Personnel Change Guidance

The purpose of this document is to provide guidance to research teams regarding requirements for informing the IRB of additions and departures of study personnel as well as changes in the roles of study personnel for studies that have not been determined to be exempt from further IRB review. The IRB does not require research teams to submit personnel updates for project that have been determined to be exempt from further IRB review.

This guidance also describes the differences in the requirements for changes in Principal Investigators (PIs) compared to those of other study personnel because of the overarching responsibility PIs assume for a protocol. If you have any questions about these guidelines, please contact the Health Sciences IRBs Office at 608-263-2362

Change in Principal Investigators (PIs)

Some of the key responsibilities PIs assume for a human subjects protocol include:

- Ensuring compliance with the principles of the Belmont Report and adherence to the regulations outlined in the Common Rule (45 CRF 46), the Food and Drug Administration (when applicable), and the VA regulations (when applicable)
- Ensuring all study team members, including the PI, complete human subjects protection training and, if applicable, HIPAA Privacy Rule training prior to engaging in human subjects research
- Providing adequate training for and oversight of study personnel
- In the case of clinical research, ensuring the protocol procedures comply with Good Clinical Practice requirements
- Ensuring compliance with the Conflict of Interest Policy.

Given the level of responsibility they assume for protocols as described above, the Health Sciences IRBs require permanent changes of PIs to be reviewed as full changes of protocol to ensure adequate vetting of the newly proposed PI’s ability to serve in this capacity and determine whether he or she meets Principal Investigator Status for UW-Madison Human Subjects Protocols. Prompt reporting of PI changes is required to ensure adequate oversight is in place for the conduct of the protocol and the protection of human subjects. The new PI should not assume responsibility for the study prior to IRB approval of the change unless the departure of the former PI was unexpected and a gap in study leadership would increase risks to subjects enrolled in the study.

Reporting Requirements for PI Changes

- **If the current PI is leaving the UW-Madison/UWHC/Madison VA**: Changes in the PI should be reported to the IRB prior to the former PI leaving the research study, if at all possible. In all cases, a PI change must be submitted no later than 14 business days after the departure of the former PI.
• If the current PI is not leaving the UW-Madison/UWHC/Madison VA and the change in PI is permanent: Changes in the PI must be reviewed and approved by the IRB prior to the new PI assuming oversight of the study.
• If a temporary change in PI is needed: Temporary changes in PI may be needed if the PI cannot provide oversight of a research study due to emergent circumstances (e.g., events requiring a sudden leave of absence) or a planned absence (e.g., parental leave, sabbatical or military service) for a substantial period of time, such as a month or longer. For shorter periods of leave or vacation, the PI is responsible either for ceasing study activities or ensuring oversight of these activities is delegated to an appropriately qualified member of the study team. In cases where the leave will be a month or longer and presumed to be temporary, the study team is required to submit a New Information Report to the IRB that a) confirms no study activities will occur during the PI's leave; b) confirms that only activities involving data or sample analysis will occur during the PI's leave; or c) identifies who will assume PI responsibilities for the study during the leave. The New Information Report should be provided to the IRB as soon as possible, preferably before the PI takes leave. A second New Information Report should be submitted to the IRB when the PI resumes his or her role as PI. If the PI cannot return from leave or changes his or her role after the leave ends (e.g., becomes a sub-investigator), a change of protocol to formally update the PI for the study would be required. If a study team needs assistance in making the change in PI, please contact the IRB Office Director, Associate Director, or Assistant Director.

Changes to Study Documents
When a PI change occurs, the research team should consider whether study documents were affected by this change, such as the consent form, HIPAA form or study protocol. If the subjects are still participating in a research study, the IRB recommends research teams provide a written update to these participants, such as an information sheet or letter, to inform them of the change in PI and to update them regarding changes in relevant telephone numbers (e.g., for study-related questions) and addresses (e.g., to withdraw authorization). Example letter informing participants of change in PI.

Changes to Study Personnel Other Than the Principal Investigator (PI)
Study teams, with the exceptions noted below, must report the removal of study personnel who fall under UW-Madison IRB purview within one (1) month of the removal of any personnel from the study, regardless of their role. If you have questions about who qualifies as study personnel, please see Key Personnel Guidance. No additional steps are required for the removal of personnel not affiliated with UW-Madison/UWHC/Madison VA or who do not fall under UW-Madison IRB purview.

Addition of Study Personnel
1. For personnel affiliated with the UW-Madison/UWHC/Madison VA, a personnel change should be submitted to the IRB prior to or at the time when the new personnel
will engage in human subjects research. Personnel can join a study prior to IRB approval of their addition under the following circumstances:

- A personnel change has been submitted to the IRB for review;
- The personnel do not have a financial conflict of interest related to the study as defined under the Conflict of Interest Policy;
- The personnel have completed the required human subject protection training as defined under UW-Madison policy or by Madison VA requirements (contact the Madison VA Research Office for information about VA training requirements);
- The personnel have completed appropriate HIPAA Privacy Rule training, if applicable;
- The personnel have received study-specific training and can adequately perform their study-related role(s); and
- The personnel are engaged in human subject research under UW-Madison, UWHC, UWMF or Madison VA appointment or as a UW-Madison student.

The IRB’s review of the request to add personnel is to ensure the above conditions have been met. Failure of a study team to ensure key personnel have met the requirements noted above before engaging in human subjects research may be considered noncompliance.

2. For personnel NOT affiliated with UW-Madison/UWHC/Madison VA AND for whom the HS-IRBs have already agreed to serve as the IRB of record, the same guidelines described above should be followed. **NOTE:**

- Do NOT add personnel who are not affiliated with UW-Madison/UWHC/Madison VA AND whose study activities will be overseen by their own IRB.
- **External personnel who are NOT engaged in research do NOT need to be added as Personnel. If those individuals need access to ARROW, please see this guidance:** Accessing ARROW for External Personnel Not Engaged in Research

3. For personnel NOT affiliated with UW-Madison/UWHC/Madison VA AND for whom the HS-IRBs have NOT already agreed to serve as IRB of record, the personnel cannot engage in human subjects research activities until a change of protocol to add the institution or personnel-individual to the study has been reviewed and approved by the HS-IRBs.

4. In the case of research studies where direct interaction with subjects does not occur, personnel changes can be batched and submitted to the IRB on a quarterly basis. The study team is still responsible for ensuring all of the conditions outlined in point 1 of this section, other than submission of a personnel change within 1 month, have been met. **This exception to the 1 month submission time frame only applies to the following application types available in ARROW:** 1) Application for Initial Review: Non-Exempt Medical Records Review (unless the application involves contacting subjects for information) or 2) Reading Center/Statistical Data Analysis Center (SDAC)/Analysis center for data, specimens and/or images.
Changes to the Roles of Current Study Personnel
The study team must report significant changes in study team roles within 14 business
days of those changes. Significant changes are defined as:
Changes in who serves as point of contact as listed in the General Information section
of the initial review application in question 1.6 and 4.4
Changes in study team roles as listed in the General Study Information section of the
initial review application in questions 4.1-4.3

When Current Study Personnel Leave UW-Madison/UWHC/Madison VA
Additional steps may need to be taken when current study personnel leave UW-
Madison/UWHC/Madison VA (including graduating students):

- If personnel leaving UW-Madison/UWHC/Madison VA will no longer be engaged
  in human subjects research for a study, these personnel can be removed as
  described above.
- If personnel leaving UW-Madison/UWHC/Madison VA will continue to be
  engaged in human subjects research for a study, the HS-IRBs cannot
  automatically remain the IRB of record for these personnel. The study team
  must contact the HS-IRBs office to discuss what additional steps may need to be
  taken to ensure these personnel continue to have appropriate IRB oversight for
  their study activities. Please see Multisite Research guidance for more
  information.

See Also:

- ARROW Guidance
- Summary of Investigator Responsibilities
- Multisite Research
- Key Personnel Guidance