

SCHOOL POLICY

Section Title: Research

Policy Name: Student Principal Investigator Status with Rutgers IRB

Responsible Executive: Assistant Dean for Research

Responsible Office: Office of Research

Originally Adopted: 03/22/2023

Revisions:

I. PURPOSE

This policy defines the eligibility under which Rutgers School of Public Health students may serve as Principal Investigator (PI) for a research project, including, but not limited to dissertation research, with the Rutgers Institutional Review Board (IRB).

II. ACCOUNTABILITY

The SPH Office of Research is responsible for implementing this policy under the general direction of the Assistant Dean for Research in consultation with appropriate academic faculty and deans.

III. APPLICABILITY

This policy is not applicable in situations where a Rutgers School of Public Health student serves as co-Investigator or study staff on an eIRB application.

A. Student PI Eligibility

PhD in Public Health students may serve as PI with the Rutgers IRB. PhD in Public Health students will be granted PI status with the IRB once they have completed and passed the School of Graduate Studies (SGS) Responsible Conduct of Research Training course (1611+2223 – Ethical Scientific Conduct, 1 credit, typically taken in Spring in Year 1). Additionally, PhD in Public Health students are required to complete the Ethical Scientific Conduct Refresher course in Year 5. The training and refresher courses are required for all SGS biomedical PhD students.

PhD in Public Health students must obtain a full-time Rutgers School of Public Health faculty member to serve as their advisor and co-investigator on the proposed human research. Prior to submitting to the IRB, PhD in Public Health students must meet with their faculty advisor to discuss the proposed human research. The SPH Office of Research is available for consultations as needed.

The IRB requires that all persons planning to conduct human subjects research must complete an online research ethics and compliance education program called [Collaborative Institutional Training Initiative \(CITI training\)](#). Proof of CITI training must be submitted with the application for IRB review.

DrPH, MPH, MS and Certificate students are not eligible to serve as PI with the Rutgers IRB.

B. Roles and Responsibilities

Student PI: Student PIs (students) have an obligation to protect the rights and welfare of human subjects participating in their research. Below is a list of student PI responsibilities outlined by the IRB in [HRP-105 Student Handbook](#).

- Research projects undertaken by students should be appropriate to their educational level and be commensurate with their training.
- Students must conduct research in an appropriate manner, consistent with ethical standards for their discipline and in accordance with federal requirements, state law, and University policies.
- Students must comply with all IRB requirements for research review (initial and continuing), its conduct and study closure. There is no special IRB review process for student research. The student researcher is expected to follow all current IRB policies, procedures and deadlines for IRB initial approval, continuing review, change requests, and other protocol matters.
- Students must maintain adequate and timely communication on all research matters with faculty advisors, IRB and other committees, University officials, and funders, if any.
- Students must identify a University faculty member to serve as their faculty advisor on the research.
- Students must protect the research data from unauthorized disclosure.

Faculty Advisor: Faculty advisors shoulder the responsibility for student PIs. The advisor will serve as co-investigator on the proposed human research and should be included as such in the eIRB application. They will assess whether the student has adequate qualifications to conduct the proposed research and will monitor study progress, ensuring it complies with necessary regulations, laws, policies and procedures regarding the safety and protection of human subjects. Faculty advisors bear the ethical responsibility for each student PI.

C. eIRB Closure

PhD in Public Health students must submit a request for study closure (final report) in eIRB when:

- (1) data collection is complete and there will be no more interactions with subjects or retention of private information, or
- (2) research cannot be completed once activities have commenced, or
- (3) research was never initiated, or
- (4) research has or will be transferred to another IRB.

The IRB [outlines](#) situations when to close a study with the IRB as well as research activities which may not occur after study closure. Prior to study closure, the faculty advisor should confirm that the PhD in Public Health student has successfully completed the research, such as defending their dissertation, and no further analysis of the research data will be necessary. For those who wish to publish based on their dissertation after leaving the University, please note that data analysis of **unidentifiable** data may continue after IRB study closure. All identifiers and data links have to be destroyed.

A request to withdraw an IRB-approved study must be submitted to the IRB if a PhD in Public Health student changes their mind about conducting the research before any research activities were initiated (such as recruitment, consent, specimen or data collection).

D. eIRB Principal Investigator Change

PhD in Public Health students may relinquish PI responsibility for the study to their faculty advisor in situations where:

- (1) protocol-defined research activities have not been completed and the faculty advisor will accept responsibility for the study in its entirety and serve as PI. This includes those actions taken before assuming the role of PI; or
- (2) the PhD in Public Health student plans on staying engaged in the study after graduation or leaving the University. This includes the reexamination of identifiable data when submitting articles for publication in peer reviewed journals after graduation.

In both situations, a modification must be submitted in eIRB requesting a change in PI from the PhD in Public Health student to their faculty advisor.

If the PhD in Public Health student does not intend on staying engaged in the study after graduation or leaving the University, they should be removed from eIRB and any IRB-approved documents.

If the PhD in Public Health student intends to stay engaged in the study after graduation or leaving the University, the PhD in Public Health student and their faculty advisor must discuss this with the SPH Office of Research and the IRB prior to submitting a modification in eIRB. Students who leave the University will need permission along with a data use agreement to access the research data in order to continue research outside the University. The SPH Office of Research will facilitate this process.

E. Graduation Requirement

PhD in Public Health Students and their faculty advisor must complete the Rutgers School of Public Health IRB Status Form. In the IRB Status Form, PhD in Public Health Students will indicate: (1) they have submitted a final report for study closure to the IRB and are awaiting a response, (2) they have been formally notified by the IRB that their final report has been approved, (3) they have submitted a modification to change the PI and are awaiting a response, or (4) they have been formally notified by the IRB that their modification to change the PI has been approved.

PhD in Public Health students must comply with policies and procedures to apply for graduation and are not eligible to receive their degree until these policies and procedures have been completed. PhD in Public Health students must prepare their Degree Certification package and the IRB Status Form is one of the required items in the Degree Certification package. Processes and deadlines for the Degree Certification package and graduation are outlined in the Rutgers School of Public Health PhD in Public Health Handbook (which may be found in the SPH PhD in Public Health Student Canvas page). If a PhD in Public Health student did not serve as PI on human research with the IRB, then the IRB Status Form is not required as part of the Degree Certification package.

The SPH Office of Research will crosscheck the information indicated in the IRB Status Form with eIRB. The SPH Office of Research will notify the Office of the Registrar if a PhD in Public Health student has an open protocol at the time of graduation. Diplomas may be held in the event the IRB does not approve a PhD in Public Health student's final report for study closure before graduation.

F. Data Retention

As per [HRP-105 Student Handbook](#), if there are no regulatory agency requirement, funding agency demand or study design justification to retain identifiers, it affords greater protections to destroy identifiers as soon as possible after the data is collected. This should be outlined in the protocol and adhered to.

While identifiers may be destroyed early, de-identified data must be preserved for a set period to comply with federal law, University policy, and funding agency requirements. Data retention requirements depend on the type of data involved. At a minimum, the University requires research data to be retained for three (3) years after study closure for studies that are unfunded or do not collect Protected Health Information (PHI). For studies that are federally funded and/or PHI was collected, research data must be retained for six (6) years after study closure.

Data retention periods vary by study sponsor. There are specific IRB-related requirements of different retention periods for research records. Please refer to [IRB Record Retention](#) for information on IRB research record retention schedules. PhD in Public Health students should consult with their faculty advisor to determine the appropriate data retention period based on the type of study conducted and the study sponsor.

When PhD in Public Health students graduate or leave the University, they must arrange to leave a copy of the research data with their faculty advisor. The original data must be retained in compliance with school security standards and for the required period of time. PhD in Public Health students must ensure that Rutgers can have access to the data upon request.