

Guidance and Procedures Number: 58

Title: Complaints and Concerns Regarding the Conduct of Human Subjects Research

Date of Last Revision: February 26, 2009

I. General Overview

This policy addresses complaints and concerns regarding human subjects research studies or the Human Research Protection Program in general that are reported directly or indirectly to the UCLA Institutional Review Board (IRB) or the UCLA Human Research Protection Program, which encompasses the IRB and is a division of the Office for the Protection of Research Subjects. Complaints or concerns regarding the conduct of human subjects research may be received by the Principal Investigator, other researchers on the study, the IRB members or staff, the OPRS Director, or other individuals or offices within the University, including the Vice Chancellor for Research, or by study sponsors or federal agencies. Investigators who receive any subject or other individual complaint or concern are required to report such incidents to the IRB.

All UCLA IRB-approved consent forms and the UCLA Research Subjects Bill of Rights include contact information for the Office for Protection of Research Subjects and advise research participants to contact the study researcher or the OPRS with any concerns, complaints or suggestions. In addition, The UCLA OPRS website links to a section called "Information for Participants" which also provides the contact information for the OPRS. The Human Research section of the OPRS website links to a section called "Program Feedback" which provides information about how to communicate concerns or complaints about the safety, welfare or rights of human subjects in research.

All complaints or concerns regarding the conduct of human subjects research that are received by or referred to the Office for Protection of Research Subjects or the Institutional Review Board will be discussed with the complainant, investigated and handled appropriately by the OPRS HRPP or the IRB as described below. If concerns or complaints are made about the IRB or the HRPP itself, then the Vice Chancellor for Research will also be involved in the investigation and resolution of the complaint.

II. Policy

- A. All concerns or complaints regarding the conduct of human research at UCLA brought to the attention of the OPRS Human Research Protection Program or the Vice Chancellor for Research are taken very seriously and will be investigated and handled appropriately as described in Section IV below.
- B. Complainants may include but are not limited to the following: subjects (past, present, or potential), subject family members, investigators, other research staff, or any person with concerns. In addition, another office within the University or an agency or individual(s) external to the University may also bring forward a complaint or concern.

- C. If the concern or complaint is an allegation of noncompliance, the matter will be handled and investigated as described in [HRPP Policy #53: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research](#).

III. Principal Investigator Responsibilities

- A. The PI is responsible for addressing as quickly as possible any concern or complaint which he or she receives from subjects or any other complainants.
 - 1. Any complaint or concern that involves potential risks to subjects or others, results in a change in the risk-potential benefit profile of the study, or cannot be resolved by the investigator/research staff must be reported as an incident to the IRB according to Section III.B of [HRPP Guidance and Procedure #57: Post Approval Reporting](#).
 - 2. Any complaint or concern received and resolved by the investigator that does not involve risk to subjects or others, or does not change the risk-potential benefit profile of the study shall be submitted in a summary format to the IRB for consideration at continuing review.
- B. The Principal Investigator is responsible for making sure IRB-approved consent documents contain contact information for the PI and the OPRS and indicate that if subjects have any concerns or complaints they may contact the researchers directly or the OPRS if they wish to speak with someone not associated with the research study.
- C. For medical studies involving a foreseeable risk of biomedical harm to the subjects, the Principal Investigator is responsible for assuring that the subject has been given a copy of the UCLA Research Participants Bill of Rights in a language that the subject can understand. The Bill of Rights contains OPRS contact information and the message to call the office if they have questions, concerns or complaints.

IV. HRPP Responsibilities

- A. The OPRS Director/Assistant Director, as designees of the IRB Chairs, are responsible for communicating with the complainant and for conducting the initial investigations of all concerns and complaints brought to the attention of the IRB/OPRS regarding research being conducted under the auspices of UCLA. The procedures for this initial inquiry and follow-up reviews and determinations by the IRB Chairs or Full committee are described below.
- B. The IRB is responsible for making sure that the IRB-approved consent documents contain contact information for the Principal Investigator and the OPRS and advise the subjects that if they have any complaints or concerns they may contact either the researchers or the office if they wish to speak with someone not associated with the research study.
- C. The HRPP is responsible for assuring the information about how to communicate concerns or complaints about the safety, rights and welfare of human research participants to the OPRS or to the Vice Chancellor for Research is posted on the

OPRS/HRPP website. It is also responsible for providing templates for the UCLA Research Participants Bill of Rights that includes OPRS contact information for questions or concerns about research studies.

V. HRPP Procedures

Concerns and complaints, whether verbal or in writing, that are received by the OPRS Director/Assistant Directors or the IRB Chairs or members are processed as described below.

- A. All complaints and concerns will be handled in a confidential manner, and all information will be kept as confidential as possible within the law.
- B. Upon receipt of a complaint or concern from a research subject or other individual, the OPRS Director/Assistant Director will assure that sufficient information is available to conduct an inquiry or investigate the claim. The Director/Assistant Director will obtain and record the following information, as appropriate, and if not already in written form from the complainant. A "Human Subjects Research Complaint/Concern Report Form" is available for this purpose.
 1. Complainant's name and contact information (i.e. address, phone number, email address). If the complaint is made anonymously, arrangements may be made for the complainant to call back and identify him or herself by using a code name. If a written report will be forwarded to the IRB, a code will replace the complainant's name.
 2. Research protocol IRB number and name of Principal Investigator, if applicable.
 3. A detailed description of the complaint or concern.
 4. Whether the complainant has contacted the PI/research staff, if applicable, or anyone else regarding the concern.
 5. A description of complainant's proposed resolution of the complaint or concern, if the complainant has such a proposal.
- C. The OPRS Director/Assistant Director will formally acknowledge receipt of the complaint or concern with the complainant either verbally or in writing. The Director/Assistant Director will assure the complainant that measures will be taken to inquire about and review the complaint or concern and provide some sense of the time frame that it is likely to take before the complainant will hear back with a resolution or a determination.
- D. The OPRS Director/Assistant Director will conduct an initial inquiry which consists of a detailed review of the protocol documents to confirm and/or substantiate the complaint or concern. Review will include but is not limited to the following: the recruitment and consent documents, a protocol summary, the sponsor protocol and/or drug and/or device brochure and any other pertinent documents.

If needed as part of the inquiry process, the OPRS Director/Assistant Director may query the study investigator, either verbally or in writing, to obtain additional information regarding the complaint or concern.

- E. All concerns or complaints are first triaged by the OPRS Director or an Assistant Director to make an initial evaluation as to whether the complaint or concern is minor and can be handled internally at an administrative level or whether the concern or complaint needs to be forwarded to the Chair and/or the IRB.
1. Complaints and concerns that do not involve potential risk to subjects or others will undergo an inquiry and corrective action taken at an administrative level by the OPRS Director/Assistant Director. The reported complaint/concern, corrective action and outcome will be forwarded to the appropriate IRB Chair or Vice Chair for review. Examples of these types of complaints or concerns are questions about contacts or study location, clarification of a minor point in the consent document, general questions about treatment and compensation for injury, concerns about not yet having received payment for participation.
 2. If the OPRS Director/Assistant Director determines that the concern or complaint may involve potential risk to the subjects or others, the written report regarding the complaint and/or concern as described above will be forwarded to the appropriate IRB Chair or Vice Chair review.
 3. If the concern or complaint is an allegation of noncompliance, then the complaints or concerns will be handled as possible noncompliance according to [HRPP Policy #53: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research Studies.](#)

VI. IRB Review Procedures

Once the OPRS Director/Assistant Director forwards the complaint/concern and the inquiry results to the IRB Chair, the following will occur:

- A. The IRB Chair or Vice Chair will make a determination as to whether the complaint/concern does or does not represent an unanticipated problem. If it does not pose risks to subjects or others or does not result in a change in the risk/benefit profile of the study, the report may be accepted and signed by the IRB Chair or Vice Chair.
- B. If, however, the IRB Chair or Vice Chair determines that the complaint or concern appears to involve unexpected risk to subjects or others, or results in a change in the risk-potential benefit profile of the study, the IRB Chair/Vice Chair may determine that the complaint/concern represents an unanticipated problem involving risk to subjects or others and therefore forward the complaint or concern to the full Committee for review and a final determination and recommendations.
- C. If the complaint or concern is of the nature that the safety, rights and welfare of subjects are at immediate risk or hazard, the IRB Chair/Vice Chair will contact the PI to establish an interim measure to be taken to protect subjects pending formal inquiry and review by the full Committee.
- D. Complaints or concerns that are reported to the IRB by the investigator as a post approval report will be processed and reviewed according to Section V of [HRPP Guidance and Procedure #57: Post-Approval Reporting.](#)

- E. Complaints or concerns that are reported to the IRB by the investigator at the time of the study's continuing review will be reviewed along with the continuation study. However, if additional information is needed or the IRB requires a separate Violations and Incident Report, a copy of which is available on the OPRS HRPP website, then a follow up review may be required.
- F. If the complaints or concerns reveal a pattern of noncompliance, then the complaints or concerns will be handled as possible noncompliance according to [HRPP Policy #53: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research](#).
- G. The OPRS Director/Assistant Director will coordinate with the IRB Chair to prepare written correspondence to be forwarded to the Principal Investigator and the complainant, if applicable, within ten working days of the final IRB determination.

VII. General Complaints about the Human Research Protection Program

- A. General concerns or complaints about the HRPP that do not involve a possible risk to subjects or others will be considered and handled on a case-by-case basis. These will be addressed by one of the OPRS Directors or Assistant Directors or the Vice Chancellor for Research, as appropriate. Any complaints or concerns that can be addressed by improving systems or procedures to improve the overall program will be implemented.
- B. General or specific complaints about the HRPP that may involve a possible risk to subjects or others will be processed according to Sections IV, V and VI above with the possible exception of including the involvement of the Vice Chancellor for Research.
- C. General or specific complaints about the HRPP that are allegations of noncompliance will be processed according to [HRPP Policy #53: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research](#).

VIII. IRB Reporting Requirements

Unanticipated problems involving risks to subjects or others; any serious or continuing noncompliance; any suspension or termination of IRB approval; and the outcome of the IRB's actions are reportable to the appropriate federal department or agency head(s) and institutional official (45 CFR 46.103(b)(5) and 21 CFR 56.108(b)) according to [HRPP Guidance and Procedure #60: IRB Reporting Procedures for Unanticipated Problems, Noncompliance, Suspension, or Termination](#).

Regulations:

The Department of Health and Human Services (DHHS) requires that the basic elements of informed consent for human subjects research will include "an explanation of whom to contact for answers to pertinent questions about a research subjects' rights and whom to contact in the event of a research-related injury to the subject" [45 CFR 46.116(a)(7)].

The Food and Drug Administration (FDA) requires that the basic elements of informed consent for human subjects research include “an explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights and whom to contact in the event of a research-related injury to the subject” [21 CFR 50.25(a)(7)].

45 CFR 46.103(b)(5)

45 CFR 46.116(a)(7)

21 CFR 50.25(a)(7)

21 CFR 56.108(b)

References:

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) *Protecting Human Research Subjects Guidebook (1993)*.