8.2 Review of Study Related Complaints

1.0 Purpose

The purpose of this policy is to describe the process for reporting research related complaints to the ORA and the IRB, and the process for review of complaints.

- 1.1. For the purposes of this policy “complaints” includes problems, concerns, or questions raised by current, prospective, or past research participants or their representatives regarding their participation in human subject research. Complaints by research personnel or other interested parties regarding the functioning of one or more components of the HRPP will be addressed as per HRPP Policies 1.22 (Assessment of the HRPP) and/or HRPP Policy 8.5 (Noncompliance by the IRB or Other Components of the HRPP).

2.0 Policy

It is the policy of the Organization that:

- 2.1. Complaints involving the human research protection program be promptly reported to the ORA and to the IRB.
- 2.2. Complaints under the jurisdiction of the IRB will be investigated and resolved as appropriate and reported to Organizational officials.
- 2.3. Findings of serious or continuing noncompliance and suspensions or terminations of IRB approval as a result of a complaint will be promptly reported to OHRP, FDA and sponsors or funding agency heads in accordance with HRPP policy 8.7 (Reporting Incidents to Institutional Officials and Federal Agencies).

3.0 Complainant (or Other Reporters’) Responsibilities

- 3.1. Complaints from current, prospective, or past research participants or their representatives may be received by the Principal Investigator, other investigators, study staff, IRB members, IRB staff, the Research Subject Advocate, or any other Organizational officials.
- 3.2. Complaints may also be received through the IRB website, utilizing the “Report a Problem or Complaint” tab, or University of Nebraska’s ethics hotline EthicsPoint.
- 3.3. Any complaint that is received by the investigator or study staff that involves risk to participants or others, or changes the risk-benefit profile of the study, or which cannot be resolved by the investigator must be promptly reported to the ORA.
- 3.4. Any complaint that is received by the investigator or study staff that does not involve risk to participants or others, or does not change the risk-potential benefit profile of the study, and that is resolved by the investigator should be submitted in a summary format to the IRB at continuing review.

4.0 ORA Responsibilities

- 4.1. Complaints received by the ORA, or reported to the ORA by the investigators will be reviewed by the IRB Executive Chair and/or IRB Analyst. Complaints found not to relate to human subject research will be referred to the appropriate office (for example, to Nebraska Medicine or CHMC Patient Relations, or to UNMC or UNO Compliance Office).
- 4.2. Complaints related to human subject research will be further reviewed by the appropriate IRB Analyst. Additional information will be obtained from the complainant, the study documents, the investigator or research staff, or from other sources as appropriate. Based on this initial review, in consultation with the Executive Chair or designee, the IRB Analyst will determine:
  - 4.2.1. Whether the complaint represents an allegation of non-compliance, an adverse event, or an unanticipated problem involving risk. If so, the complaint will be handled in accordance with HRPP policy 8.1 (IRB Review of Adverse Events or Adverse Device Effects), HRPP Policy 8.3 (IRB Review of Unanticipated Problems Involving Risk to the Subject or Others), or HRPP Policy 8.4 (Review of Noncompliance Involving the PI and Study Personnel).
  - 4.2.2. Whether the complaint involves risk to participants or others, or changes the risk-benefit profile of the study. If so, the complaint will be reported and reviewed by the full IRB at a convened meeting {HRPP policy 2.2 (Full IRB Review)}.
  - 4.2.3. Whether additional actions need to be taken immediately to protect the rights and

welfare of human subjects, in accordance with HRPP policy 8.6 (Study Hold, Suspension, and Termination).
- 4.3. The IO will be notified of all complaints which involve risk to participants or others, or which change the risk-benefit profile of the study.
- 4.4. The PI and other involved individuals will be promptly notified of the concerns expressed in the complaint, unless such notification would compromise handling of the complaint.

5.0 IRB Responsibilities

- 5.1. Complaints that do not involve risk to participants or others, or do not change the risk-benefit profile of the study are reported to the IRB (either at the time of continuing review, or as a special notification item).
- 5.2. Complaints that involve risk to participants or others, or change the risk-benefit profile of the study, or which cannot be resolved by the investigator will be reviewed by the full IRB at a convened meeting. The IRB will determine:
  - 5.2.1. Whether the complaint constitutes noncompliance per HRPP policy 8.4 (Review of Noncompliance Involving the PI and Study Personnel).
  - 5.2.2. Whether the complaint constitutes an unanticipated problem involving risk per HRPP policy 8.3 (IRB Review of Unanticipated Problems Involving Risk to the Subject or Others).
  - 5.2.3. Whether the research continues to satisfy the criteria for approval under 45 CFR 46.111, 21 CFR 56.111, and HRPP policy 2.5 (Criteria for IRB Approval).
  - 5.2.4. Whether further actions are necessary to protect the rights and welfare of human subjects. Such actions may include (but are not limited to):
    - 5.2.4.1. Requiring modification of the research protocol or the consent form
    - 5.2.4.2. Notification of current participants if such information may relate to participants' willingness to continue to take part in the research, with or without requiring re-consent.
    - 5.2.4.3. Requiring additional information be provided to past participants.
    - 5.2.4.4. Modification of the continuing review schedule.
    - 5.2.4.5. Monitoring of the research or the consent process.
    - 5.2.4.6. Study hold, suspension or termination.
    - 5.2.4.7. Referral to other organizational entities.

6.0 Reporting Complaints 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).

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Revised: 1/18/2023 - Clarified definition of "complaints"; noted additional policies related to complaints by research personnel or other interested parties regarding the functioning of one or more components of the HRPP; clarified that the ORA only investigates complaints related to human subjects research; added that complaints that do not involve risk to participants or others, or do not change the risk-benefit profile of the study are reported to the IRB (either at the time of continuing review, or as a special notification item); added comment that all required reports will be submitted to Institutional Officials and Federal Agencies in accordance with HRPP policy 8.7; reorganized sections; stylistic changes.{Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

Revised: 5/8/2023 - Changed "IRB Administrator" to "IRB Analyst"{Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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