

University of California, San Diego  
Human Research Protections Program  
Institutional Review Board  
Standard Operating Policies and Procedures

Section 3.18  
Review of Subject Complaints/Concerns/Questions

***Policy***

The right of research subjects to complain, voice a concern, or ask a question about a research study and to have the complaint, concern or question resolved in a timely manner is taken very seriously by the UCSD Human Research Protections Program. Complaints/Concerns/Questions may be raised by research subjects (past, present and potential), family members, designated spokespersons or anyone and provided to the HRPP by phone, in writing or in person. Consent documents approved by the IRB include information for contacting the Principal Investigator should the subject have questions or research-related problems and for contacting the HRPP Office if the subject has questions about the subject's rights as a research subject or to report research-related problems.

***Procedures***

1. Principal Investigator Responsibilities/Procedures
  - a) The Principal Investigator will address complaints/concerns/questions received from subjects or others as quickly as possible.
    1. If the complaint/concern of a subject or others indicates an unanticipated risk or a change in the risk/benefit ratio associated with the study or the complaint/concern cannot be resolved by the Principal Investigator, it must be reported as an unanticipated event involving risks to subjects or others up with 10 working days (see SOPP, Section 3.13, Reporting Adverse Events and Unanticipated Events Involving Risks to Subjects or Others).
    2. If the complaint/concern does not indicate an unanticipated risk or a change in the risk/benefit ratio associated with the study or the complaint/concern can be resolved by the Principal Investigator, the information associated with the complaint/concern will be included as part of the continuing review submission for review by the IRB.
  - b) The Principal Investigator is responsible for ensuring the IRB-approved consent documents contain accurate information for contacting the Principal Investigator should the subject have questions or research-related problems and contact information for the HRPP should the subject have questions about the subject's rights as a research subject or to report research-related problems.
2. HRPP Responsibilities/Procedures
  - a) The HRPP Director, or when the Director is unavailable, an HRPP Associate Director, is responsible for initial review of the complaint/concern/question and communicating with person with the complaint/concern/question.
    1. The Director will obtain and document the following information, as appropriate:

- a) The person's name and contact information (address, phone number, e-mail address). Collection of this information is not mandatory. However, if the person wishes to remain anonymous, the person will be advised that a thorough review may not be possible and that without this information, follow-up with the person would not be feasible.)
  - b) The HRPP project number and name of the Principal Investigator
  - c) The person's relationship to the study such as past participant, present participant, potential participant, participant family member, etc.).
  - d) A detailed explanation of the complaint/concern/question.
  - e) Who the person has contacted regarding the complaint/concern/question such as the Principal Investigator, research staff or anyone else and when such contact was made.
  - f) A description from the person of a proposed resolution of the complaint/concern, if the person has such a proposal.
2. The Director will communicate to the person that he/she will inquire into the circumstances associated with the complaint/concern/question and that a response regarding the resolution of or a determination about the complaint/concern/question will be provided to the person along with an approximate estimate of when the response will be provided. The Director will also inform the person about the limits of confidentiality in regards to the inquiry including who may be informed, what information may be reviewed, etc.
  3. The Director will review study documents and other relevant information to begin the initial review of the complaint/concern/question. The Director may also contact the Principal Investigator, either verbally or in writing, to obtain information in association with the initial review.
  4. After performing the initial review, the Director will determine whether the complaint/concern/question is minor and can be handled administratively or whether the complaint/concern/question needs to be reviewed by the IRB Chair and/or the IRB.
    - a) If the complaint/concern/question is determined to be minor including those that do not involve potential risk to subjects or others or cause a change in the risk/benefit ratio associated with the study such as the subject not receiving approved compensation for participation, the review and response for such complaints/concerns/questions may be done at the administrative level by the HRPP Director. The written report associated with the complaint/concern/question and response including corrective action will be made a part of the project file and need not be provided to the appropriate IRB Chair for review.
    - b) If the complaint/concern/question is determined to involve potential risk to subjects or others or cause a change in the risk/benefit ratio associated with the study, the written report will be provided to the appropriate IRB Chair for review.
    - c) If the complaint/concern/question is determined to be an allegation of noncompliance, the complaint/concern/question will be reviewed as outlined in the SOPP, Section 5.2, Communications, Sanctions, Appeals and Disciplinary Actions.

### 3. IRB Chair/IRB Review Procedures

- a) After the HRPP Director has provided the report and response regarding the complaint/concern/question to the IRB Chair, the IRB Chair will do the following:
  1. If the IRB Chair determines that the complaint/concern/question does not involve potential risk to subjects or others or cause a change in the risk/benefit ratio associated with the study, the Chair may accept the report and provide to the HRPP Director written acceptance of the report. The report and acceptance of the report will be made a part the project file.
  2. If the IRB Chair determines that the complaint/concern/question does involve potential risk to subjects or others or cause a change in the risk/benefit ratio associated with the study, the IRB Chair may determine the complaint/concern/question requires review by the full Committee and will return the report and response to the HRPP Director so the report and response may be placed on the next appropriate meeting agenda for IRB review.
  3. If the IRB Chair determines that the complaint/concern/question would have an immediate effect to the health, welfare and/or rights of subjects, the IRB Chair will contact the Principal Investigator of the study to establish procedures for the protection of subjects pending review by the IRB.
  4. If the complaint/concern/question is reported to the IRB by the Principal Investigator, the complaint/concern/question will be reviewed as outlined in SOPP, Section 3.11, Continuing Review; Section 3.13, Reporting Adverse Events and Unanticipated Events Involving Risks to Subjects or Other; Section 3.14, Protocol and Regulatory Violations; and/or Section 5.2, Communications, Sanctions, Appeals and Disciplinary Actions.
  5. If the IRB determines that the complaint/concern/question is an unanticipated problem(s) involving risks to others; serious or continuing noncompliance; or results in suspension or termination of IRB approval, the determination and appropriate information must be reported to the Institutional Official and appropriate federal agencies.
  6. The PI will be informed in writing of the results of the review of the complaint/concern/question by IRB within 10 working days.
4. Complaints/concerns/questions about the HRPP
  - a) If the complaint/concern/question does not involve risk to subjects and others, the HRPP Director will review and respond/resolve the complaint/concern/question on a case-by-case basis. The resolution may include changes to the standard operating policies and procedures.
  - b) If the complaint/concern/question involve risk to subjects and others, the review/response will be done as noted above.

#### ***Applicable Regulations***

[21 CFR 50.25\(a\)\(7\)](#)

[21 CFR 56.108\(b\)](#)

[45 CFR 46.103\(b\)\(5\)](#)

[45 CFR 46.116\(a\)\(7\)](#)