GUIDELINE FOR INVESTIGATORS LEAVING THE NIH

This guideline outlines the expectations of OHSRP 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, the PI is 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 the departing PI 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*.
- If the investigator plans to continue to participate in NIH research after their departure, they 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.). Also see the attached *Decision Tree for Investigators Leaving the NIH and Wanting to Continue Research Activities on an NIH Protocol*.

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

- As 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 the PI responsibilities.
- The transfer of responsibilities to the new PI must occur before the departing PI leaves NIH, in order to ensure effective planning and continuity especially as it relates to subjects enrolled in the study.
- An amendment 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 amendment must indicate the removal from the protocol of the outgoing PI and addition of the incoming PI.
    - The protocol, consent, Study Personnel Page (SPP) and relevant documents must be updated in NIH electronic IRB system to reflect the change in PI.
    - Please submit these updated documents in the NIH electronic IRB system for the amendment submission requesting change in PI:
        - Amendment Form
        - Study Application updated with the new NIH PI of the study
        - SPP
        - Revised protocol
        - Revised Consent
        - Other supporting documents as applicable
    - This submission is usually reviewed as an expedited amendment.
    - Approval of the amendment will be sent to the new PI via the NIH electronic IRB system.
- If the PI wants to take data and/or specimens to their 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, the PI should contact their tech transfer office well in advance of their 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 the PI's 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

- Arrangements for continued IRB oversight must be made for continued involvement of the 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.

D. Process When the NIH PI is Leaving NIH and Has a Protocol That is Overseen by a Non-NIH IRB

- The departing NIH PI must notify the non-NIH Reviewing IRB that they 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 the former NIH PI wishes 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. The departing NIH PI should consult with the OHSRP Reliance and sIRB Team in this event prior to leaving NIH.

E. Responsibility for Record Retention

- The departing PI 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.

DECISION TREE FOR INVESTIGATORS LEAVING THE NIH AND WANTING TO CONTINUE RESEARCH ACTIVITIES ON AN NIH PROTOCOL

This decision tree should be used by NIH investigators who will be leaving the NIH and plan to continue to conduct research on an NIH protocol.

The questions in the blue boxes are directed at the departing NIH investigator and will determine:

1. If the planned on-going research activities will need IRB oversight; and
2. If they do, whether any additional agreements (e.g., Reliance Agreement, Individual Investigator Agreement, or FWA Coverage Agreement) must be put in place to ensure appropriate IRB oversight.

The last two pages of this document provide an overview of the additional agreements.

The policy basis for these guidelines is found in NIH HRPP Policies **100**, **105,** and **109**. If additional guidance is needed after reviewing the decision tree, please contact the **NIH Reliance and Single IRB Team**.

Q1. Will you be conducting human subjects research (HSR)?

HINT: An investigator conducts HSR when doing one or more of the following for the purposes of research:

- Interacts / intervenes with subjects;
- Obtains consent from subjects;
- Accesses identifiable private information;
- Works with identifiable data/samples;
- Works with coded data/samples and has code key; or
- Works with coded/deidentified data/samples but can reidentify subjects based on prior protocol

If an investigator is conducting HSR, their activities "engage" their institution in HSR.

No

In NIH protocols, the researcher is considered a "Collaborator" not an "Investigator"

STEPS FOR THE NIH STUDY TEAM

- If the protocol does not already allow for sharing deidentified data/ samples, or coded data/ samples without the code key, ensure there is a description in the protocol that has been reviewed and approved by the NIH IRB.
- Collaborators may be identified on the *Study Personnel Page* but must not be identified on the iRIS *Study Application.*

STEPS FOR THE INVESTIGATOR LEAVING THE NIH

- An approval from the new home institution may be needed to continue to be involved in the NIH protocol.

STOP

Yes

"Engaged" investigators on NIH protocols need:

1. To be covered by an institutions' Federalwide Assurance (FWA) *defined in "hint" below;*

AND

2. Regulatory review and oversight from an Institutional Review Board (IRB).

GO TO QUESTION 2

Q2. After leaving the NIH, will your on-going NIH research activities be covered by the NIH Federalwide Assurance (FWA)?

HINT: All investigators conducting HSR on NIH protocols must be covered by an active FWA. A FWA is an institution's written commitment to comply with the federal regulations that relate to the protection of human subjects under 45 CFR 46.

Being "covered" under the NIH FWA means that investigators are acting on behalf of the NIH and that the NIH is responsible for their actions when conducting HSR.

The NIH FWA automatically covers the following individuals:

- **NIH Employees** (intramural and extramural);
- **Special Volunteers**, **Visiting Fellows**, **Intramural Research Training Awardees**, or **Cancer Research Training Awardees**; and
- **NIH Contractors** (subject to terms of the contract), if:
  - The contractor is working at an NIH site with an NIH employee; or
  - The NIH Office of Human Subjects Research Protections (OHSRP) Director/designee has determined that the NIH FWA covers the contractor's activities.

Investigators conducting HSR who do not fall into any of the above categories are not automatically covered by the NIH FWA. However, if eligible, the NIH FWA can be *extended* to them through a separate written agreement.

Select "No" if, after leaving the NIH, the leaving investigator will not fall into any of the above categories. Please note that IRB approval for research activities is separate to being covered by an FWA and continues to be required if they are "engaged" investigators i.e., the answer to question 1 above was "Yes".

No

- Before exploring whether the NIH FWA can be extended to a leaving investigator, inquiries need to be made to establish if another institutions' FWA covers them.

GO TO QUESTION 3

Yes

The leaving investigator is still considered part of the NIH study team and the Reviewing IRB will continue to provide oversight for their research activities provided their IRB approval for NIH's activities continues.

STEPS FOR THE NIH STUDY TEAM WHEN NIH IS THE REVIEWING IRB

To continue to have IRB oversight, the investigator must be:

i. Identified in the iRIS *Study Application*
   a. **section 3.2 (c)** if they are in NED or
   b. **section 5** if they are not in NED;
ii. Identified as an Associate Investigator (AI) on the Study Personnel Page as they are covered by the NIH FWA; and
iii. Compliant with the training requirements in **NIH HRPP Policy 103**, and the conflicts of interest requirements of **NIH HRPP Policies 102 and 103** if involved in a 'covered' protocol..

STEPS FOR THE NIH STUDY TEAM WHEN THE REVIEWING IRB IS EXTERNAL

- Consult with the Reviewing IRB and the **NIH Reliance and Single IRB Team** to establish what needs to be in place to ensure continued IRB oversight for the leaving investigator.

STEPS FOR THE INVESTIGATOR LEAVING THE NIH

- Ensure compliance with all applicable training requirements in **NIH HRPP Policy 103**.
- Ensure compliance with **NIH HRPP Policy 109**, section E.4. "Responsibilities of non-NIH Investigators/Institutions"

STOP

Q3. Are you moving to an FWA-holding institution whose FWA will cover your conduct of HSR on an NIH protocol?

HINT: The leaving investigator should contact the Human Research Protections Program/ IRB office at their new institution to establish if they will be covered by their FWA for the on-going NIH HSR activities.

Being "covered" under an FWA means that investigators are acting on behalf of the FWA-holding institution, and that the institution is responsible for their actions when conducting HSR. Institutions typically limit FWA coverage to their employees as it provides a mechanism for accountability and oversight. However, institutions may choose to "extend" their FWA coverage to non-employees e.g., visiting academics, students etc.

To find out if the new institution has an active FWA, click on the FWA tab on the home page of this searchable database and search by the institution's name.

No

The conduct of HSR on an NIH protocol by the leaving investigator **will not** be covered by any institutions FWA.

STEPS FOR THE NIH STUDY TEAM

- Request that the NIH *extend* its FWA to the leaving investigator via written agreement.
- Only the NIH Institutional Official (IO) or designee (**NIH OHSRP**) has the authority to determine this. Investigators do not.
- If the NIH FWA is extended, it means that the leaving investigator is considered part of the NIH study team and their research activities on the NIH protocol will continue to be overseen by the Reviewing IRB as part of its review of the NIH protocol.

The NIH FWA is typically extended via an

1. ***FWA Coverage Agreement,***
   or
2. ***Individual Investigator Agreement***

GO TO THE LAST PAGE TO LEARN ABOUT THESE OPTIONS, IDENTIFY THE APPROPRIATE ONE FOR THE LEAVING INVESTIGATOR, AND FIND OUT HOW TO SUBMIT A REQUEST.

Yes

- The conduct of HSR on the NIH protocol by the leaving investigator **will** be covered by their new institution's FWA.
- The leaving investigator is considered affiliated with the new institution and is no longer considered part of the NIH study team.

STEPS FOR THE NIH STUDY TEAM

- The next task is to ensure continued IRB oversight for the HSR. The options are outlined below and depend on the identity of the Reviewing IRB.

- If an **external IRB is reviewing the NIH protocol**, the investigator leaving the NIH needs to work with their new institution's HRPP/IRB office to identify the best way to secure IRB oversight for their proposed on-going HSR.

- The options if **NIH IRB is reviewing the NIH protocol** are:
  1. Apply for a ***Reliance Agreement*** between the NIH and the leaving investigator's new FWA-holding institution;
  2. Have the leaving investigator's new FWA-holding institution conduct ***Local IRB Review*** of the NIH protocol; or
  3. Request a ***FWA Coverage Agreement*** from NIH OHSRP.

GO TO THE NEXT PAGE TO LEARN ABOUT THESE OPTIONS, IDENTIFY THE APPROPRIATE ONE FOR THE LEAVING INVESTIGATOR, AND FIND OUT HOW TO SUBMIT A REQUEST.

OPTIONS IF YOUR ANSWER TO Q.3 IS "YES"

NOTE In general, each of the options below is finalized *after* the investigator in question has left the NIH and it may require them to submit a request in parallel at their new institution.

Reliance Agreement

What? A written agreement between institutions performing multi-site research that identifies which institution will serve as the Reviewing IRB and which will cede IRB review i.e., Relying Institution. Provides a mechanism for the leaving investigator's new institution to cede IRB oversight to the NIH IRB for the on-going research activities. The agreement is negotiated and finalized by the respective Human Research Protections Program's. It is an option only available to FWA-holding institutions.

How? The NIH PI needs to submit a reliance application to the **NIH OHSRP** requesting that the external institution rely on the NIH IRB. The OHSRP Office of IRB Operations (IRBO) will review the request, issue the agreement, and work with the external institution to finalize. Once in place, an action is submitted to the NIH IRB to add the new institution as a Participating Site. The submission will document the reliance arrangement in the Study Application, remove the former NIH investigator from the Study Personnel Page, identify them as the Site PI for their new institution, and updates the NIH protocol to ensure there is a description of the HSR that will be conducted by the former NIH investigator under the external institution's FWA.

Need more information? See **NIH HRPP Policy 105** and the resources on the IRBO website.

Local IRB Review

What? Local IRB Review means that an investigator's own institution reviews their conduct of HSR on a protocol. The FWA-holding institution may determine that they want to review their investigator's HSR on the NIH protocol, or the NIH might determine that its IRB cannot be relied upon via a Reliance Agreement. *This is only an option if the NIH protocol is not subject to any single IRB mandates – the requirement that multi-site research be reviewed by a single IRB.*

Need more information? To determine if a protocol is subject to an sIRB mandate, consult with the Reliance & Single IRB (sIRB) Team.

FWA Coverage Agreement

What? The FWA Coverage Agreement is used by the NIH to extend its FWA to those leaving NIH if **all the following** are met:

i. The research to be performed will be part of the same NIH protocol that the leaving investigator was involved in when at the NIH;
ii. The research is limited only to the analysis of identifiable data* from that same NIH protocol;
iii. The research will be conducted under the oversight of the NIH PI; and
iv. If the leaving investigator has moved to a FWA-holding institution, that institution must provide written verification that it agrees with the activities being conducted under the oversight of the NIH.

Uniquely, this agreement is an option for those who reached question 3 above and answered yes or no. It is available to those not covered by an institution's FWA and it can also be used by those at an FWA-holding institution *provided* the new institution is comfortable with their new investigator being covered by the NIH FWA for the HSR being conducted on the NIH protocol.

How? To request an FWA Coverage Agreement, the NIH PI or designee needs to complete a Request Form. IRBO reviews the requests, confirms if the agreement is appropriate, and communicates that to the NIH PI and OHSRP Director. If OHSRP agrees to extend the NIH FWA, an agreement is issued and signed by the NIH PI, the non-NIH investigator, and the OHSRP Director.

Need more information? See **NIH HRPP Policy 109** to learn about the mechanism for extending the NIH FWA and to review the responsibilities of the NIH PI and the non-NIH investigator when this is done.

**In this context, the analysis of identifiable data encompasses working with coded data with access to the code key; and circumstances where an investigator will be working with coded/ de-identified data with no access to the code key but can reidentify subjects based on their prior role in the protocol.*

OPTIONS IF YOUR ANSWER TO Q.3 WAS "NO"

NOTE In general, each of the options below is finalized *after* the investigator in question has left the NIH and it may require them to submit a request in parallel at their new institution.

FWA Coverage Agreement

What? The FWA Coverage Agreement is used by the NIH to extend its FWA to those leaving NIH if **all the following** are met:

v. The research to be performed will be part of the same NIH protocol that the leaving investigator was involved in when at the NIH;
vi. The research is limited only to the analysis of identifiable data* from that same NIH protocol;
vii. The research will be conducted under the oversight of the NIH PI; and
viii. If the leaving investigator has moved to a FWA-holding institution, that institution must provide written verification that it agrees with the activities being conducted under the oversight of the NIH.

Uniquely, this agreement is an option for those who reached question 3 above and answered yes or no. It is available to those not covered by an institution's FWA and it can also be used by those at an FWA-holding institution *provided* the new institution is comfortable with their new investigator being covered by the NIH FWA for the HSR being conducted on the NIH protocol.

How? To request an FWA Coverage Agreement, the NIH PI or designee needs to complete a Request Form. IRBO reviews the requests, confirms if the agreement is appropriate, and communicates that to the NIH PI and OHSRP Director. If OHSRP agrees to extend the NIH FWA, an agreement is issued and signed by the NIH PI, the non-NIH investigator, and the OHSRP Director.

Need more information? See **NIH HRPP Policy 109** to learn about the mechanism for extending the NIH FWA and to review the responsibilities of the NIH PI and the non-NIH investigator when this is done.

**In this context, the analysis of identifiable data encompasses working with coded data with access to the code key; and circumstances where an investigator will be working with coded/ de-identified data with no access to the code key but can reidentify subjects based on their prior role in the protocol.*

Individual Investigator Agreement (IIA)

What? An IIA is the appropriate mechanism to extend NIH's FWA if the HSR to be conducted by the former NIH investigator will go beyond working with identifiable data and they will not be covered by any other institution's FWA. It can also be used for investigators not associated with an FWA-holding institution.

How? The extension of the NIH FWA to a non-NIH investigator using this mechanism is considered on a case-by-case basis and is ultimately at the discretion of the NIH IO/ designee. The NIH PI/ designee should consult with the Reliance & sIRB Team to determine if this is a viable option. If OHSRP agrees to extend the NIH FWA, an agreement is issued and signed by the NIH PI, non-NIH investigator, the non-NIH investigator's employer/supervisor (if applicable), and the OHSRP Director.

Need more information? See **NIH HRPP Policy 109** to learn about the mechanism for extending the NIH FWA and to review the responsibilities of the NIH PI and the non-NIH investigator when this is done.