

Human Research Protections Program

Instructions for Change of PI

Purpose: This guidance document is for use by HSC Investigators, Department Leadership, and Research staff. Please review this guidance in its entirety before beginning. If you require further assistance, the HRPO contact information is found at the end of this document.

Confirming Eligibility for the new PI

- 1. Ensure that the new PI is eligible to be PI: <u>https://hsc.unm.edu/research/compliance/hrpo/investigators.html</u>
- 2. Ensure that the new PI has completed all the required training: CITI, FCOI (required every 3 years), their COI/ERA account is active, and their Huron IRB account is active

Email request from Department Chair to the HRPO

This option is available **ONLY** when the current PI has left the institution without transferring the research to another eligible PI. The request should follow the submission of an RNI, which can be submitted by any member of the study team, to report the non-compliance of the study being without PI oversight from the date the current PI left the institution.

- 1. This is not an email template for the Department Chair. However, the following information should be included in the email from the chair to the HRPO.
 - a. The HRRC ID# of the research project.
 - b. The current PI's name who has left the institution.
 - c. An official request from the Department Chair on behalf of the current PI to the HRPO for the assistance of submitting the forthcoming modification and any subsequent clarification response to continue the HRRC review process.
 i. If the modification is in pre-submission, include the modification ID#.
 - d. An attestation that an eligible PI has been identified and is qualified to take oversight of the applicable research.
 - e. Signed off by the Department Chair. Email signature with credentials will suffice.

Create a modification for the applicable study to change the PI

If the current PI is unavailable to make the required changes, the assigned PI Proxy or Primary Contact should complete the following steps. If there is no assigned PI Proxy, Primary Contact and the current PI is no longer with the institution to make the required changes, an email must be sent from the Department Chair to request the HRPO to assist with the change of PI modification.

- 1. Sign in to Huron IRB (<u>https://irb.health.unm.edu</u>) and navigate to the applicable study homepage.
- 2. Select "Create a new modification/Continuing Review/ Closure".
 - a. **Modification Scope:** select "Other parts of the study" **AND** "study team member information".
 - i. If the new PI is already listed as a study team member you will need to remove them.



ii. If the current PI will remain on the study in another role such as a Co-Investigator, add them to the study team list.

b. Modification Information:

- i. <u>Study Enrollment Status</u>: select the appropriate box that confirms the current enrollment status.
- ii. <u>Notification of subjects</u>: select the box or boxes that accurately capture which subjects will be notified of these changes.
- iii. <u>Summarize the modifications</u>: include a list of all study documents that have the current PI's name on them and have been revised with the new PI's information. List the names of study team members that are being updated.

c. Basic Information:

- i. <u>Principal Investigator</u>: Change the name of the PI to the new PI.
- ii. <u>Attach the protocol</u>: UPDATE (**Do Not** delete and do not ADD) the protocol with the revised document.
- d. **Funding Sources**: Update as necessary to ensure any applicable funding lists the new PI's information.
- e. **Study Scope**: review the responses to all three questions to ensure they have been completed and all required documents have been uploaded.
- f. Local Site Documents: UPDATE (Do Not delete and do not ADD) the consent form(s) that have been revised with the new PI's information.
- g. **Recruitment Materials**: Update any revised documents with the new PI's information.
- h. **Other Attachments**: Upload any other documents such as approved PI eligibility request form, LAT, questionnaires, or other study documents not uploaded earlier.
- i. **Do Not Remove** any previously uploaded and approved document such as the current PI's CV.
- 3. Select Finish then Submit Modification.
- 4. Once the submission has entered the Administrative Review state, the submission will begin a review by the HRPO staff. If there are additional changes needed, the assigned staff member will request clarifications.
- 5. **No changes may be implemented** until the modification has been approved by the HRRC and an approval letter has been sent.

Troubleshooting Help

If you run into issues creating the modification, revising study documents, or submitting the modification for review, please reach out to the HRPO and a member of our staff will schedule a consult to assist you further.

Human Research Protections Office Contact Information

Phone: 505-272-1129 Email: <u>HSC-HRPO@salud.unm.edu</u>