

- 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.