INVESTIGATOR MANUAL:
A GUIDE TO HUMAN SUBJECTS’ PROTECTION IN RESEARCH
HRP-103
## Table of Contents

_Skip To Section: Hold **CTRL** + **Click (Below)** To Follow Link in **Blue**_

1. **Introduction To The Investigator Manual** | 3
2. **What Is Human Subjects' Research?** | 3
3. **What Is An Institutional Review Board (IRB)?** | 3
4. **What Is The Human Subjects Protection Program (HSPP)?** | 3
5. **What Training Do Investigators And Study Staff Need To Conduct Human Research?** | 4
6. **When Am I “Engaged” In Research?** | 4
7. **Who Is Qualified To Conduct Human Research And What Responsibilities Do They Have?** | 4
8. **What Financial Interests Must Investigators And Study Staff Disclose?** | 6
9. **How Do I Submit An Application For IRB Review Of My Research?** | 6
10. **How Do I Write An Investigator (Research) Protocol?** | 6
11. **How Do I Compose A Consent Document?** | 7
12. **What Are The Different Regulatory Classifications That Research May Fall Under?** | 8
13. **How Does The IRB Decide Whether To Approve Research?** | 9
14. **What Are The Decisions The IRB Can Make When Reviewing Proposed Research?** | 10
15. **What Will Happen After IRB Review?** | 11
16. **What Are My Obligations as an Investigator?** | 12
17. **What Are My Responsibilities to Communicate with the IRB After Approval?** | 13
18. **How Long Do I Keep Research Records?** | 14
19. **What Are IRB Review Fees?** | 15
20. **What Other Things Are There To Consider?** | 15
   A. Emergency Use Of An Unapproved Drug, Biologic Or Device | 15
   B. Other Required Reviews And Approvals | 16
   C. International Research | 16
   D. Clinical Trial Registration | 17
21. **Will HSPP Conduct a QA Audit of My Research?** | 17
22. **How Do I Get Additional Information And Answers To Questions?** | 17
23. **For Further Information And Guidance** | 17
24. **Appendices** | 18

Unless indicated otherwise, all documents referenced in the document are available on the [HSPP website](#).
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: 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 (Subjects’) Research?

The University follows the regulatory definitions of “Human Subjects Research”, which are described in the Human Subjects Protection Program Plan [HRP-101: HSPP Plan]. An algorithm for determining whether an activity is Human Research can be found in a worksheet [HRP-310: 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://orra.rutgers.edu/howtosubmit and follow the instructions.

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 locate the IRB designated to oversee your Department/School’s research, go to https://orra.rutgers.edu/pickirb.

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

The mission of the Human Subjects Protection Program (HSPP) is to support the University’s research enterprise by ensuring the protection of individuals who participate in research; ensuring compliance with all pertinent federal and state laws and regulations; fostering the
ethical conduct of human subjects research; and providing education and other services to
the University's researchers regarding regulatory requirements and best practices.

The HSPP contains three IRBs and a Quality Assurance and Development Unit.

The documents [HRP-101: HSPP Plan] and [HSPP Policy: HSPP Standard Operating
Procedures] describe the University’s overall plan to protect Humans in research including,
but not limited to, the mission of HSPP, the ethical principles and applicable laws that the
University follows governing the conduct of Human Research, and the roles and
responsibilities of individuals within the University relative to Human Research.

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://orra.rutgers.edu/citi
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 be 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, a site is considered to be
“engaged” in Human Research when it receives a direct Federal award to support the
research. For more information, go to HSPP Guidance on the topic at
https://orra.rutgers.edu/engagement-research or review [HRP-311 Worksheet:
Engagement Determination].

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 Appendix A-3], as applicable.

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 Appendix A-3], as applicable. The FDA outlines additional responsibilities when conducting a clinical investigation of a drug, biological product, or medical device. Go to https://orra.rutgers.edu/investigator-responsibilities 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. Depending on the IRB designated to oversee your Department/School’s research, go to HealthSci Guidance at https://orra.rutgers.edu/who-may-be-principal-investigator and ArtSci Guidance at https://orra.rutgers.edu/researchroles to learn more about these qualification requirements.

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, go to https://orra.rutgers.edu/policies-and-guidance and click on [HRP-105: Student Handbook].
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 the IRB to assure there are no conflicts of interest in research that could affect human subject participation and protection. Individuals involved in the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, or service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards must disclose financial interests or circumstances that could result in the actual, potential, or perception of conflict of interest.

Prior to the approval of an IRB protocol, all individuals involved in the design, conduct, or reporting of Human Research must complete an fCOI Certification disclosure found at https://orra.rutgers.edu/coi when the following occur:

- On submission of an application for IRB initial review of proposed Human Research;
- At least annually as part of IRB continuing review of Human Research; and
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) new interests with respect to potential conflict of interest which otherwise changed since the original disclosure.

For additional information about disclosure of financial interests, go to [Rutgers Policy 90.2.5 Investigator Conflict of Interest] at https://orra.rutgers.edu/coipolicies-and-guidance.

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

The IRB which your Department/School is assigned determines the submission process used to apply for IRB review of proposed Human Research. To locate the IRB designated to oversee your Department/School’s research, go to https://orra.rutgers.edu/pickirb. Then go to https://orra.rutgers.edu/howtosubmit and click on the appropriate IRB. The site offers information and detailed instructions about how and what to submit for IRB review.

10. **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. The site currently offers three protocol templates: (1) Interventional Studies; (2) Non-Interventional Studies; and (3) Retrospective Record Reviews. Go to [HRP-503a, 503b, and 503c Templates], respectively, to access them. Use the template applicable to your research as a starting point for drafting a new protocol.

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, go to [HRP-320 Worksheet: Scientific or Scholarly Review] and ethical safeguards, go to [HRP-314 Worksheet: Criteria for Review].

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 [Section 12 Regulatory Classifications In This Document].

11. 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 the [HSPP Forms and Template] page to choose the template that best meets the needs of your study https://orra.rutgers.edu/formsandtemplatesirb. Templates include suggested consent language and documentation requirements. To learn more about what informational elements are required in a consent document, go to https://orra.rutgers.edu/informed-consent.

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. See Section 10 above for more information. See also the [HSPP Guidance and Toolkit] page for more information on topics related to the consent process, https://orra.rutgers.edu/policies-and-guidance.
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, go to:

- HealthSci [https://orra.rutgers.edu/hsicwaiver](https://orra.rutgers.edu/hsicwaiver)
- ArtSci [https://orra.rutgers.edu/waiversofinformedconsent](https://orra.rutgers.edu/waiversofinformedconsent)

If your research plans include enrolling persons who do not speak English, go to [https://orra.rutgers.edu/non-english-speaking-subjects](https://orra.rutgers.edu/non-english-speaking-subjects) for guidance on how to ensure clear communication with persons who have limited or no English language proficiency, as well as, the documentation requirements for same.

12. 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 Subjects 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.

  Student projects that are solely classroom-directed exercises may not require IRB review if they meet certain criteria. Responsibility for determining whether classroom exercises require IRB review/approval rests with the IRB. Faculty will find guidelines to submit to request an IRB review of class-based research assignments to determine if the activities constitute Human Research at [https://orra.rutgers.edu/student-research-projects](https://orra.rutgers.edu/student-research-projects). Regardless of whether or not projects require IRB review, both faculty and students should follow federal regulations and University policy when designing and conducting class exercises with Humans.

  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 used to determine Human versus not Human subjects’ research, go to [HRP-310 Worksheet: Human Research](https://orro.rutgers.edu/hsicwaiver).

- **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 in one of six
categories of research. It is the responsibility of the IRB, not the investigator, to
determine whether proposed Human Research is exempt from review. Investigators
must submit an application to the IRB for review; the IRB will review and issue an
exemption notification if the research qualifies. If a change in study plans occurs after an
IRB determination of exemption, you may need to request another IRB review. Call your
IRB for more information. To learn more about exemption qualifications, go to [HRP-312
Worksheet: Exemptions]. When your study is complete, submit a study closure 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
of nine 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, go to [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 (otherwise called a ‘Full
Board’ meeting).

13. How Does The 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 at [HRP-314 Worksheet:
Criteria for Approval]. For proposed exempt research, go to [HRP-312 Worksheet: Exemption] and for proposed expedited research, go to [HRP-314 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 [Appendix A-1]. To read the Common Rule, go to
https://orra.rutgers.edu/hspp-policies.

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
[Appendix A-2]. 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 protections for vulnerable populations, go to the HSPP policy and guidance page https://orra.rutgers.edu/policies-and-guidance. There you will find links to the applicable federal regulations, NJ State laws, and University policy regarding safeguards for vulnerable populations. Click on the IRB that oversees your School/Department to find guidance, as well as, related protocol, consent and assent templates on how best to protect 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 HealthSci https://orra.rutgers.edu/hipaa-personal-identifiers-and-phi or ArtSci https://orra.rutgers.edu/hipaa. These sites also outline under what circumstances an investigator may request a waiver of the HIPAA Authorization (Permission to use protected health information for research). To view a HIPAA Authorization, go to [HSPP HealthSci Forms and Templates] https://orra.rutgers.edu/formsandtemplateshealthsci and click on the Adult Consent Form Template. The Authorization Section begins on page 9 of the template. For ArtSci see Addendum HIPAA Protected Health Information https://orra.rutgers.edu/formsandtemplatesirb.

To learn about other laws and regulations that may apply to your research, go to [HSPP Policy and Guidance].

14. 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 Subjects Research:** [See Section 12 above].

- **Approved:** The IRB deems the proposed research activity, as submitted, meets the criteria for approval as defined by regulation. To review what regulatory criteria must be met before IRB approval is granted, go to [HRP-314 Worksheet: Criteria for Approval].

- **Approved with Conditions:** To secure approval, the IRB requires 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.

15. **What Will Happen After IRB Review?**

The IRB Office staff 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.

16. 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.
- 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 [See Section 20b].
- 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 [See Section 17]:
  o Submit a continuing review application as requested in the IRB approval letter.
  o Submit proposed modifications to approved study plans for IRB review and approval before making changes to study plans.
  o Report unanticipated problems, adverse events, protocol deviations or other events to the IRB. Go to HealthSci https://orra.rutgers.edu/healthscipaperforms or ArtSci https://orra.rutgers.edu/reportable-events to learn about reporting requirements and reporting time frames.
  o 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 or misconduct, go to https://orra.rutgers.edu/healthscipolicies. For guidance on how to report research misconduct, go to https://orra.rutgers.edu/healthscipolicies and click on [University Policy 90.2.2. Research Misconduct]. Federal guidance on the topic may also be found at the site.

• 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.

17. What Are My Responsibilities To Communicate With The IRB After Study Approval?
You are responsible to communicate with the IRB when certain events or milestones occur in the conduct of IRB-approved Human Research:

• Continuing Review – 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. [See https://orra.rutgers.edu/formsandtemplatesirb]. 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. [See https://orra.rutgers.edu/formsandtemplatesirb].

• **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://orra.rutgers.edu/reportableevents. 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 http://policies.rutgers.edu/sites/policies/files/70.1.3-%20current.pdf].

• **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. For guidance see https://orra.rutgers.edu/closures. Please 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). For guidance see https://orra.rutgers.edu/closures.

**18. 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, go to http://orra.rutgers.edu/recordretention.

19. 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://orra.rutgers.edu/irbfees.

20. What Other Things Are There To Consider?
a. 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 [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] 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. 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.

b. 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 [LINK Under Construction].

c. International Research
If Human Research will take place outside of the United States, there are a number of ethical and compliance matters to consider:

- 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://rusecure.rutgers.edu/content/it-security-guidelines-domestic-and-international-travel
• Last, 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 ORRA Export Control website to learn more about research rules and responsibilities around export control https://orra.rutgers.edu/exportcontrol.

d. 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://orra.rutgers.edu/clinicaltrialsgov.

21. Will HSPP Conduct a QA Audit my Research?
Consistent with its mission to create a culture of research integrity and compliance, the HSPP Audit Team conducts random, periodic audits of University research involving human subjects. Your research may (or may not) be subject to an unannounced quality assurance audit sometime before study closure. To learn more about audits or the regulations that shape them, visit https://orra.rutgers.edu/qaaudit.

22. 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 hspp.

• If you have any questions or concerns about or for the Human Subjects Protection Program, contact: Dr. Paula Bistak, Executive Director, 333 George Street, Liberty Plaza, Suite 3100, New Brunswick, NJ 08901, (732) 235-9806 or email: bistakpa@ored.rutgers.edu.
• If you have questions or concerns about or for the IRB, go to https://orra.rutgers.edu/hspp and click on the Contact Link to select the IRB that serves your Department/School.
• If you wish to express a concern about research non-compliance, contact your local IRB: https://orra.rutgers.edu/contactus.
• If you wish to report research misconduct, go to https://orra.rutgers.edu/research-integrity.
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.

23. For Further Information and Guidance
Contact your local IRB. Go to https://orra.rutgers.edu/contactus for contact information.

24. Appendices
The Appendices highlight additional requirements that must be satisfied for different types of research. Click on the links below or go to the HSPP Toolkit [https://orra.rutgers.edu/hspp-toolkit] to view the collection in its entirety.

- **HRP-103 – SOP – APPENDIX A-1** - Additional Requirements for DHHS-Regulated Research
- **HRP-103 – SOP – APPENDIX A-2** - Additional Requirements for FDA-Regulated Research
- **HRP-103 – SOP – APPENDIX A-3** - Additional Requirements for Clinical Trials (ICH-GCP)
- **HRP-103 – SOP – APPENDIX A-4** - Additional Requirements for Department of Defense (DOD) Research
- **HRP-103 – SOP – APPENDIX A-5** - Additional Requirements for Department of Energy (DOE) Research
- **HRP-103 – SOP – APPENDIX A-6** - Additional Requirements for Department of Justice (DOJ) Research *(Includes Research Funded By The Bureau Of Prisons And National Institute Of Justice Research)*
- **HRP-103 – SOP – APPENDIX A-7** - Additional Requirements for Department of Education (ED) Research
- **HRP-103 – SOP – APPENDIX A-8** - Additional Requirements for Environmental Protection Agency (EPA) Research