, go to

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<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.

What are my obligations as the overall study PI for an sIRB study?

- 1) Coordinating with HSPP 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.
- 2) Identifying all sites that will be engaged in the human research and requiring oversight by the IRB.
- 3) 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.
- 4) 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.
- 5) Respond to questions or information requests from study teams or the IRB or HRPP staff at relying sites.
- 6) Provide relying site investigators with the policies of the reviewing IRB.
- 7) Provide relying site investigators with the IRB-approved versions of all study documents.
- 8) 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.

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- 9) 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.
- 10) Ensuing 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.
- 11) Providing site investigators with all determinations and communications from the reviewing IRB.
- 12) Submitting reportable new information from relying sites to the reviewing IRB in accordance with the terms outlined in the authorization agreement or communication plan.
- 13) 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.
- 14) Providing study records to the relying institution, reviewing IRB or regulatory agencies upon request.

What are my obligations as investigator when relying on an external IRB?

- 1) Obtain appropriate approvals from this institution prior to seeking review by another IRB.
- 2) Comply with determinations and requirements of the reviewing IRB.
- 3) 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.
- 4) Notifying the reviewing IRB when local policies that impact IRB review are updated.
- 5) 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.
- 6) Disclosing conflicts of interest as required by the reviewing IRB and complying with management plans that may result.
- 7) 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.
- 8) When enrolling participants, obtain, document and maintain records of consent for each participant or each participant's legally authorized representative.
- 9) Promptly reporting to the reviewing IRB any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement.
- 10) Proving the reviewing IRB with data safety monitoring reports in accordance with the reviewing IRB's reporting policy.
- 11) Reporting non-compliance, participant complaints, protocol deviations or other events according to the requirements specified in the reliance agreement.
- 12) Specifying the contact person and providing contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.



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How do I get additional information and answers to questions?

To find Toolkit items and Guidance referenced in this Manual, go to <https://go.rutgers.edu/HSP-Toolkit> to obtain referenced Toolkit Forms and Templates and <https://go.rutgers.edu/HSP-Guidance> to obtain referenced Guidance documents.

If you have any questions or concerns, about the Human Research Protection Program, contact the IRB Reliance Administrator at IRBRelianceAdmin@research.rutgers.edu.