POLICY: Subject Complaints and Allegation of Non-compliance

1. PURPOSE

1.1. This procedure establishes the process to manage subject complaints, and allegations of non-compliance with study procedures.
1.2. This procedure begins when the Assistant Director of IRBs is made aware of a subject complaint or alleged non-compliance issue(s).
1.3. This procedure ends when all applicable actions and resolutions have been implemented to address a subject complaint or alleged non-compliance issue(s).

2. POLICY

2.1. All complaints regarding study conduct are referred to the Assistant Director of IRBs or designee.
2.2. Complaints or allegations of non-compliance can be submitted to the IRB by a third party on behalf of a subject, by study staff, or others (hereby referred to as complainants). Regardless of how the IRB receives the allegation or complaint, they are all investigated.
2.3. Once the Assistant Director for IRBs receives a new subject complaint or allegation of non-compliance, the initial review will be completed within one business day.
2.4. The PI and/or complainant will be contacted within 3 Business Days following initial review of their complaint.
2.5. Ask for guidance from IRB Chair, IRB Vice Chair, Chair Designee, Director of Research Operations and Services, General Counsel’s Office, Self-Insurance Trust Fund, or Institutional Official as needed.

3. RESPONSIBILITY

3.1. The Assistant Director of IRBs or designee performs these procedures.

4. PROCEDURE

4.1. Contact the PI and, unless the complaint is anonymous, the complainant to discuss the reported issue.
   4.1.1. Gather information as necessary from the subject or complainant, i.e. subject number, study number or title, e-mail address, mailing address, cell phone number, work number, etc.
   4.1.2. Ask the complainant if his or her name can be used when the involved parties are contacted.
   4.1.3. Ask whether the complainant wishes to be advised when contact has been made with involved parties, and the anticipated next steps.
4.2. Assess the situation (review of IRB approved submission, protocol, consent and other relevant documents) and identify any possible past reported complaints associated to the same research staff and or site to determine if there is a pattern of similar complaints or allegations
   4.2.1. Outline the nature of the call.
   4.2.2. The Assistant Director or designee may provide a copy of any written complaint to the investigator.
4.3. If regulatory non-compliance is confirmed, instruct the investigator to submit a Reportable Event to the IRB. Follow "Policy: Reportable Events (HRP-112)".
4.4. Work with the involved individuals to resolve the complaint.
4.5. If serving as the reviewing IRB for a non-local site, notify the relying IRB that a subject complaint or allegation of non-compliance has been received.
4.6. If appropriate, ask the involved parties to keep the IRB informed of steps being taken to resolve the complaint.
4.7. If the complaint remains unresolved, review at least every 15 days and record any actions taken or reasons why the complaint remains open.

4.7.1. If the complaint remains unresolved for more than 30 days, discuss with the Director of Research Operations and Services or Institutional Official.

4.8. If appropriate, draft a written response.

4.8.1. Consider the privacy issues involved and the wishes of the complainant or other involved parties.

4.8.2. When appropriate notify the investigator, sponsor, and institution following resolution of the complaint.

5. REFERENCES

5.1. None