Policy Number: 108

**SOP Title:** OHSRP Quality Assurance and Quality Improvement Program

**Distribution:** Scientific Directors; Clinical Directors; Clinical Investigators, IRB Chairs, IRB Administrators, Protocol Navigators

**Revision Approval:**

[Signature]

Deputy Director for Intramural Research

11/19/2019

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POLICY

A. PURPOSE

1. 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.

B. SCOPE

1. This policy applies to OHSRP, including its Office of IRB Operations (IRBO), and to the NIH IRB.

C. POLICY

1. The OHSRP office of Compliance and Training will conduct periodic quality assessments of the NIH IRB and the IRBO to ensure compliance with federal regulation and policy. (See e.g., 45 CFR 46 and, as applicable, 21 CFR parts 50, 56, 312, and 812.)

D. DEFINITIONS

1. **Quality Assurance (QA)** – A systematic evaluation of program functions to maximize the probability that quality standards are being attained. In the context of Policy 108 Quality Assurance and Quality Improvement Program for the NIH IRB, this means auditing the NIH IRB to determine whether they are effectively meeting established NIH policies and regulatory requirements. QA includes a systematic and independent examination of IRB related activities and documents, including IRB operations.

2. **Quality Improvement (QI)** – The effort to take measures to improve the level of performance of a program, process, or institution.

3. **Quality Assurance/Quality Improvement Review (QA/QI Review)** (For the purposes of Policy 108 Quality Assurance and Quality Improvement Program for the NIH IRB) – A comprehensive, systematic, and independent assessment of the NIH IRB regarding protocol review and approval as well as review of documentation of IRB activities. Such reviews may result in identification of measures that need to be taken to improve IRB compliance, performance, and quality. The types of QA/QI reviews established by the QA/QI program are defined below:
   a. **Routine**: A planned periodic QA/QI review to provide a regulatory assessment of the activities of the IRB. The selection of studies uses a random or risk-based approach and may include such factors as study risk, enrollment of vulnerable populations, and...
degree of external oversight. These reviews may also include attendance by the QA/QI reviewer at a convened IRB meeting(s).

b. **Directed**: A comprehensive or targeted QA/QI review requested by NIH HRPP leadership to provide an assessment of IRB compliance. The review may be focused on one aspect of the IRB review or a broader review of the IRB.

4. **Review Finding** – A noted deficiency during a QA/QI review.

E. **RESPONSIBILITIES AND REQUIREMENTS**

1. The OHSRP office of Compliance and Training is responsible for QA/QI reviews of NIH IRB and IRBO activities. (See Policy 101 Organizational Structure of the OHSRP.) This office is responsible for the following activities related to QA/QI:

   a. Conducting ongoing, periodic quality assessments to assess the effectiveness of the NIH IRB and the activities of the IRBO (see C.1. above). These may include the following:

      I. A random sampling of protocols;
      II. A selection of studies using a risk-based approach; and/or
      III. A review of documentation or observation of a meeting.

   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. (See Policy 100 NIH Intramural Research Program’s Human Research Protection Program for a description of HRPP leadership.)

   c. Managing the activities related to the QA/QI program, including but not limited to preparing, planning, and/or executing routine or directed 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. Some of these activities may be coordinated with other offices or contracted out under the direction of this office.

   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 to:

      I. Facilitate the sharing of best practices;
      II. Develop and encourage the use of tools to facilitate compliance with federal regulation and policy; and
III. To improve investigator research practices for the protection of human subjects participating in research.

e. Soliciting feedback from NIH investigators and Institute/Centers (IC) leadership regarding the IRB and IRBO activities, and encouraging NIH investigators to communicate concerns or suggestions directly with appropriate entities within the OHSRP regarding IRB activities.

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.

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. (See Policy 802 Non-Compliance in Human Subjects Research.)

F. REFERENCES

1. Regulation
   HHS: 45 CFR 46
   FDA: 21 CFR parts 50, 56, 312, and 812

2. Policy
   Policy 100 NIH Intramural Research Program’s Human Research Protection Program
   Policy 101 Organizational Structure of the OHSRP
   Policy 802 Non-Compliance in Human Subjects Research

3. Guidance: None

G. APPENDICES: NA

H. REVISION HISTORY: NA

I. SUPERSEDES DATE: 11/02/2020

   SOP 23 - Quality Management System for the NIH
   HRPP