TITLE: Institutional Review Board Review of Research
RR 411 Participant Complaints

POLICY STATEMENT: The purpose of this policy is to establish procedures for handling concerns/complaints received by the Office of the Institutional Review Board (IRB) regarding research involving human subjects. The right of research participants to lodge a concern/complaint and to be assured that the concern/complaint is taken seriously and resolved in a timely manner is of prime importance. The IRB Chairperson is responsible for investigating all concerns/complaints from subjects and any improprieties involving investigators or their staff. Concerns/complaints are handled in a timely manner, assuring protection of human subjects and holding any violators accountable to the applicable regulation. A research subject (past, current or prospective), a designated spokesperson, family member or anyone with a concern about a human research study may raise concerns/complaints about a research project by telephone, in writing, or in person to the IRB Chairperson.

GENERAL PROVISIONS:

A research participant or anyone with a concern/complaint regarding a research study involving human subjects may raise the concern/complaint. The complainant may contact the study coordinator, the principal investigator or the Office of the IRB to express their concerns. The receiver of the complaint should provide the options for reporting a concern or complaint. Complainants may choose to report their concern or complaint by phone to the IRB Chairperson, by email to the Office of the IRB research complaints email address, or by completing the online Form for Research Concerns or Complaints.

Upon receipt of a completed concern/complaint, the study coordinator, Principal investigator or Office of the IRB staff member must immediately notify the IRB Manager of the complaint. In all scenarios, the IRB Chairperson is to receive a notification of the initial complaint as soon as possible after receipt of the complaint.

Participants are to be informed they have the option of contacting the Office of the IRB directly if they have a complaint that involves the study coordinator or principal investigator. If a participant chooses to use this avenue for voicing their complaint, the recipient of the phone call informs the complainant that they are transferring their call to the IRB Manager.

1. The IRB Manager gathers the following information from the complainant:
   - Contact Information for individual reporting the complaint (e.g. Subject’s or complainant’s name, address, and phone number). This information is not mandatory, and a caller may report an incident anonymously; however, the IRB Manager advises the caller that a thorough review may not be possible, and that, without this information, follow-up responses to the subject are not feasible.
   - A summary of the incident
   - Name or description of the study
   - The study contact at our organization
   - Details about who the reporting individual has contacted
   - Details about the individuals study status and experience
   - Details about the desired outcome of this complaint
Institutional Policy & Procedure

2. The subject is assured that an inquiry into the circumstances will be undertaken and that the IRB and other parties will take appropriate measures to address the issue. The subject is informed that a response will be forthcoming as rapidly as possible provided that contact information is given (i.e. if possible, within 2 to 3 weeks of the complaint). The limits to confidentiality are also explained to the subject at the time the issue is reported.

3. Concerns/complaints are handled in a confidential manner to the extent allowed by law. The IRB limits access to information concerning the complaint to employees with responsibilities that require knowledge of the concern/complaint. The IRB Manager notifies the IRB Chairperson of the complaint.

4. The IRB Manager conveys the information regarding the concern/complaint to the PI of the study, legal counsel and others as necessary (e.g. Institutional Official, IRB Coordinator, Legal, Risk and Compliance Department) in a timely manner.

5. The IRB Manager promptly investigates the concern/complaint, evaluates the alleged impropriety on a case-by-case basis, and makes every effort to correct the issue(s) at the administrative level.

6. If the alleged impropriety involves potential harm to subjects or others, the IRB Chairperson (or designee) notifies the IRB for immediate action pending formal inquiry. The IRB Manager reports concerns/complaints involving serious issues immediately to the Institutional Official, Legal Counsel and the Institutional Review Board.

7. The IRB Specialist/IRB Coordinator assists in managing the inquiry, preparing related correspondence, and maintaining documentation of the review for up to seven years from completion of the inquiry or closeout of the IRB file, whichever is longer.

8. The IRB Manager, in collaboration with the IRB Specialist/IRB Coordinator and IRB Chairperson, ensures appropriate response to each complaint and reports the action(s) taken to the IRB. If the complaint or concern is of a minor nature such as a payment issue, the issue may be resolved without bringing it forth for an IRB committee vote. The IRB Manager refers major issues such as failure to acquire signed informed consent forms from potential subjects (if required), to the IRB Chairperson so it may be presented to the IRB. Any actions by the IRB are voted on. All actions taken are at the institutional level and appropriate for the circumstances, and the final course of action is entirely dependent on the nature, severity, and degree of seriousness of the findings.

9. Depending on the nature of the event or circumstances, actions that may be taken include but are not limited to:
   • Further inquiry;
   • Administrative action;
   • Details and recommendations forwarded to the appropriate committee Chairs (e.g., IRB, Conflict of Interest, ethics or an IRB assigned review Committee) for consideration in their committees;
   • Details and recommendations forwarded to the appropriate department leadership for action as appropriate;
   • Details and recommendations forwarded to the Executive Director of Research and Innovation, and/or Legal Counsel for action;
   • Notification to the FDA, OHRP or other regulatory bodies as required by Federal Regulations.
   • Details and recommendations forwarded to the appropriate officials at affiliated institutions for notification, action, and/or follow-up, if applicable;
   • Other actions as deemed appropriate.

10. The IRB will monitor any concerns/complaints that are received for issues of non-compliance and/or serious non-compliance. The IRB Chairperson brings issues involving noncompliance to the attention of the IRB Committee and the Institutional Official.

REFERENCES:
   45 CFR 46.101
   21 CFR 56. 104, 105

ATTACHMENTS:
RR 411 A- Research Form for Research Concerns or Complaints
<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
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<tbody>
<tr>
<td>IRB Coordinator/IRB Specialist</td>
<td>1. Provide oversight of research complaint email inbox.</td>
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<tr>
<td></td>
<td>2. Distribute incoming complaints to IRB Manager.</td>
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<td></td>
<td>3. Maintain and make available to appropriate parties information collected during the complaint review process.</td>
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<td></td>
<td>4. Assist in the organization of documentation gathered during the complaint review process.</td>
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<td></td>
<td>5. Assist in the review of complaints and other tasks as designated by IRB Chairperson and/or IRB Manager.</td>
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<tr>
<td>IRB Manager</td>
<td>1. Review the complaint and route through complaint review process involving appropriate parties as described in the policy.</td>
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<tr>
<td>IRB Chairperson</td>
<td>1. Responsible for ensuring complaint is properly reviewed and resolved.</td>
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<tr>
<td>Institutional Official</td>
<td>1. Refer complaints that are considered non-compliance to the Federal authorities as required by federal regulations.</td>
</tr>
</tbody>
</table>

CONCURRENT CONSENTS:

Institutional Official

[Signature]