3.9 Subject Complaints

3.9.1 Purpose

The purpose of this procedure is to establish the process to manage subject inquires and complaints. This procedure lays out the steps undertaken by the Institutional Review Board (IRB) after notification of a complaint and follows through to its resolution.

3.9.2 Policy

All subject inquiries/complaints are referred to the University's IRB, including complaints reported by the site/sponsor via a continuing review form or a promptly reportable information form or other method.

A subject inquiry or complaint includes an inquiry or complaint by a third party on behalf of a subject.

Initial reviews of new subject inquiries/complaints are to be completed within four work hours of receipt. Complainants are to be contacted within 24 hours of receipt of their inquiry/complaint.

3.9.3 Responsibility

The IRB is responsibility for the actions set forth in this procedure.

3.9.4 Procedure

a) If the call or email is concerning a complaint, follow the process outlined below, but if the contact is just a simple inquiry from a subject/subject's representative, it is acceptable to respond to the inquiry and consider the issue resolved.

b) Verify that the complaint is not a duplicate.

c) Create a new subject complaint record and record on-going progress and resolution in the record, including association of any documents received, such as e-mails or faxes.

d) Contact the complainant to discuss the reported issue.
   - Inform the complainant of the role of the IRB and ask the complainant what their expectation is for the IRB to assist in resolving concern.
   - As appropriate, gather information as necessary from the complainant; e.g., subject number, e-mail address, cell phone number, work number, etc.
   - Ask the complainant for permission to contact the site on their behalf.
   - Ask the complainant if his or her name can be used when the site is contacted.
   - Ask whether the complainant wishes to be advised when contact has been made with the site and the sponsor/ contract research organization (and institution, if applicable), and the anticipated next steps.

e) Assess the situation and identify any possible past reported complaints associated to the same research staff and or site to determine if there is a pattern of reported subject complaints.

f) If permitted by the complainant, contact the site.
   - Outline the nature of the call.
   - Explain that the sponsor/ contract research organization will likely be appraised of the call.

g) Notify the sponsor/contract research organization of the complaint.

h) If the study has dual or split IRB oversight, notify the other IRB that a subject complaint has been received.

i) If the investigator is at an institution for which the University is providing IRB services, notify the institution's contact.

j) If the institution, sponsor/contract research organization, or other third parties authorized by Legal Counsel asks for a copy of the complaint, provide a copy and redact private information unless authorized by the complainant and requested by the requestor.

k) Work with the involved individuals to resolve the complaint.

l) If requested by the complainant, advise the complainant when contact has been made with the site and the sponsor/Chief Research Officer (CRO) (and institution, if applicable), and the anticipated next steps.

m) If appropriate, ask the sponsor/CRO (and institution, if applicable) to keep the IRB informed of steps being taken to resolve the complaint.
   - If the complaint remains unresolved, review every 15 days and record any actions taken or reasons why the complaint remains open.
   - If the complaint remains unresolved for 30 days, discuss with the Provost or CRO how to proceed.

n) If appropriate, draft a written response.
   - Consider the privacy issues involved and the wishes of the complainant, CRO and sponsor.
   - When appropriate draft separate responses to the investigator, sponsor/CRO, and institution (when applicable) following resolution of the complaint.

References: None

Version Number	Posted Date	Implementation Date	Summary of Changes
Draft	4/19/2023		