NIH Policy Manual

3014-109 - Coverage Under the NIH Federalwide Assurance

Issuing Office: OD/OIR/OHSRP **Phone:** (301) 402-3713

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Transmittal Notice

1. **Explanation of Material Transmitted:** NIH Human Research Protection Program (HRPP) policies have been revised to comport with the revised DHHS Common Rule (45 CFR 46) and to reflect the newly consolidated IRB structure within the NIH Intramural Research Program. This policy describes when the NIH may choose to extend its Federalwide Assurance (FWA) to cover non-NIH investigators or institutions conducting human subjects research on NIH protocols, via a written agreement, other than a reliance agreement. Upon implementation, this policy supersedes *SOP 20D NIH FWA Coverage for Non-NIH Employees Working on NIH Protocols*
2. **Filing Instructions:**

    - **Insert:** NIH Manual Chapter 3014-109, dated 05/15/2020
    - **Implementation Date:** 07/06/2020

1. **PLEASE NOTE:** For information on:

    - The current policies can also be found at: https://irbo.nih.gov/confluence/display/ohsrp/Policy.
    - Content of this chapter, contact the issuing office listed above.
    - NIH Policy Manual, contact the Division of Compliance Management, OMA, on (301) 496-4606, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

1. Describes when the NIH may choose to extend its Federalwide Assurance (FWA) to cover non-NIH investigators or institutions conducting human subjects research on NIH protocols. Such coverage may be extended by a written agreement, other than a reliance agreement (e.g., FWA Coverage agreement or Individual Investigator Agreement).

    Note: For the remainder of this policy, the term “non-NIH investigators” includes both former NIH investigators and non-NIH investigators and institutions, unless otherwise specified. NIH Investigators are already covered by the NIH FWA, as described in

Policy 3014-100.

B. Scope

1. This policy applies to NIH Principal Investigators (PIs) who wish to request NIH FWA coverage for collaborators that are engaged in human subjects research conducted on NIH protocols.
2. This policy applies to non-NIH investigators conducting human subjects research on NIH protocols, whose home institution will not cover this research activity under its FWA or who are not associated with an FWA-holding institution.
3. This policy does not apply to non-NIH investigators who to do not meet the criteria in *B.2.* above.
4. This policy applies to the NIH Institutional Official (IO), who is also the Deputy Director for Intramural Research (DDIR).
5. This policy applies to the OHSRP including its offices and staff.

C. Policy

1. All human subjects research conducted on NIH protocols must be conducted by institutions that have an active FWA on file with the HHS Office for Human Research Protections (OHRP).
2. The NIH IO or designee (e.g., the OHSRP Director), has the authority to determine whether the NIH will extend its FWA to cover the human subjects research activities of non-NIH investigators who seek to serve as investigators on NIH protocols.

    a. Consistent with this policy, the NIH IO, or designee, has the authority to determine which investigators are covered by the NIH FWA with no written agreement, and which investigators will be covered under the NIH FWA with a written agreement (e.g., an Individual Investigator Agreement, or FWA Coverage Agreement). (See Policy 3014-100 NIH Intramural Program's Human Research Protection Program.)
    b. .Only the NIH IO, or designee, may execute FWA coverage agreements for non-NIH investigators.
    c. NIH PIs do not have the authority to extend NIH's FWA coverage to a non-NIH investigator. Upon request from an NIH PI, OHSRP may choose to extend the NIH FWA.

3. The NIH will only extend its FWA for human subjects research conducted on behalf of the NIH IRP when it is in the interest of the NIH, and through a written agreement (agreement) executed by the IO, OHSRP Director or designee. (For more information about who is covered under the NIH FWA without a written agreement, see Policy 3014-100 NIH Intramural Program's Human Research Protection Program.)

    a. In order to consider extending its FWA, the NIH must be assured that:

I. The non-NIH investigator conducting the research has adequate training to conduct the approved research; and
II. The NIH PI will provide oversight of the non-NIH investigator to ensure compliance with all applicable federal regulation and policy, including NIH policy.

b. The non-NIH investigator or institution, when conducting research activities on NIH protocols, to whom the FWA coverage will be extended must comply with the terms of the agreement, and applicable federal regulation and policy, including NIH policy.

4. The OHSRP will review requests for FWA coverage and, upon approval by the NIH IO, or designee, prepare any necessary agreements.

D. Definitions

OHSRP has developed a comprehensive glossary of definitions that describe the terms listed below. The glossary can be found at the following link: NIH IRP HRPP Policy Glossary.

Note: There may be more than one definition per term, so please review terms carefully to make sure they match the terms listed below. Qualified terms are indicated with a parenthetical qualification. When reviewing a definition, be sure that you are reviewing the appropriate definition that links to this policy. To further assist the reader, each term in the glossary cites the relevant policy number(s) indicating where the term is utilized.

1. Federalwide Assurance (FWA)
2. NIH Investigator

E. Responsibilities and Requirements

1. **Responsibilities of NIH Principal Investigators:**

a. The NIH PI must request permission from OHSRP for FWA coverage of a non-NIH investigator not otherwise automatically covered by the NIH FWA. (For information about all other non-NIH investigators or institutions seeking NIH IRB review, see Policy 3014-105 IRB Reliance. For information about which investigators are and are not automatically covered under the NIH FWA, see Policy 3014-100 NIH Intramural Program's Human Research Protection Program)
b. When seeking permission from OHSRP for the NIH to extend FWA coverage to a non-NIH investigator, the NIH PI must verify that:

I. The non-NIH investigator for which they are seeking FWA coverage is not affiliated with an FWA-holding institution.

i. If the non-NIH investigator is affiliated with an FWA-holding institution, then in general, the collaboration should be conducted under a reliance agreement with that institution. (see Policy 3014-105 IRB Reliance. For information about which investigators are and are not automatically covered under the NIH FWA, see Policy 3014-100 NIH Intramural Program's Human Research Protection Program)

II. When the collaborator is a former NIH investigator, the NIH may choose to extend its FWA to that non-NIH investigator, even if the non-NIH investigator is currently affiliated with an FWA-holding institution. When the NIH will provide FWA coverage for this investigator, all of the following conditions must be met:

i. The research to be performed by the former NIH-investigator is a continuation of the same research conducted while an NIH investigator;
ii. The research must be limited only to the analysis of identifiable data from that same protocol;
iii. The research must be conducted under the oversight of the NIH PI; and
iv. If the non-NIH investigator is affiliated with an FWA-holding institution, that institution must provide a written verification that it is in agreement with the activities being conducted under the oversight of the NIH.

c. Upon receiving confirmation from IRBO that the NIH has agreed to extend the NIH FWA to a non-NIH investigator, the NIH PI must:

I. Ensure that the non-NIH investigator is listed in the electronic IRB system.
II. Ensure that the non-NIH investigator conducting the research has adequate training.
III. Ensure that the activities of the non-NIH investigator are described in the approved protocol.

i. If necessary, the NIH PI should submit a modification to the protocol for review by the IRB.

d. Upon receipt of the fully executed agreement, the NIH PI must:

I. Provide a copy of the agreement and any materials (see *E.2.c.* below), if any, as directed by IRBO to the non-NIH investigator; and
II. Retain the agreement in the research record and in accordance with Policy 3014-300 Investigator Responsibilities and NIH records policy.

e. The NIH PI is accountable for the research activities of the non-NIH investigator, and assuring such activities are consistent with the terms of the agreement and NIH policy.
f. The NIH PI must promptly notify the non-NIH investigator, if the NIH withdraws its FWA coverage.
g. The NIH PI is responsible for informing the IRBO, ideally in advance if feasible, when:

    I. There are any changes to the protocol, or in the research activities of the non-NIH investigator;
    II. There is any change in the status of the non-NIH investigator that affects the validity of the agreement (e.g., the non-NIH investigator is now associated with an FWA-holding institution or changes institutions).
    III. The agreement is no longer in effect.

2. **Responsibilities of OHSRP Office of IRB Operations (IRBO):**

a. The IRBO must review requests to extend the NIH FWA and recommend an appropriate mechanism (e.g., FWA coverage or a reliance agreement). (*See* Policy 3014-105 IRB Reliance.) The IRBO must communicate their recommendation to the NIH PI and the OHSRP Director.
b. When appropriate, the IRBO must prepare and maintain agreements for extending coverage under the NIH FWA.
c. When providing an agreement extending the NIH FWA to the non-NIH investigator, the IRBO must also provide copies of, or access to, the following documents to the NIH PI, who provides the agreement to the non-NIH investigator:

    I. The Belmont Report;
    II. HHS Common Rule (45 CFR 46);
    III. The NIH FWA; and
    IV. Relevant institutional and Human Research Protection Program (HRPP) policies (e.g., Policy 3014-801 Reporting Research Events and Policy 3014-103 Education Program*)*.

3. **Responsibilities of the NIH IO, OHSRP Director or designee:**

a. The NIH IO, OHSRP Director or designee, must determine whether the NIH will extend its FWA to cover the human subjects research activities of non-NIH investigators or institutions.
b. The NIH IO, OHSRP Director or designee may execute written agreements extending NIH FWA coverage when appropriate.

    I. NIH investigators may not execute these agreements on behalf of the NIH.

4. **Responsibilities of non-NIH investigators/Institutions:**

a. The non-NIH investigator must:

I. If affiliated with an institution (whether or not that institution holds an FWA), verify to the NIH PI that the institution permits the conduct of the NIH research under the NIH FWA;
II. Provide the NIH PI and/or NIH IRB with any information requested to facilitate the review of the request;
III. Know and comply with all applicable federal, state and local laws and regulations, including but not limited to, the Privacy Act (5 U.S.C. § 552a) and the HHS Protection of Human Subjects regulations (45 C.F.R. § 46);
IV. Follow the policies of his/her home institution;
V. Follow the relevant NIH institutional and NIH HRPP policies (e.g., reporting unanticipated problems consistent with Policy 3014-801 Reporting Research Events, human subjects protection training, consistent with Policy 3014-103 Education Program, conflicts of interest, and the requirements of this policy);
VI. Follow the relevant NIH IRB procedures;
VII. Follow the instructions of the NIH PI for the conduct of the research;
VIII. Adhere to the protocol, and to the non-NIH investigator's assigned role on the research;
IX. Not share any data from the NIH protocol;
X. Maintain the confidentiality of all data; and
XI. Comply with any directives and/or determinations of the NIH IRB.

b. The non-NIH investigator must comply with the responsibilities described in the agreement extending coverage of the NIH FWA.
c. The non-NIH investigator may not commence research until the NIH PI has provided:

I. Proof of NIH IRB approval for the research activities of the non-NIH investigator; and
II. A copy of the fully executed agreement extending the NIH FWA coverage.

d. The non-NIH investigator may not make any changes to the research or the non-NIH investigator's activities covered by the agreement.

I. If the non-NIH investigator wishes to make any changes, a request for approval must be made to the NIH PI. Such changes may not commence unless:

i. It is consistent with the terms of the agreement;
ii. The NIH PI agrees to the change; and
iii. The NIH IRB and/or IRB has provided approval.

e. The non-NIH investigator must promptly inform the NIH PI when the agreement is no longer in effect or when there is a change in status that may affect the validity of the agreement, such as a change in employment status.

F. References

1. **Regulation**

HHS: 45 CFR 46

2. **Policy**

Policy 3014-100 NIH Intramural Program's Human Research Protection Program

Policy 3014-103 Education Program

Policy 3014-105 IRB Reliance

Policy 3014-300 Investigator Responsibilities

Policy 3014-801 Reporting Research Events

3. **Guidance and Tools**

The Belmont Report

Individual Investigator Agreement

FWA Coverage Agreement