8.5 Noncompliance by the IRB or Other Components of the HRPP

1.0 Purpose

The purpose of this policy is to describe the process for reviewing and reporting incidents of noncompliance by the IRB and/or other components of the HRPP.

2.0 Policy

It is the policy of the Organization that:

- 2.1. Reports of noncompliance with Federal Regulations related to human subjects research or HRPP policies by the IRB or other components of the HRPP shall be reviewed, investigated and reported as outlined below
- 2.2. Findings of serious or continuing noncompliance will be reported to OHRP, FDA and sponsors or funding agency heads in accordance with the requirements of 45 CFR 46.108(a)(4) and 21 CFR 56.108(b), and the Organization's Federalwide assurance, as specified in HRPP policy 8.7 (Reporting Incidents to Institutional Officials and Federal Agencies).

3.0 Definitions

- 3.1. Noncompliance by the IRB or other components of the HRPP is defined as failure to follow federal regulations (including but not limited to 45 CFR 46, and applicable subparts, or 21 CFR 50, 56), HRPP policies, and/or Organizational policies. Noncompliance may be serious and/or continuing, or neither serious nor continuing.
  - 3.1.1. Serious noncompliance by the IRB or other components of the HRPP is defined as a violation of federal regulations, HRPP policies, and/or Organizational policies which (a) significantly increases the risk to subjects, or otherwise compromises the rights and welfare of research subjects, or (b) places the Organization at risk of significant regulatory, financial or reputational harm.
  - 3.1.2. Continuing noncompliance by the IRB or other components of the HRPP is defined as (1) repeated incidents of the same or substantially similar noncompliance, after the IRB or other component has been notified that the action represents non-compliance, or despite appropriate retraining and/or specific corrective action, or (2) repeated incidents of the same or substantially similar noncompliance of such a nature that the IRB or other component of the HRPP should have reasonably been expected to know that such an action was noncompliance.

4.0 Responsibilities of the ORA, Chief Compliance Officer (CCO) and Institutional Official (IO)

- 4.1. Upon receipt of a report of noncompliance attributable to any component of the HRPP:
  - 4.1.1. The ORA will conduct the initial investigation. Additional information will be obtained from the reporter, ORA or HRPP records, and/or from other sources as appropriate.
  - 4.1.2. If the initial investigation does not confirm that noncompliance occurred, the ORA will prepare a report to the CCO describing the allegation, and explaining why it does not represent noncompliance. The CCO may accept the report and notify the IO and IRB, or may request clarification or additional information, or may conduct further investigation.
  - 4.1.3. If the initial investigation confirms that noncompliance occurred, the Executive Chair of the IRB, the Assistant Vice Chancellor for Regulatory Affairs or designee will prepare a report to the CCO describing the noncompliance. The report will classify the noncompliance as minor, serious and/or continuing and include a proposed corrective action plan (CAP) as appropriate.
  - 4.1.4. The CCO may:
    • Accept the report and CAP as proposed
    • Request modifications to the CAP
    • Request clarification or additional information
    • Conduct further investigation
  - 4.1.5 Upon conclusion of the investigation of noncompliance, a report of the noncompliance and the CAP will be presented to the IRB, IO and other organizational officials as appropriate.
- 4.2. The IRB Executive Chair/designee and/or CCO, as appropriate, will initiate all necessary

action(s) to ensure that human subjects are fully protected, and the interests of the Organization are appropriately considered.
- 4.3. A record of the report and actions taken under this policy will be maintained by the ORA.

5.0 Reporting Noncompliance to Organizational Officials, OHRP, FDA and Department or Agency Heads

All required reports will be submitted in accordance with HRPP policy 8.7 (Reporting Incidents to Institutional Officials and Federal Agencies).

DOCUMENT HISTORY:

Written: 1/20/2016 (Approved: 1/20/2016) - original author not recorded

Revised: 1/11/2018 - revision not documented

Revised: 3/7/2023 – revised definitions; clarified that the ORA will conduct initial evaluation and pass recommendations to CCO; simplified throughout; stylistic changes.{Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

Revised: 5/9/2023 – Deleted reference to “minor” non-compliance and substituted “neither serious nor continuing”; revised definition of serious non-compliance to include putting Organization at risk of significant regulatory, financial or reputational harm; revised definitions of serious non-compliance and continuing non-compliance to delete parts of the definition more appropriate for PI or research staff non-compliance; clarified possible actions of CCO.{Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

Revision #6
Created Thu, Oct 24, 2019 9:45 PM by Autumn M Eberly
Updated Fri, May 19, 2023 1:02 AM by Robert A Lewis