NIH Policy Manual

3014-108 - OHSRP Quality Assurance and Quality Improvement Program

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

Release Date: 11/19/2019 ? **Technical Revision Date:** 11/16/2022 ?

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 (IRP). This policy describes the quality assurance (QA) and quality improvement (QI) program of the OHSRP, including the NIH Institutional Review Board (IRB). Upon implementation, this policy fully supersedes the *SOP 23-Quality Management System for the NIH HRPP*.
2. **Filing Instructions:**

    - **Insert:** NIH Manual Chapter 3014-108, dated 11/19/2019
    - **Implementation Date:** 11/02/2020

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 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 regulationand policy. (See e.g., 45 CFR 46 and, as applicable, 21 CFR parts 50, 56, 312, and 812.)

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. Quality Assurance (QA)
2. Quality Improvement (QI)
3. Quality Assurance/Quality Improvement Review (QA/QI Review) (For the purposes of Policy 3014-108 Quality Assurance and Quality Improvement Program for the NIH IRB)
4. Review Finding

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 3014-101 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 *D.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 3014-100 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/Center (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 3014-802 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 3014-100 NIH Intramural Research Program's Human Research Protection Program

Policy 3014-101 Organizational Structure of the OHSRP

Policy 3014-801 Non-Compliance in Human Subjects Research

3. Guidance: None