Leaving the University of Pittsburgh

Overview:

All investigators have the responsibility to manage the disposition of their studies before leaving the University. This is true not only for the Principal Investigator, but for any member of the research team who may wish to continue to participate in research at Pitt after their departure. Department administrators and faculty mentors have a responsibility to ensure this is accomplished before the investigator departs and it should be a component of the exit interview process. Too often, the PI departs without closing, transferring or identifying another individual to assume the role of the PI. Because it may take some time to effectively manage the transfer of study responsibilities, investigators should initiate this process as soon as they have informed University administrators of their planned departure.

Description:

The University of Pittsburgh Research Conduct and Compliance Office has prepared a document, '**Investigators Leaving the University of Pittsburgh**', that provides detailed information to assist in issues to consider and whom to contact for assistance.

- ✓ Institutional Review Board (IRB) should be notified well in advance of the departure of the PI so that arrangements can be made to either close the study or name another appropriately qualified individual currently at the institution to serve as the PI.

- ✓ Office of Research is a valuable resource to assist in the management of research data, specimens and funding. The University of Pittsburgh has ownership of the research data and therefore has specific policies on data access, retention, and transfer. It is important to contact the office early in the process to ensure a smooth transition which may require written agreements and interactions with funding agencies.

Note: the Pitt IRB will no longer cover an investigator once they leave the institution even if they are still listed as a member of the research team. If they retain a role in the research study, this must be clearly stated in the IRB application and if "engaged in research", this individual must obtain IRB approval from their new institution. If their new institution does not have an IRB, an independent IRB review may be needed.

- If a role in the study is maintained, the new contact information and affiliation must be updated at www.hsconnect.pitt.edu

- If the previous PI will no longer be listed on a clinical study that includes a drug, device, or other intervention, active subjects (and any subject with an implantable device) should receive a letter which provides new contact information should they have questions about the research.

OSIRIS:

A modification is needed for all investigator changes to expedited and full board OSIRIS applications.

When the modification is created to change the PI, select the reason, "change in protocol." This allows changes to any sections in the IRB application.

  - If the PI on an existing ***Exempt*** application changes, a new study must be submitted.

- If the modification is created to add or remove study team members, select the reason as "change in study team." This process is called "Mod lite" and only a few sections of the IRB application can be edited. The "Mod lite" process cannot be used to change the name of the PI.

- If a federal grant had been uploaded in the IRB application, but is now being transferred to another institution, the IRB application needs to be modified to reflect the changes in scope of work or oversight responsibilities at Pitt.

- Important Tip: Remember to look for other items which include the name of the previous PI or other members of the research team who have departed (e.g., consent forms, recruitment materials, scripts, subject correspondence, etc., that are still in use).

  - Use Control + F in reviewer version to search in the IRB application (uploaded documents will need to be reviewed individually).

  - Make sure that any waiver justifications in 2.14.2 and/or 4.7 regarding medical records are still accurate.