Ascension Wisconsin IRB Guidance

Investigators and Key Research Personnel

As part of the Ascension Wisconsin IRB review process, all individuals engaged in human subject research must be identified to the IRB as key research personnel on the Mentor protocol page. Key research personnel include individuals who intervene or interact with subjects OR who access identifiable private information about the subjects for research purposes.

Because of the variability in research situations, it is impossible for the IRB to define precisely every person or role who could be considered to be a member of the research team. The Investigator must make the determination of who to identify as research personnel and who to delegate responsibilities to.

All research personnel listed in the IRB application must complete initial human subject protection (HSP) training and have an up-to-date COI training/disclosure before the IRB will issue initial or continuing approval on a research protocol. The Investigator is also responsible for assuring that all members of the research team receive protocol training specific to their role before they conduct any research activities.

Definitions

Key research personnel: Persons who have direct contact with subjects, contribute to the research in a substantive way, have contact with subjects' identifiable data or biological samples (e.g., tissue, blood, urine, plasma, saliva), or use subjects' personal information for research.

This includes the Principal Investigator and Sub/Co-Investigators, Research Coordinators, individuals named on a grant or contract application or listed on an FDA form 1572, anyone obtaining informed consent or are named as contact persons in the informed consent documents or recruitment materials, or individuals who are obtaining individually identifiable health information.

May also be referred to as: study staff, study team member, research team member, key personnel.

Principal Investigator: The Principal Investigator (PI) bears ultimate responsibility for all activities associated with the conduct of a research project, including compliance with federal, state and local laws, institutional policies and ethical principles. The PI remains ultimately responsible even when some aspects of the research are delegated to other members of the study team.

Typically, associates or members of the medical staff at Ascension Wisconsin are able to serve as PIs. The IRB may grant exceptions to this requirement and allow a non-Ascension Wisconsin associate to serve as PI as appropriate. Graduate students/trainees are permitted to serve in the role of PI, but must have a staff or faculty advisor who shares in the student's responsibility for the conduct of the research.

Co-Investigator/ Sub-investigator: Co-Investigator (Co-I) or Sub-investigator (Sub-I) is an individual who can make important trial-related decisions . They must be qualified by training and experience to conduct his or her responsibilities on the research project and may be responsible if the PI is not available. Co-Is are obligated to ensure that the project is designed and conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of human subjects research.

Faculty or Staff Advisor: All research conducted by students/trainees must include a Faculty or Staff Advisor (called "Instructor" in Mentor) as a member of the study team. In addition to the expectation that the Advisor provide active mentorship to the student during the conduct of the research, they also share responsibility with the student/trainee researcher for the ethical conduct of the research and are institutionally accountable for the study.

Students/Trainees: Supervision by faculty/staff members is required for any research performed by students/trainees in any role, to ensure the proper conduct of research and protection of subject rights and welfare. Ascension Wisconsin associates who are also students are able to serve as PI in their associate roll, and do not require additional faculty or staff member named as an "Instructor" in Mentor.

Examples

Persons who should be listed as research personnel for the *local site* (not the overall study) include anyone who has/will:

- design the research
- direct the research or serve as the principal investigator for the study
- make decisions related to eligibility to participate in research
- enroll research subjects (including obtaining informed consent or screening potential subjects)
- conduct study procedures
- collect identifiable research data
- analyze or report research data
- analyze or report adverse events

Persons who should not be listed as research personnel for the *local site*:

- Anyone from the Sponsor or CRO (for industry sponsored studies) that conducts any of the above activities.
- Members of the hospital, such as laboratory technologists/technicians, radiological technologists/technicians, pharmacists, phlebotomists, patient care services staff, interviewers or administrative staff who provide standard clinical services or perform routine clinical tests as part of their institutionally designated non-research responsibilities are not considered research personnel.

  For example, a pharmacist responsible for drug accountability and dispensing would not need to be identified as research personnel since those activities are a normal job responsibly as outlined in the local pharmacy SOPs for handling investigational product. Similarly, you would not identify a phlebotomist who is doing a blood draw for a research study nor administrative staff who schedule visits (and who schedule appointments as part of their normal work) as research personnel.

  If the involvement of these staff in the research is outside of the scope of their usual non-research responsibilities or if they are making a direct and significant contribution to the data for a particular study, then they should be listed as research personnel.

- Individuals who are involved in the research but DO NOT intervene or interact with subjects and DO NOT access identifiable private information about the subjects should are not considered research personnel. This may include individuals whose role in the research is limited to providing consultation on the development of questionnaires or analyzing de-identified data.

- The Department/Service Line Leader is required to review all new human research studies prior to IRB review to provide approval of the submission to the IRB and certify that the investigator is credentialed, has appropriate training to conduct the research, and has adequate resources and staff to perform procedures outlined in this study. The PI is responsible for identifying the appropriate person to provide this approval and sign the IRB application; they are not research personnel and are not identified in Mentor.

Research Personnel Roles in Mentor

As described above, all individuals engaged in human subject research must be identified to the IRB as research personnel on the IRB Mentor protocol page. Before an individual can be identified as research personnel in Mentor, they need to have a Mentor account. Account set-up needs to be done only one time per person.

The role titles in Mentor are based on the privileges each role has in the system. The role assignment or titles of research personnel in Mentor may be different from that on the Site Delegation of Authority Log or other study documentation. A Study Site Signature & Delegation of Responsibility Log is normally provided by the Sponsor; a template log is also is available on the REQM website.

The Mentor Protocol application requires individuals to be identified as one of the following roles:

- **PI:** This is the Principal Investigator, as defined above. All approval notices, expiration reminders and other announcements and notifications from Mentor will be sent to the PI.
- **External PI:** The designation should be used when the PI is someone external to Ascension Wisconsin with no formal affiliation to the institution. This person would have the research personnel role of Co-I or Sub-I. If added as an External PI in Mentor, they will not be able to access Mentor at all; if they require access, they could request a Mentor user account.
- **Sub-I:** The Sub-I role in Mentor should include all Sub-I's and Co-I's as defined above. Persons assigned to this role will have access to view all information in Mentor, but will not receive notifications and are not able to submit and manage protocols.
- **Research Coordinator:** Principal investigators may designate one or more other Mentor users as Research Coordinators. Research coordinators are authorized to submit and manage protocols on behalf of their PI. They will also receive all approval notices, expiration reminders and other announcements and notifications from Mentor that are sent to the PI.

  In addition, research coordinators must be assigned to the PI before they are available to be selected as a coordinator for studies where that investigator is the PI. See the Mentor User Manual for instructions on designating a coordinator.
- **Research Associate:** Any other study staff should be identified in Mentor as a research associate. Research associates have access to view all information in Mentor, but will not receive notifications and are not able to submit and manage protocols.

For additional information to help you in determining who constitutes your research team, see:

- IRB policy: PI & Research Staff Education
- IRB policy: Disclosure, Management and Reporting Financial COI
- OHRP "Guidance on Engagement of Institutions in Human Subject Research" .

You may also contact IRB staff with questions.