This document summarizes changes in *Policy 108 OHSRP Quality Assurance and Quality Improvement Program* (referred to as Policy 108 in this document) that NIH investigators should be aware of, from the SOPs mentioned below.

The policy describes the Office of Human Subjects Research Protections (OHSRP) Quality Assurance (QA) and Quality Improvement (QI) Program (QA/QI Program) used to ensure that NIH Institutional Review Board (IRB) determinations are conducted in accordance with federal regulations and policy, including NIH policy.

OHSRP, including IRBO, staff are responsible for reviewing Policy 108 and complying with the requirements of the policy.

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

Policy 108 OHSRP Quality Assurance and Quality Improvement Program	**SOP Superseded by Policies:**
Policy 108 fully supersedes	**SOP 23 Quality Management System for the NIH HRPP** When inactivated, this SOP will be archived in the Policy Archive.
Policy 108 fully supersedes	**SOP 26 - Evaluation of NIH IRB Chairs, Vice Chairs and Members, IRB Administrative Staff and IRB Committee Activities**

Applicability of Policy 108 - This policy applies to:

- OHSRP, including its Office of IRB Operations (IRBO), and
- the NIH IRB.

Policy Requirement	**SOP Requirement**
Section C.1. – *The OHSRP office of Compliance and Training* (oC&T) *will conduct periodic quality assessments of the NIH IRB and the IRBO* (Office of IRB Operations) *to ensure compliance with federal regulation and policy.* AND See also ***Section E.1.*** – The oC&T is responsible for QA/QI reviews of NIH IRB and IRBO activities as described in section E.1. of Policy 108. Policy 108 has been reorganized as a result of restructuring the OHSRP.	**SOP 23, section 23.1.** – *NIH is committed to ongoing evaluation and improvement of the Human Research Protection Program (HRPP).* The OHSRP oC&T is a new office. This was previously the responsibility of the OHSRP.
Section E.1.a*. – Conducting ongoing, periodic quality assessments to assess the effectiveness of the NIH IRB and the activities of the IRBO. These may include:* *I. A random sampling of protocols;* *II. A selection of studies using a risk-based approach; and/or*	**SOP 23, section 23.5.3.K.** – *Develops standards and procedures for evaluation of NIH IRB operations as well as the performance of IRB Chairs, members, and IRB staff, as indicated in SOP 26 - Evaluation of NIH IRB Chairs, Vice Chairs and Members, IRB Administrative Staff and IRB Committee Activities.* See *Policy 101 Organizational Structure of the OHSRP* for information about evaluation of IRB

III. A review of documentation or observation of a meeting. Policy 108 has been reorganized as a result of restructuring of the OHSRP.	members and Chairs, this is now the responsibility of the NIH IRB Executive Chair. The requirements for OHSRP QAQI of IRB and IRB operations are unchanged. Policy 108 adds specificity for clarity.
Section E.1.b. – *Conducting a directed QA/QI review at the request of NIH HRPP leadership to provide an assessment of IRB compliance. This review may be a comprehensive or targeted review of IRB compliance.* AND ***Section E.1.c. –*** *Managing the activities related to the QA/QI program, including … auditing of IRB and IRBO activities consistent with relevant federal regulation and policy (including NIH policy), using objective measures to assess quality and efficiency of the program.* Policy 108 reflects the restructuring of the OHSRP.	**SOP 23, section 23.5.3.A.** – *Works closely with IC QA personnel to assist when an IC or IRB identifies a need for a QA review.* There is no change in this responsibility under Policy 108. Policy 108 adds specificity for clarity.
Section E.1.d. – *Enhancing educational opportunities based on QA/QI review findings of QA/QI assessments and to provide ongoing education and assistance to NIH investigators, the IRB, and IRBO.* Policy 108 adds flexibility in how educational program and tools are delivered by removing reference to website dissemination.	**SOP 23, section 23.5.3.E.** – *Develops educational programs/announcements for investigators and their research staff, via website, to disseminate formal and informal guidance.* There is no change in this responsibility under Policy 108.
Section E.1.e – *Soliciting feedback from NIH investigators and Institute/Center (IC) leadership …, and encouraging NIH investigators to communicate concerns or suggestions.* Soliciting feedback from NIH investigators and IC leadership was not addressed in SOP 23.	N/A
Section E.2. – *The NIH IRB Executive Chair or the Director of the IRBO is responsible for:* *a. Providing timely written responses to each QA/QI review finding regarding evaluations of the IRB or the IRBO, respectively.*	**SOP 23, section 23.5.6.A** – *The IRBs, Institutes/Centers and/or OHSRP develop corrective plans as needed in response to findings of internal and external investigations and inspections.*

Policy 108 reflects the restructuring of the OHSRP and centralization of the NIH IRB and IRB operations in IRBO.	
Section E.3. – *The Director of the OHSRP and the Institutional Official (IO), as representatives for the Institution, are responsible for reviewing QA/QI review findings and taking all appropriate actions to remediate any identified non-compliance.* There is no change in this responsibility under Policy 108.	**SOP 23, section 23.5.7.E.** – *OHSRP, IRBs or an institutional official receive, investigate and respond to allegations of non-compliance.*