Study Team Roles

The following roles are available for study team members in eIRB and a general description of each role responsibility. Please review these role descriptions when adding new study team members to ensure the role selected aligns with the planned responsibilities of that study team member. For each role, it is important to also designate whether the individual will have consenting responsibilities.

Principal Investigator (PI) - PIs bear ultimate responsibility for the conduct of Human Subjects Research (HSR) studies and for the safety of human subjects participating in them. PIs and their study teams must comply with federal, state, and local laws and regulations, Organization policies, and the determinations of the JHM IRBs. PIs are responsible for properly training research staff in activities or procedures required for the research's conduct.

Co-Investigator- An individual working in partnership with the Principal Investigator in the management, development and/or execution of the project.

Consent Designee-Study team member trained to obtain consent from a research participant. Consent designees must be knowledgeable about the study and must be capable of answering study-related questions posed by the potential participant.

Non-Conflicted Designee- Is assigned the responsibility for answering study-related questions when the PI has a conflict of interest and the management plan prevents them from participating in the consent process. The Non-Conflicted Designee must not have a conflict of interest related to the study.

Lead Research Nurse- Provides nursing support to the PI and may help with patient care.

Research Nurse- Provides nursing support to the PI and may help with patient care.

Lead Site Co-Investigator- Responsible for the management, development and/or execution of the project at an approved study location.

Site Investigator- Responsible for the conduct of the research at a particular site.

Lead Study Coordinator- Oversees the day-to-day operations of a given study under the guidance of a Principal Investigator.

Study Coordinator- Supports the management and coordination of research studies.

Regulatory Staff-Is responsible for maintaining the regulatory documents related to a research study. May be listed on the application even if they have no other responsibilities for the study.

Research Manager-Is responsible for management and coordination of the research study/project.

Statistician-Is responsible for gathering, analyzing, and interpreting research data.

Other Staff-This is selected when no other role describes the study team member's responsibilities. Some examples are visiting student, visiting scholar, visiting faculty, volunteer, etc. Other staff generally do not have consenting responsibilities.

FAQ-

Who can be Principal Investigator? The following may serve as PIs of HSR studies reviewed by the JHM IRBs:

- Faculty members of The Johns Hopkins University who are compensated from the institution (including Part Time Faculty)
- Properly credentialed clinicians, employed by a JHM entity
- The following groups of people may serve as PI if they meet the educational, experience and any additional requirements agreed upon by their departments and the OHSR, and provide a letter of support from an appropriate department representative
    - Designated senior staff members of the Johns Hopkins Applied Physics Lab
    - Registered nurses or Nurse Practitioners in the Johns Hopkins Health System (JHHS)
    - Non-faculty pharmacists in the Department of Pharmacy at the Johns Hopkins Hospital
    - Non-faculty physical and occupational therapists in the Department of Physical Medicine and Rehabilitation
    - Senior staff members designated by departmental authorities

For further explanation of PI responsibilities and requirements, see the JHM IRB guidance "Investigator Responsibilities."

Can there be two Principal Investigators on an application? No. Hopkins only recognizes one Principal Investigator.

If a Principal Investigator or study team member has left Hopkins and maintains an adjunct role, can he/she still be listed on the study as a study team member? It depends. In order to remain a member of the study team, the person must hold compensated position with Johns Hopkins. If they do not, the individual must be removed as a study team member. Continued oversight for their activities may be permitted via a reliance agreement where the JHM IRB agrees to provide oversight for an individual/organization external to JHU. Please contact the JHM IRB Reliance Program (JHMIRBReliance@jhmi.edu) to begin the process.

What if there is a student Principal Investigator (PI) on the project? A student who needs to complete a research study/project will need to find a qualified Faculty member to serve as Principal Investigator and provide mentorship and oversight for the study. Typically, this individual will have a direct mentorship relationship with the student. The student can be listed as Co-investigator on the study/project.

We have a Summer student/volunteer, can they be listed and what role should they have? Yes, they can be listed as long as they adhere to the institution's policies on visitors/volunteers. Once added to the study they should be listed as "Other Staff". Generally Other Staff does not consent participants. [link to visitor and volunteer policy]

How can I add a study team member who is not affiliated with Hopkins? Non-Hopkins affiliates who will be engaged in human subject research with SOM PIs must submit a request to the JHM IRB to

provide oversight for their activities via a reliance agreement. The PI should contact the JHM IRB Reliance Program (JHMIRBReliance@jhmi.edu) to begin the process.

What if the PI or a study team member has a conflict of interest? If PI or study team member has a conflict of interest associated with the research activity, the selected role must align with the management plan and any limitations placed on the study team member must be reflected in the role selected (for example, if a conflicted individual may not participate in the consent process that person cannot be listed as a "consenter" in eIRB).