

Section 17. Complaints

The medical school Hotline is 269.337.6505.

The IRB manager shall promptly address and, if appropriate, investigate all complaints, concerns, and appeals received by HRPP/IRB staff. This includes complaints, concerns, and appeals from investigators, research staff, participants, and any others, by any means of communication.

All complaints, written or oral (including telephone complaints), and regardless of point of origin, are recorded in writing and forwarded to the IRB manager and IRB chair. The IRB manager maintains a log of complaints, and provides regular reports to the IRB director and associate dean for Research Compliance, and a report at least annually to the Institutional Official.

Upon receipt of the complaint, the IRB chair or vice chair makes a preliminary assessment whether the complaint warrants immediate suspension of the research project. If a suspension is warranted, the procedures in Section 8 are followed.

If the complaint meets, or may meet, the definition of non-compliance, it is managed as an allegation of non-compliance according to Section 16.

If the complaint meets, or may meet, the definition of an unanticipated problem involving risk to subjects or others, it is managed according to Section 15.

If the complaint is actually an inquiry from a subject regarding study procedures, such as not receiving a payment, the complaint may be forwarded to the investigator and research staff to address. The investigator and research are required to inform the IRB within two weeks of the management plan, and also when the matter is considered closed including whether the subject is satisfied with the response.

Within five (5) working days of receipt of the complaint, HRPP/IRB staff generate a letter to acknowledge that the complaint has been received and is being investigated, if the person making the complaint provided contact information.