



Title:	Questions, Concerns, or Complaints from Research Participants or Third Parties		
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1 PURPOSE

- 1.1. UNC-CH is committed to protecting the rights, safety and welfare of research participants. Consistent with this commitment, this SOP establishes the procedures for handling questions, concerns or complaints from subjects or third party.

2 RESPONSIBILITY

- 2.1 Investigators are responsible for following the requirements described in 3.1 and 3.4 of this SOP.
- 2.2 Compliance Manager is responsible for managing complaints received by the Office of the Human Research Ethics (OHRE).
- 2.3 Director of OHRE and Chair are responsible for providing consultation.

3 PROCEDURE

- 3.1 Participants are encouraged to ask questions or voice any concerns or complaints they may have about the research. The investigator is responsible for answering all questions, addressing all concerns, and responding to all complaints raised by subjects to the best of his/her ability. The name and contact information of the investigator responsible for the research is required in all UNC consent documents.
- 3.2 Participants are also encouraged to discuss their rights or to voice their concerns or complaints about the research with OHRE. The telephone number and email of the UNC IRB is required in all UNC consent documents. . OHRE contact information is available to participants and third parties on the OHRE website.
- 3.3 When the UNC IRB waives the requirement for the investigator to obtain a signed consent form, contact information for the investigator is included in a study information sheet or other written information about the research.
- 3.4 Complaints received by Investigators or study personnel:
 - 3.4.1 Investigators are responsible for ensuring that complaints are handled in a thorough, timely and respectful manner. Participants should not be penalized or lose any benefits they are receiving or have a right to receive.
 - 3.4.2 The investigator will address the complaint in a timely manner and communicate its resolution to the complainant, generally within 30 days.
 - 3.4.3 Investigators must document all complaints received from participants or third parties and their resolution and report them to OHRE at continuing review.
 - 3.4.1 When, despite best efforts, the investigator is unable to resolve a complaint, the complaint should be reported to the IRB as per SOP 1401, Table 1, New Safety Information.
 - 3.4.2 Investigators will cooperate with the IRB to resolve complaints.
- 3.5 Complaints received by OHRE:
 - 3.5.1 Complaints received by OHRE will be managed by the OHRE Compliance Manager. OHRE will maintain privacy of the complainant where privacy is a concern or when requested by the complainant
 - 3.5.2 Complaints received outside of IRBIS (not directly from the investigator), regardless of point of origin, are recorded in writing and provided to the Compliance Manager.

- 3.5.2.1 The Compliance manager will inform the investigator of the complaint and request a response to the issues raised in the complaint.
 - 3.5.3 The OHRE Compliance Manger will work with the investigator and OHRE Director and/or Chair to resolve the complaint.
 - 3.5.4 OHRE will address the complaint in a timely manner and communicate its resolution to the complainant, generally within 30 days of receipt of the complaint.
 - 3.5.5 OHRE will maintain records of complaints and their resolution, and a copy will be retained in the applicable protocol file.
- 3.6 Should the complaint result in an allegation of noncompliance or be cause for suspension or termination of the research, OHRE will follow the procedures outlined in SOP 1402.