

GUIDELINE FOR INVESTIGATORS LEAVING THE NIH

This guideline outlines OHSRP's expectations when a Principal Investigator (PI) or an Associate Investigator (AI) who is conducting human subjects research leaves the NIH. This does not address the requirements of the Institute or Center (IC), or other offices within the NIH. It is the responsibility of the departing investigator to be aware of all applicable NIH policies and ensure that requirements are followed.

While this guideline predominantly addresses responsibilities of the NIH PI when they leave NIH, information related to required actions needed when an AI leaves NIH and wishes to continue conducting human subjects research on the NIH protocol is also included below. When relevant to both, the term "investigator" is used to include both departing PIs and AIs.

A. KEY POINTS

- There can be only one NIH PI for protocols conducted by the NIH Intramural Research Program (IRP).
- A PI must be approved by the IC leadership, based on the IC leadership's determination that the PI is qualified on the basis of education, training and experience to conduct the proposed research. PIs must also meet the criteria delineated in [Policy 300-Investigator Responsibilities](#).
- When leaving the NIH, you, as the PI, are responsible for
 - Revising the protocol and obtaining IRB approval of a new PI who is suitably qualified to be responsible for the conduct of the research. This must be completed prior to the PI leaving the NIH.
 - Ensuring that data and specimens are transferred to/retained by you only in accordance with appropriate permissions, forms, and IC oversight and consistent with the protocol and terms of the Informed Consent.
- Following any additional NIH requirements, for example as outlined in [Manual Chapter 2300-940 Clearance of Personnel for Separation or Transfer](#).
- Arrangements for continued IRB oversight must be made for continued involvement of any former NIH investigator if they will continue to conduct human subjects research (HSR) on the NIH protocol.

Contact the NIH OHSRP [Reliance and sIRB Team](#) to establish whether the departing investigator will continue to be covered by the NIH FWA and, if they won't, whether any other written agreement needs to be executed to allow for continued research activities.

B. RESPONSIBILITIES AS PI WHEN LEAVING NIH AND HUMAN SUBJECT RESEARCH ACTIVITIES WILL CONTINUE AT NIH

- If you are a PI on a human subjects research protocol (whether exempt or non-exempt), and if the protocol is to be continued at NIH, another investigator must be identified to take over your responsibilities.
- The transfer of responsibilities to the new PI must occur before you leave NIH, in order to ensure effective planning and continuity especially as it relates to subjects enrolled in the study.
- A modification must be submitted to the Institutional Review Board (IRB) in the NIH electronic IRB system for review and approval of a new PI who is suitably qualified to be responsible for the conduct of the research.
- The modification must indicate you are being removed from the protocol as PI and that there is addition of the incoming PI.
 - The Basic Study Information Smart Form, protocol, consent, and relevant documents must be updated in the NIH electronic IRB system to reflect the change in PI.
 - Please submit these updated documents in the NIH electronic IRB system with the modification submission requesting change in PI:
 - Modification Form
 - Basic Study Information Smart Form updated with the new NIH PI of the study
 - Revised protocol
 - Revised Consent
 - Other supporting documents as applicable
 - This submission is usually reviewed as an expedited modification.
 - Approval of the modification will be sent to the new PI via the NIH electronic IRB system.
- If you want to take data and/or specimens to your new non-NIH institution, ensure the data/specimens are transferred to/retained only with appropriate permissions, forms, and IC oversight. (See, e.g., [NIH Manual Chapter 1743, Managing Federal Records, Manual Chapter 2300-940 Clearance of Personnel for Separation or Transfer](#) and the [HHS Technology Transfer Policies and Procedures Manual](#).)
- If there is a technology transfer agreement in place for the study, you should contact your Tech Transfer office well in advance of your departure so that the CRADA, licensing agreement, etc. can be amended as needed.
- If the protocol is going to be closed, follow the requirements specified in [Policy 205 Requirements for IRB Submission](#). The closure of the protocol should occur prior to your

departure from NIH. All required materials for closure of the protocol must be submitted through the NIH electronic IRB system for IRB review and approval.

C. REQUIREMENTS FOR INVESTIGATORS WHO WILL BE CONTINUING HUMAN SUBJECTS RESEARCH ON THE SAME NIH PROTOCOL AFTER DEPARTING NIH

- If you will continue to participate in NIH research as an NIH Special Volunteer after your departure, the NIH FWA will continue to cover your human subject research related activities. If you plan to continue to participate in NIH research after your departure and will not be an NIH Special Volunteer, you are responsible for contacting the Office of Human Subjects Research Protections (OHSRP) [Reliance and sIRB Team](#) in advance of departure to determine what type of agreement may be needed. (See Policies [3014-105 IRB Reliance and Collaborative Research](#) and [3014-109 Coverage under the NIH Federalwide Assurance](#) for more information.).

D. PROCESS WHEN THE NIH PI IS LEAVING NIH AND HAS A PROTOCOL THAT IS OVERSEEN BY A NON-NIH IRB

- You must notify the non-NIH Reviewing IRB that you are leaving NIH and convey which investigator will serve as the new NIH Site PI. The new NIH PI must be qualified to serve in the capacity of PI as per NIH policies.
- When the reviewing IRB is not the NIH IRB, then OHSRP office of IRB Operations (IRBO) must be informed as soon as possible, to ensure that any applicable reliance agreements are revised accordingly to indicate the new NIH PI. (See [Policy 3014-105 IRB Reliance and Collaborative Research](#) for more information.)
- If you wish to remain involved in the NIH study after moving to the new institution, decisions and arrangements for FWA coverage and IRB oversight must be made. You should consult with the OHSRP [Reliance and sIRB Team](#) in this event prior to leaving NIH.

E. DEPARTING PI RESPONSIBILITY FOR RECORD RETENTION

- You must engage an appropriate IC official to identify the successor responsible for maintaining the research records at NIH consistent with NIH records requirements. (See [Policy 300 Investigator Responsibilities](#), [1743 - Managing Federal Records](#), the [NIH Intramural Records Retention Schedule](#), [Manual Chapter 2300-940 Clearance of Personnel for Separation or Transfer](#) and the [NIH Privacy Act Policy](#).)