Individuals are encouraged to inform the Institutional Review Board (IRB) when they feel that they may have been harmed or put at risk by their participation in a research study or treated in a way that they find inappropriate. The IRB takes all subject complaints seriously.

Complaints may be identified in a number of ways, including a complaint:
- Made by an individual directly to the IRB office, the Office of Regulatory Affairs, or to another committee, department, or official
- Identified through the IRB continuing review of ongoing research
- Discovered during compliance reviews (post approval monitoring) conducted by the Human Research Liaison office
- Reported by the study sponsor’s monitoring entity

Individuals who wish to report complaints directly to the IRB may do so (e.g., through a telephone call, email). Individuals may report complaints anonymously, if they wish. However, information such as a principal investigator (PI) name and/or study title is needed to identify the research study for corrective actions, if needed.

If a research subject or potential research subject complains to the PI or to any member of the research team, the PI must report the complaint to the IRB.

The IRB chair, in consultation with the Human Research Protection Program (HRPP) director when appropriate, evaluates complaints on receipt and, if needed, arranges for review by the IRB.

Each subject complaint will be evaluated by the IRB chair as possible:
- Unanticipated problem involving risk to subjects or others pursuant to the HRPP Manual 9-1 “Unanticipated Problems Involving Risk to Subjects or Others”
- Noncompliance pursuant to HRPP Manual 9-2 “Noncompliance”

If the IRB chair deems it is warranted to protect subjects, s/he may suspend the research study pending review by the IRB. See HRPP Manual 9-3 “Termination or Suspension of Research.” Once the complaint is reported, the IRB chair will mediate...
discussions between the investigator and the complainant, if applicable, in order to resolve the issue.

When needed, complaints should be reported to the IRB as discussion items. The report to the IRB should be a description of the subject complaint and the actions taken to resolve the issue. The complaint need not be resolved to be brought to the attention of the IRB.

The IRB will discuss the complaint that is brought to their attention and decide what additional action, if any, needs to be taken.

When reviewing complaints, the following should be taken into consideration:

- Was any subject put at risk?
- Was the investigator following the research study’s approved protocol?
- Does this complaint warrant a change in the research study?
- Does immediate action need to be taken?
- Does the IRB need to be consulted to determine appropriate resolution?