



SOP 907: RESEARCH COMPLAINTS AND CONCERNS

PURPOSE

The University of Utah IRB is committed to the protection of research participants. Research participants are encouraged to express any concerns or complaints regarding the involvement in a research study.

SCOPE

This policy applies to human subject research conducted at the University of Utah.

POLICY

Consent documents must include the investigator's contact information for any questions, complaints and/or concerns the participant or legal representative may have about the research or related matters. Consent documents must also include contact information for the IRB office and for the Research Participant Advocate. Such contact information is made available for the reporting of questions, complaints and/or concerns. Information about how to report complaints or concerns is also provided on the IRB website. Additionally, the IRB provides a Participant Survey on the IRB website.

The IRB will investigate all complaints or concerns received regarding human subject research conducted under its jurisdiction. All complaints or concerns will be handled in a confidential manner. This includes any reporting of an alleged violation of investigator compliance.

PROCEDURES

1. Handling of Complaints Received by the IRB

- 1.1. Complaints received by an investigator or members of the research staff must be reported to the IRB according to IRB SOP 901: Unanticipated Problem Involving Risks to Participants or Others.
- 1.2. Complaints directly reported to the IRB will be documented using the Report Form for Research Concerns or Complaints and handled according to IRB SOP 901: Unanticipated Problems Involving Risks to Participants or Others.
- 1.3. The IRB Director, an IRB Administrator, or designee will attempt to find a suitable resolution and response to the complaint or concern in a timely manner. As necessary, complaints may be brought to the IRB Executive Committee for discussion and recommendations.
- 1.4. If the concern or complaint involves possible non-compliance or research misconduct, the complaint will be handled according to IRB SOP 903: HRPP and Non-Compliance.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.