14.3 RESEARCH SUBJECTS/FAMILY CONCERNS AND COMPLAINTS

The Institution is committed to the protection of research subjects and their families. Even with the best efforts on the part of investigators and study staff, complaints or concerns may arise as a result of study participation.

Research subjects and their families are encouraged to express concerns at any time to the PI or any other member of the study staff. All consent forms must contain, at a minimum, the contact information for the PI/research staff and the IRB Office. All issues brought forward will be addressed in a timely and thorough manner.

A. Procedure for Addressing Concerns or Complaints

i. When Reported to the PI or other study staff:

a. Any PI, member of the study staff or individual who receives a complaint from a subject/family member must first address the complaint and take the necessary actions for resolution.

b. If the complaint is concerning an event that meets the criteria of an unanticipated problem (i.e., related to the research, unexpected, and could adversely affect the rights or welfare of the participant or others), an Incident report must be submitted through the electronic IRB system. Otherwise, the complaint is to be reported via the Renewal submission.

c. If an Incident report is submitted, the complaint and any action taken by the PI, will be reviewed according to the procedures outlined in Section 13 of this manual. Resolution of the complaint may involve further discussion with the subject/family, the PI, members of the study staff and others as appropriate.

d. The PI is responsible for reporting all subject/family complaints at the time of Renewal.

e. IRB members will be informed of subject/family complaints as appropriate (either via the Incident report or Renewal in the electronic IRB system).

ii. When Reported Directly to ORIC:

a. If the complaint is made directly to ORIC by anyone other than the PI, the Director, ORIC or the IRB Chair will contact the PI to ensure that they are aware of the concern or complaint.

b. The Director, ORIC will review the complaint(s), and in consultation with the PI, recommend a course of action, and steps to be taken to address the issue(s). This may involve discussions with the subject/family, the PI, members of the study staff and others as appropriate. The PI will be advised to report the complaint either via an Incident Report or the Renewal in the electronic IRB system.

c. The subject/family will also be informed that they will be contacted within 10 working days with an update on the inquiry and resolution of the event, if appropriate. If the issue is not resolved within 10 working days, then the subject/family is updated on a weekly basis until resolution.

d. IRB members will be informed of subject/family complaints as appropriate (either via the Incident report or Renewal report in the electronic IRB system).

B. Addressing Concerns and Complaints of Serious or Continuing Non-Compliance

If the complaint reveals concerns related to suspected serious or continuing non-compliance, the event will be referred to the Director, ORIC and IRB Chair, or designee, for initial review. Actions following this initial review (i.e. the need for an investigation, etc.) will be conducted according to the policy as outlined above.

14.4 REPORTS OF UNAUTHORIZED DISCLOSURE OF PHI

Investigators and research staff also have a responsibility to report all unauthorized disclosures of protected health information (PHI) protected under HIPAA (i.e., individually identifiable health information that contains one or more of the 18 identifiers). The ORIC staff will consult with the Privacy Office to assess and mitigate the disclosure. A disclosure determined to be a breach would be considered serious noncompliance and processed as outlined above.