Study Personnel Changes

REISSUED: June 13, 2014
Date originally in effect: October 10, 2012

In our continued efforts in supporting the research community, The Icahn School of Medicine at Mount Sinai’s Program for the Protection of Human Subjects (PPHS) office is announcing a change in processing study personnel changes for human subjects research. This change is justified and supported under 21 CFR 312.53(a), FDA form 1572, and 46 CFR 46.103(b)(4)(iii).

1. 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. As a reminder, this information is only for correspondence and the policy below applies to personnel who will be involved in the design, conduct, or reporting of human research.

2. Personnel changes will not require IRB review and approval prior to implementation for 2.1-2.3 listed below:
   2.1 The addition, replacement or removal of research coordinators
   2.2 The replacement of personnel for which the person assuming the assigned role/tasks has the same/similar qualifications (including Co-Is) as the person being removed
   2.3 Changes only impact PPHS forms and templates (protocol template when there is a separate comprehensive protocol on file, HRP-211), unless the change falls under points 3.2 or 3.3 below
   The PPHS recommends that the protocol template include the roles/qualifications available as resources to conduct the study, without the inclusion of actual names.

   At the time of continuing review, include in your submission HRP-213 Modification of Approved Research Form detailing all personnel changes made since last continuing review, and an updated HRP-211 form and protocol template (if applicable) with track changes including all personnel changes made during the approved period.

3. Personnel changes that are not affected by this change in process continue to require IRB review and approval prior to implementation:
   3.1 Named individuals in the protocol
   Note: This is different than 2.3 above; this means a change to the official protocol, or to the protocol template only if there is not a separate protocol.
   3.2 The removal of someone the PI considered essential to the conduct of the study, or personnel required by the IRB.
   Note: This means that a particular resource/set of qualifications would be removed from the study and not replaced. Contact the PPHS office if you are unsure if the removal requires prior IRB review.
   3.3 Any PI changes
   It is the expectation of the PPHS office that each investigator maintain a regulatory binder for each study and that the regulatory binder is kept current at all times, including a log of research staff and their qualifications (i.e. completion certificates for education requirements and CVs).

The PI is responsible for ensuring that all study personnel complete all other institutional requirements, such as disclosure of financial conflicts of interest in research and PPHS-required trainings. It is the PI’s responsibility to ensure that the time allocation for personnel is feasible and that department policies are followed. 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.
Justification for the change:

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 (a.k.a 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).