
IRB PROCEDURES TO BE FOLLOWED WHEN A PRINCIPAL INVESTIGATOR LEAVES UTHSC OR ONE OF ITS PARTNER INSTITUTIONS

When a Principal Investigator Leaves UTHSC or one of its partner institutes

When **Principal Investigators (PIs)** leave UTHSC or one of its partner institutions (Campbell Clinic, Le Bonheur Children’s Hospital, Methodist Healthcare – Memphis Hospitals, or Regional One Health), they are responsible for ensuring the disposition of their human subjects research studies prior to their departure. Likewise, **faculty advisors** and **department administrators** have a responsibility to ensure these duties are carried out before the PI leaves.

Below are the procedures to be followed when a PI, conducting human subject research, leaves UTHSC or one of its partner institutions. Please consider the status of the study as well as the PI’s future plans related to the study when reading the instructions below.

Study Completed:

If all research study activities have ceased and no research data or specimens will be transferred to a new institution, submit a *Form 7: Study Closure Form* via iMedRIS. The research records should be retained for as long as the applicable regulations require [see the [UTHSC IRB SOP: Study Closure and Record Retention](#)].

Study Active – PI Will No Longer Be Involved in Study:

If the study will remain active at UTHSC or one of its partner institutions, and the departing PI will have no further involvement with the study, submit a *Form 2: Change Request & Amendment* via iMedRIS:

- Assign a qualified individual as the new PI;
- Revise the *UTHSC IRB Form 1: Study Application*, in Sections 3.0 and (415) listing the new PI;
- Revise the appropriate study documents (e.g., consent forms, recruitment materials, etc.) to list the new PI’s name and contact information;
- Route the *Form 2: Change Request & Amendment* to the new PI and Department Chair (if the new PI’s department is different than the departing PI’s) so that they can apply their electronic signatures prior to submission to the UTHSC IRB; and
- Confirm that all electronic and physical study records including data and specimens have been securely transferred to the new PI.

Study Active – PI Wishes to Continue Involvement in Study:

If the study will remain active at UTHSC or one of its partner institutions, and the departing PI will continue as part of the research team, submit a *Form 2: Change Request & Amendment* via iMedRIS to:

- Assign a qualified individual as the new PI;
- Revise the *UTHSC IRB Form 1: Study Application*, in Sections 3.0 and (415) listing the new PI;
- Revise the appropriate study documents (e.g., consent forms, recruitment materials, etc.) to list the new PI's name and contact information;
- In the procedures section of the study application, explain the departing PI's new role in the study, including a description of any continued access to research data and/or specimens, and provide the departing PI's new contact information and institutional affiliation;
- Confirm that all electronic and physical study records including data and specimens have been securely transferred to the new PI, or explain any alternate arrangements;
- Submit a copy of the departing PI's IRB approval from his/her new institution, OR consult the [IRB Reliance Manager](#) regarding a possible [IRB Authorization Agreement or Individual Investigator Agreement](#)

Transfer of Human Subjects Research Data/Specimens to a New Institution:

Any departing investigators wanting to transfer research records including human subjects' data and specimens to a new institution must do the following:

- Contact the IRB (901.448.4824) to determine next steps. The IRB is obligated to ensure protections promised to research participants are maintained.
- Contact Brenda Murrell, Assoc. Vice Chancellor for Research, Office of Sponsored Programs (bmurrell@uthsc.edu) to ensure all University requirements are met, such as whether a data use agreement (DUA) or materials transfer agreement (MTA) is necessary.
- After consulting with the IRB and OSP and completing any related tasks, you must submit a written request to Dr. Wesley G. Byerly, Vice Chancellor for Research (wbyerly1@uthsc.edu) for permission to take data/specimens to a new institution.