

Policy 109 Coverage Under the NIH Federalwide Assurance – Policy Changes Overview

This document summarizes changes in *Policy 109 Coverage under the NIH Federalwide Assurance* (FWA) (referred to as Policy 109 in this document) that NIH investigators should be aware of, from the SOP mentioned below.

The 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, and that such coverage may be extended by a written agreement other than a reliance agreement (e.g., FWA Coverage agreement or Individual Investigator Agreement).

NIH investigators are responsible for reviewing Policy 109 and complying with the requirements of the policy.

Note: Text from the policy and other policy titles are italicized.

Policy 109 Coverage Under the NIH Federalwide Assurance	SOP Superseded by Policy 109
Policy 109 fully supersedes:	SOP 20D NIH FWA Coverage for Non-NIH Employees Working on NIH Protocols When inactivated, this SOP will be archived in the Policy Archive.
Policy 109 partially supersedes:	SOP 20 NIH HRPP Requirements for Collaborative Research When inactivated, this SOP will be archived in the Policy Archive.
Policy Requirement	SOP Requirement
NIH PIs should review <i>Policy 100 NIH Intramural Research Program’s Human Research Protection Program</i> to learn more about who is covered under the NIH FWA with and without a written agreement.	SOP 20D – <i>The NIH FWA covers both intramural and extramural NIH employees and certain other categories of personnel as set forth in this policy.</i> SOP 20, Section 20.4.B.1. – <i>If the non-NIH collaborating researcher is engaged in human subjects research activities, the NIH must ask whether the collaborating institution has a Federalwide Assurance (FWA) and IRB review and oversight.</i>
Section C.2.b. – <i>Only the NIH IO, or designee, may execute FWA coverage agreements for non-NIH investigators. Who may be designated has changed based on the reorganization of OHSRP. The OHSRP Director is generally the party designated by the DDIR to sign these agreements.</i> Section C.2.c. – <i>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.</i>	SOP 20D, Section D7 – Previously, the OHSRP Director or Deputy Director made this decision as delegated by the Deputy Director for Intramural Research (DDIR) (the NIH Institutional Official). SOP 20D, Section D6 – This section describes the procedures for obtaining an FWA coverage agreement for former employees or staff who wish to continue to perform data analysis on a protocol that they worked on at the NIH. This section

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<p>This represents a policy and operational change. The NIH PI may sign the revised FWA Coverage Agreement, but only to certify that s/he will provide oversight over the activities of the former NIH staff member. The agreement may only be executed by NIH IO or designee (OHSRP Director) and at the discretion of the NIH.</p> <p>Note that there is no change to who may execute the <i>Individual Investigator Agreement</i>. The NIH is no longer using the <i>Institutional Investigator Agreement</i>.</p>	<p>permitted the NIH PI to execute the FWA Coverage Agreement.</p>
<p>Section E.1.b.i. – The NIH PI must certify to OHSRP, when seeking FWA coverage for a non-NIH investigator that, the non-NIH investigator for which they are seeking FWA coverage is not affiliated with an FWA-holding institution.</p> <p>If the non-NIH investigator is associated with an FWA-holding institution, generally a reliance agreement will be sought. The NIH PI should also review and comply with <i>Policy 105 IRB Reliance and Collaborative Research</i>.</p> <p>However, if the non-NIH investigator is affiliated with an FWA-holding institution, and NIH FWA coverage will be extended (in lieu of a reliance agreement), then that institution must provide a written verification that it is in agreement with the activities being conducted under the oversight of the NIH.</p>	<p>SOP 20D, Section D7 – Presumed that the NIH would only extend FWA coverage to those physicians or small practices that do not hold an FWA.</p> <p>Since the implementation of that SOP, some FWA holding institutions prefer NIH FWA coverage to a reliance agreement when the NIH is not entering into collaborative research with that institution. NIH FWA coverage may be appropriate when the only activity covered under the NIH FWA for the former NIH employee is ongoing data analysis for an NIH protocol, and the new institution prefers that the NIH continue its oversight.</p>
<p>Section E.1.c. – Describes the responsibilities of the NIH PI when the NIH has agreed to cover a non-NIH investigator under its FWA. The non-NIH Investigator must be listed in the electronic IRB system.</p>	<p>This is a change from SOP 20D and is based in changes to NIH iRIS, the electronic IRB system, and IRB procedures.</p>
<p>Section E.1.g. – Describes the responsibilities of the NIH PI to inform the IRBO of any changes that might affect the status of any executed FWA coverage agreements.</p> <p>NIH PIs should review this section and are accountable for knowing when to inform IRBO of such changes.</p>	<p>This is a change from SOP 20D and is based on the expanded role of the Office of IRBO Operations.</p>