

## **17 Complaints**

The [IRB Director] will promptly handle (or delegate staff to handle), and, if necessary, investigate all complaints, concerns, and appeals received by the IRB Office. This includes complaints, concerns, and appeals from investigators, research participants and others.

All complaints, written or oral (including telephone complaints), and regardless of point of origin, are recorded in writing and forwarded to the IRB Director.

Upon receipt of the complaint, the IRB Director will make a preliminary assessment whether the complaint warrants immediate suspension of the research project. If a suspension is warranted, the procedures in Section 8 will be followed.

If the complaint may meet the definition of non-compliance, it will be considered an allegation of non-compliance according to Section 16.

If the complaint may meet the definition of an unanticipated problem involving risk to subjects or others, it will be handled according to Section 15.

If the complaint is actually a query from a subject regarding study procedures, payments not received, etc., it will be forwarded to the investigator/study team for handling. The investigator/study team will be required to inform the IRB when the matter is closed (and the subject is satisfied with the answer).

Within 3 business days of receipt of the complaint, the IRB Director will generate a letter to acknowledge that the complaint has been received and is being investigated, if the person making the complaint provided contact information.