Icahn School of Medicine at Mount Sinai

Institutional Review Board
Program for the Protection of Human Subjects

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Study Personnel Changes

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1. Changing the contact person only: If the contact person for an entire research portfolio has changed, this change can be made globally through a request from the PI to the IRB@mssm.edu mailbox. The contact person is only for correspondence purposes (reminders, notifications, etc.). If the contact person has other responsibilities on the study, follow the guidelines below.

2. Personnel changes that require IRB review and approval before the change can go into effect:
   (Submit a modification)
   a. Personnel named in the protocol or protocol template
   b. The removal of personnel or a role required by the IRB (for example, if the IRB required a licensed MD, a radiologist or an independent monitor, this cannot be changed without IRB approval)
   c. The removal of personnel previously considered essential to the conduct of the study
   d. Change in PI
   e. Addition of personnel who will write prescriptions or perform invasive study procedures (such as implanting a study device)

3. Personnel changes that do not require IRB review and approval prior to making the change, **unless the above criteria (2a-e) apply**:
   (Inform the IRB during continuation submission)
   a. The addition, replacement, or removal of research coordinators
   b. The replacement of personnel for which the person assuming the assigned role/tasks has the same/similar qualifications as the person being removed
   c. The addition of personnel when the assigned role/task already exists and the added personnel have the same/similar qualifications to personnel on the study.

4. Basic Requirements of all study personnel (Regardless of when to submit for IRB review):
   a. The PI is responsible for ensuring that all study personnel complete all institutional requirements, such as disclosure of financial conflicts of interest in research and PPHS-required trainings.
   b. It is the PI's responsibility to ensure that the time allocation for personnel is feasible and that department policies are followed.
   c. Completion of education requirements will be verified during continuing review; failure to remain in compliance with institutional policy must be reported to the PPHS and may result in further action.
   d. The PI is also responsible for maintaining a regulatory binder for each study, including a log of research staff and their qualifications as well as when they worked on the study.

Justification:

Per FDA regulations, a sponsor is obligated to "select only investigators qualified by training and experience as appropriate experts to investigate the [study] drug." 21 CFR 312.53(a)

The same regulation requires investigators, by way of a signed Investigator's Statement (also known as FDA Form 1572) to "personally conduct or supervise the described investigation" and "ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations…." See 21 CFR 312.53(c). See also FDA Form 1572.

Thus, by regulation, a sponsor must select qualified investigators, and investigators are personally responsible for the conduct/supervision of the investigation and those persons assisting with the investigation. Despite the fact that multiple research staff may assist an investigator with an investigation, the FDA regulations and the Form 1572 do not require the review or submission of credentials of any research staff person other than the investigator (principal investigator or "PI"). This is because the PI is solely responsible and accountable for the conduct of the study at his or her site. By reviewing and approving the PI, the Board is expecting that any person the PI selects to assist in the research is appropriately qualified. Moreover, the Board is expecting that the PI will provide appropriate oversight of all staff persons involved in the research.

Per 45 CFR 46.103(b)(4)(iii), the IRB is required to review and approve changes to approved research, except when necessary to eliminate apparent immediate hazards to the subject. Therefore, any changes to the research protocol must be reviewed and approved prior to implementation. Changes to PPHS forms designed for internal and institutional purposes do not constitute a change to the approved research, thus HRP-211 must be current at the time of submission for continuing review; however, changes to the official protocol, or protocol template that is serving as the official protocol, must be submitted for IRB review and approval according to this regulation.

Finally, each investigator is expected to keep a regulatory binder for every study he/she conducts. This binder must contain a log of all research staff and the CV and credentials of these persons. A checklist for making sure your study binders meet regulatory requirements is available as a tool for self-assessment from the PPHS website (http://icahn.mssm.edu/static_files/MSSM/Files/Research/Resources/Program%20for%20the%20Protection%20of%20Human%20Subjects/HRP-430%20-%20CHECKLIST%20-%20Investigator%20Quality%20Improvement%20Assessment.doc).