100 PR.11 Research Staff Engaged in Research Projects

1. Overview

This document specifies which team members engaged in conduct of human subjects research must be listed in the Yale IRB electronic system. The procedure also describes steps to obtain permission to serve as the Principal Investigator on a research project for individuals who do not meet the eligibility requirements to serve as investigators on sponsored projects set forth in the Faculty Handbook.

2. Listing Research Team Members in the IRB Electronic System

The research record in the IRB electronic system, IRES IRB, must include the names of the following team members engaged in human subjects research under Yale IRB or HRPP purview:

- Principal Investigator (PI),
- PI Proxy, if one is identified for the study,
- Investigators,
- Individuals external to Yale who require a reliance agreement OR Unaffiliated Investigator Agreement, *and*
- Other members of the research team who report financial interests related to the research.

Team members who do not meet these criteria do not need to be listed in IRES IRB.

Principal Investigator conducting a clinical trial must maintain a Delegation of Authority and Responsibility log, which documents delegation of specific tasks related to conduct of the research to other research staff. The log is not part of the submission to the IRB and may include individuals who are not required to be listed in the IRES IRB. The log should be maintained in the study regulatory binder and be updated with addition or removal of the research team members or when the nature of the delegated tasks change.

If the Principal Investigator wishes to list all of the members of the research team in IRES IRB, the study team members page in the system includes a selection of available roles to further describe research roles of each individual.

The sections below address the specific roles of individuals who must be listed in the IRES IRB system.

3. Principal Investigator

The Yale IRB recognizes only one Principal Investigator (PI) for each project. The PI bears the ultimate responsibility for the conduct of the research even if parts of the research are delegated to other investigators/research staff as documented in the Delegation of Authority log. The PI must agree to conduct the research according to ethical principles and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects.

In addition, at the time of the submission of the research project to the IRB for review, the PI is asked to attest that he/she:

- has provided complete and accurate information regarding the research project,
- has secured sufficient time and adequate resources to carry out the research,
- will apprise all members of the research team of the research goals, provide adequate training to and oversight of study personnel,
- will obtain approval for the research study and any subsequent revisions prior to initiating the study or any change and will obtain continuing approval of this study prior to the study's expiration date,
- will register studies and provide updated information to ClinicalTtrails.gov, when required,
- will report to the IRB any serious injuries, unanticipated problems involving risk to participants or others, and incidents of noncompliance per the IRB policies, and
- will identify a qualified successor should he/she cease the role as the principal investigator and facilitate a smooth transfer of investigator responsibilities or will close out the study at its completion.

3.1. Additional Responsibilities for Multi-Site Research and Research with Satellite Locations

Should the research project include Yale serving as the coordinating center for a study or the PI serving as the overall PI of the study (lead PI), there are additional requirements that the PI must comply with. That includes first selecting qualified sites for participation in the research and ensuring that all investigators and the research team members at the external or satellite sites are trained on the study procedures, data collection, and reporting requirements.

The overall PI must ensure that the IRB approvals from all sites are in place before human subjects research occurs at those sites and before any changes are implemented. Should the Yale IRB serve as the single IRB of record (reviewing IRB of all sites), the PI must ensure that research does not start at the site until appropriate institutional agreements are in place.

It is the lead PI's responsibility to confirm that the collaborating sites use the correct version of the study protocol. The lead PI or the coordinating center must have a procedure in place to promptly disseminate information about changes to the protocol to the participating sites and ensure that changes are implemented per the approved protocol. The PI must apprise the site PIs of any unanticipated problems involving risks to the subjects or others.

The lead PI is responsible for monitoring progress of the study. That involves responsibility for the analysis, reporting, integrity and accuracy of the data. A data safety monitoring plan must be submitted to and reviewed by the IRB describing the procedures in place to oversee the overall conduct of the study at all participating sites.

More information about conducting research with satellite sites and multi-site research is available in the Investigator's Handbook and the Policy 120 on Investigator Initiated and Multicenter Research.

3.2. Eligibility to Serve as the Principal Investigator on a Research Project

At Yale, appropriately trained full-time faculty members are eligible to serve as the Principal Investigators on human research projects if they meet criteria to serve as the Principal Investigators on sponsored projects, as described in the Yale Faculty Handbook.

Examples of Yale faculty appointments permitted to serve as PI:

- Professor,
- Assistant Professor,
- Associate Professor,
- Senior Research Scientist,
- Research Scientist/Scholar,

Examples of Yale-affiliated individuals generally not permitted to serve as PI on a research project:

- Associate Research Scientist,
- Adjunct faculty,
- Visiting faculty,

- Volunteer faculty,
- Students, postdoctoral fellow, and other trainees.

For non-Yale institutions that cede IRB review to Yale designated IRB, the Yale designated IRB will accept protocols submitted by personnel of the non-Yale entity in accordance with established approval procedures conducted by the non-Yale entity or according to the terms of the IRB Authorization Agreement. For example, submission of research projects from Yale New-Haven Hospital staff requires an approval from the YNHH Human Subject Protection Administrator prior to IRB review.

Should the research require skills or experience beyond those held by the proposed Principal Investigator, the IRB may request a change of the PI, a modification to the protocol to meet the investigator's skills, or addition of one or more additional qualified faculty as investigators identified on the research protocol.

3.3. Obtaining Special Permission to Serve as the Principal Investigator

Individuals who do not meet the eligibility criteria to serve as the Principal Investigator as described above, may request a special permission to serve as the PI with the Department Chair's and the appropriate Dean's support documented on the PI Eligibility Request Form. It is the PI's responsibility to obtain the permission from the Chair and the Dean. The completed PI Eligibility Form must be submitted along with the research project to the IRB for review.

If the research protocol is sponsored by an external sponsor and the Special Permission to Serve as the PI on a sponsored project has been approved and is on file with the Office of Sponsored Projects, the IRB will accept that approval.

3.4. Students and Trainees

Students and individuals considered to be trainees are not permitted to serve as the Principal Investigators on research involving human subjects. In order to be listed as a PI on a research study in IRES IRB system, they must have a Faculty Advisor/Faculty Sponsor who meets the PI eligibility criteria and who agrees to serve in that role. The Faculty Advisor must agree to fulfill the responsibilities of the PI of the study. In addition, the Faculty Advisor will agree to train the student investigator in matters of appropriate research compliance, protection of human subjects and proper conduct of research involving human subjects.

In special circumstances, the IRB can agree to allow the student to identify a Faculty Advisor who does not meet Yale criteria to serve as the PI. The decision may be made in conjunction with the Dean of the student's School to ensure proper oversight of the student's research.

4. Investigators

For purposes of this procedure[1], an investigator is considered an individual who, as part of the research team, will assist the Principal Investigator by making a direct and significant contribution to the data and the execution of a project in a substantive and measurable way. The contributions of the investigators are not easily replaced in that the investigator's absence from the project would be expected to negatively impact the approved scope of the project or research progress.

Individuals who meet that definition must be listed in IRES IRB if they are also engaged in the portion of the research that involves human subjects. For example, if an individual makes an intellectual contribution to the scientific development of the project and also performs research procedure required by the study protocol, this individual must be listed as an investigator in IRES IRB.

Investigators who are NOT engaged in the human subjects research should not be listed in IRES IRB.

5. PI Proxies

PI Proxy is a role designated in the IRES IRB system. It provides the ability to submit research documents to the HRPP/Yale IRB and respond to the IRB's or HRPP's requests for revisions on behalf of the Principal Investigator. The designation of the PI Proxy is not a delegation of responsibility for the study to another person. It is only

[1] The criteria for investigators to be listed in IRES IRB may differ from the FDA definition of a sub-investigator or NIH definition of key personnel. The assessment of who should be listed on FDA Form 1572 or who should be included in the grant application to NIH must be made independently of this procedure.

giving an individual an ability to submit documents in the IRES IRB system. The PI gets notified via system generated email when the PI Proxy makes a submission on his/her behalf.
The Principal Investigator should establish an internal procedure related to working with PI Proxies that will allow for proper sign-off on any documentation prior to submitting them in the electronic system.
The role of a PI Proxy is protocol specific. In order to designate a PI Proxy on a study, the individual must be listed on a study team member list. For an ongoing study, a modification must be submitted to the protocol to add the person to the list. Once included on the study team member list, the PI can assign PI Proxy in the main study workspace in IRES IRB. Quick guide with screenshots is available the IRES IRB Help Center.

6. External Investigators

Individuals engaged in human subjects research who are not formally affiliated with Yale or with an institution that relies on Yale IRB for review of research studies via a reliance agreement (e.g., Yale New Haven Hospital, Haskins Labs) must be listed in IRES IRB. Often, individuals who do not have Yale netID or who have been assigned a Yale netID as a Sponsored Identity will be considered external to Yale. They will require additional agreements in place such as Unaffiliated Investigator Agreement or a reliance agreement if the external individual is acting as an agent of an institution with a Federalwide Assurance. Procedure 910 PR.1 Unaffiliated Investigator Requests describes necessary steps to enter into unaffiliated investigator agreement.

Individuals who do not have Yale netIDs can be listed on an External Research Team Members log, which must be uploaded into the Study Team Members page along with the documentation of required training. Names of external individuals who have received Yale netID will be available for selection in the Study Team Members page. Completion of training documented in Training Management System will show in IRES IRB.

7. Research Staff with Reported Significant Financial Interest Related to the Research

It is the PI's responsibility to verify with each member of the research team whether he/she has any financial interest related to the study. If there is a financial interest related to the study, the research team member must be listed in the Study Team Members page with the indication of a financial interest. Such individual should also complete a Conflict of Interest disclosure form (https://your.yale.edu/research-support/conflict-interest-office) to the Conflict of Interest Office. The IRB will review the information regarding financial interest in accordance with its policy, HRPP Policy 500 Disclosures and Management of Personal Interests In Human Research.

8. Verification of Required Training for Research Staff

All individuals affiliated with Yale must complete Compliance Assessment through Training Management System (TMS) on annual basis or when their engagement in human subjects research changes. The requirements for training will be assigned based on the responses on the assessment:

- Individuals engaged in human subjects research must have a valid Human Subject Protection Training, completed within the previous three years;
- Individuals engaged in conduct of social behavioral or biomedical clinical trials must have a valid Good Clinical Practice Training, completed within the previous 3 years (does not replace need for the Human Subject Training referenced above);
- Investigators from HIPAA covered entities must complete HIPAA training if the research includes collection or interacting with the protected health information (does not replace the need for Human Subjects Training or Good Clinical Practice training referenced above).

In addition, the IRB or Yale leadership can require supplemental training for the PI or research team members for certain types of studies. The supplemental training requirement will be communicated directly to the PI.

8.1. Study team members listed in IRES IRB

The PI should verify that all research team members are compliant with their training requirements before submitting protocol or personnel modifications in IRES IRB. The information about compliance status is available in the Study Team Members page in IRES IRB. Individuals who are not compliant with their training requirements related to human subjects research should not be included in the submission until the training is completed.

Once the submission is with the HRPP Office, the HRPP staff will verify the training compliance of the research team members.

8.2. Study team members not listed in IRES IRB

It is the PI's responsibility to ensure that all members of the research team are compliant with their training requirements. Certificates of completion of training for all research staff should be kept with the study file.

When research staff become noncompliant with their training requirements, the TMS will generate a notification to the individual and his/her business office with a prompt to complete the required training. The individual cannot engage in human subjects research unless the training has been completed.

In addition, on annual basis, the HRPP will generate a list from TMS of individuals who report being engaged in human subjects research but remain noncompliant with their training requirements. The HRPP will reach out to the individual to help resolve the noncompliance. The Department Chair may be notified if the outreach is unsuccessful.

9. Revision History

Date	Description
05/01/2021	Initial effective