8.7 Reporting Incidents to Institutional Officials and Federal Agencies

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements to ensure prompt reporting of incidents to Institutional Officials, Federal Agencies (including OHRP and FDA) and other Common Rule Departments and Agencies, and to AAHRPP.

2.0 Policy

It is the policy of the Organization that:

- 2.1. Unanticipated problems involving risk to the subject or others (UPs), serious or continuing noncompliance, suspensions of IRB approval, and terminations of IRB approval will be promptly reported to the Institutional Official (IO).
- 2.2. Unanticipated problems involving risk to the subject or others (UPs), serious or continuing noncompliance, suspensions of IRB approval, and terminations of IRB approval related to research subject to 45 CFR 46 and/or FDA regulations be reported to OHRP, FDA, and other Common Rule Department or Agencies, in accordance with 45 CFR 46.108(a)(4) and 45 CFR 46.113, and 21 CFR 56.108(b) and 21 CFR 56.113 as applicable.
- 2.3. Unanticipated problems involving risk to the subject or others (UPs), serious or continuing noncompliance, suspensions of IRB approval, and terminations of IRB approval related to research not subject to 45 CFR 46 and/or FDA regulations, will be reported to OHRP and funding agencies at the discretion of the Institutional Official.
- 2.4. The Organization will report to AAHRPP as soon as possible (but generally within 48 hours) after the Organization becomes aware of: (1) any negative actions by a government oversight office related to human research protections; (2) any litigation, arbitration, or settlements initiated related to human research protections; and (3) any press coverage of a negative nature regarding the Organization's HRPP.

3.0 Definitions

- 3.1. Unanticipated Problems Involving Risk to the Subject or Others: as per HRPP policy 8.3 (IRB Review of Unanticipated Problems Involving Risk to the Subject or Others).
- 3.2. Serious Noncompliance: as per HRPP policies 8.4 (Noncompliance Involving the PI and Study Personnel) and 8.5 (Noncompliance by the IRB or Other Components of the HRPP).
- 3.3. Continuing Noncompliance: as per HRPP policies 8.4 (Noncompliance Involving the PI and Study Personnel) and 8.5 (Noncompliance by the IRB or Other Components of the HRPP).
- 3.4. Suspension of IRB Approval of Research: as per HRPP policy 8.6 (Study Hold, Suspension, and Termination).
- 3.5. Termination of IRB approval of Research: as per HRPP policy 8.6 (Study Hold, Suspension, and Termination).

4.0 IRB/ORA Responsibilities

- 4.1. The IRB Executive Chair/designee will submit all required written reports to the IO promptly (as appropriate in consideration of the nature of the event but no longer than 30 days following determination that the event is a reportable incident). Follow-up reports will be provided as necessary in conjunction with ongoing investigations.

5.0 Institutional Responsibilities

- 5.1. For research subject to the 45 CFR 46, the IO will submit all required written reports to OHRP and Department or Agency heads as appropriate promptly (as appropriate in consideration of the nature of the event but no longer than 30 days following determination that the event is a reportable incident). Follow-up reports will be provided as necessary in conjunction with ongoing investigations.
- 5.2. For research subject to FDA regulations, the IO will submit written reports to FDA promptly (as appropriate in consideration of the nature of the event but no longer than 30 days following determination that the event is a reportable incident). Follow-up reports will be provided as

necessary in conjunction with ongoing investigations.

- 5.3. For research neither subject to 45 CFR 46 nor subject to FDA regulations, written reports may be submitted to FDA and/or OHRP and Department or Agency heads, at the discretion of the IO. The decision to report will be made by the Institutional Official after due consideration of recommendations of the IRB and the IRB Executive Chair.
- 5.4. Copies of the report (including any additional materials submitted to FDA, OHRP or Department or Agency heads) will be made available to the PI after submission.
- 5.5. Reporting events which occur at institutions not under the jurisdiction of the UNMC IRB are the responsibility of the external institution.
- 5.6. Reporting of events which occur at other institutions when UNMC acts as the reviewing IRB for that institution will be reported either by UNMC or by the relying institution, as described in HRPP Policy 1.3 (UNMC IRB Serving as the Single IRB for Multisite Research) and per the terms of the reliance agreement.

6.0 Investigator Responsibilities

- 6.1. For Federally funded research, it is the responsibility of the PI to notify the federal department or agency sponsoring the research. Any expenditure of federal funds during research which is not in compliance with federal regulations is prohibited. Verification of this notification must be provided to the IRB.
- 6.2. For commercially sponsored research, it is the responsibility of the PI to notify the sponsor and the Contract Research Organization (as applicable) and provide verification of this notification to the IRB.

7.0 Contents of Reports

- 7.1. Reports to the IO, OHRP, FDA and Common Rule Department or Agencies must include the information described in OHRP document “Guidance on Reporting Incidents to OHRP (2011)”, or any succeeding guidance.
- 7.2. Reports to FDA must also include IND or IDE number, if applicable.

8.0. Reports to AAHRPP

- 8.1. The ORA will report to AAHRPP as soon as possible but generally within 48 hours after the organization or any researcher (if the researcher is notified rather than the organization) becomes aware of:
  - 8.1.1. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
  - 8.1.2. Any litigation, arbitration, or settlements initiated related to human research protections.
  - 8.1.3. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization’s HRPP.
- 8.2. Investigators and research teams are responsible for notifying the ORA if they become aware of any of the actions noted above.

Document History:

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

Revised: 2/2/2018 - revision not documented

Revised: 8/15/2022 - Clarified that IO may (but is not required to) report incidents or noncompliance or UPs not associated with Federally funded research to Federal agencies; clarified that decision by the IO to report is made after due consideration of recommendations of the IRB, and in consultation with IRB Executive Chair and Organizational officials; clarified that copies of the report will be made available to the PI after submission to the agencies; referenced HRPP 1.3 for reporting of incidents where UNMC is the IRB of record for other relying sites; reorganized lists of responsibilities for clarity. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

Board notified: 1/16/2023

Revised: 8/1/2023 – added sections 2.4 and 8.0 regarding notification to AAHRPP.{Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

Revision #7
Created Thu, Oct 24, 2019 9:45 PM by Autumn M Eberly
Updated Mon, Aug 28, 2023 9:36 PM by Robert A Lewis