

Complaints and Concerns from Research Subjects

Current, former, and prospective research participants may email the Woman's Hospital Research Center at research@womans.org or may call the Human Protections Administrator (HPA) directly with any questions, concerns, or complaints. The HPA will be responsible for handling all complaints and questions about research subjects' rights from current, former, and prospective research subjects. The HPA will record a progress note about the complaint and will notify the Institutional Review Board (IRB) Chair.

The subject should be updated within 72 hours as to the status of their complaint or question. The HPA and IRB Chair will determine how to proceed with the complaint or question based on the nature of the grievance. The subject will be notified via phone and in writing of the resolution of their complaint or question and will be asked to notify the HPA if there are unresolved issues. A copy of this letter to the subject will be filed in the IRB study file and the IRB will be notified of the communication with the research subject at the next meeting.

Other potential actions include notifying and consulting with the principal investigator, forming a committee of IRB members to review the complaint, and consulting the Allegations of Noncompliance or Allegations of Scientific Misconduct policies for guidance on handling a grievance.