

**University of California, Irvine
Human Research Protections
Standard Operating Policies and Procedures**

Policy Number: 54

Title: Concerns and Complaints Regarding Human Subjects Research

Date of Last Revision: 01/21/2007; 11/08/2010; 05/01/16; 09/17/2022

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to investigate all concerns or complaints received regarding human subjects research conducted under its jurisdiction.

- I. The Director of Human Research Protections or designee must investigate all concerns or complaints received regarding human subjects in research under UCI IRB's jurisdiction. The level of investigation will depend on the seriousness of the situation and the potential risk to participants. Concerns or complaints may come from any source including IRB Committee members, Investigators, participants and their families, Institutional personnel, other Institutional Committees, UCI Whistleblower Office, the media, anonymous sources, or the public.
- II. Concerns or complaints may come from any category of research reviewed and may include anyone involved or not directly involved in the research process/study
- III. Investigations should result in finding a suitable resolution and response to the complainant in a timely manner.
- IV. All concerns and complaints will be handled in a confidential manner. This includes any individual involved in notifying the UCI IRB of an alleged violation of Investigator compliance.
- V. Concerns or complaints that are substantiated will be further investigated through a directed audit conducted by the IRB Education and Quality Improvement Team, and actions will be taken as deemed appropriate by the IRB. The IRB Committee may involve a Subject Advocate or UCI Medical Center Patient Affairs, if applicable.
- VI. Concerns or complaints of a sensitive nature may be brought to the IRB Working Group meeting for discussion and recommendation.
- VII. Human Research Protections provides a suggestion box on its website to allow individuals to voice any suggestions, concerns or complaints. If any concerns are emergent in nature or are such that a participant may potentially be placed at risk, the suggestion box states to please call the IRB directly at (949) 824-8170 or via email at IRB@research.uci.edu.

References:

Institutional Review Board Management and Function; Bankert, E.Gordon, B, Hurley, E, and Shriver, S ; 2022 Jones and Bartlett Publishers, Inc.

Procedure Number: 54.A

Title: Procedure for Concerns and Complaints Regarding Human Subjects Research

Procedure:

The purpose of this procedure is to outline the actions of the UC Irvine (UCI) Institutional Review Board (IRB) in managing a concern or complaint received regarding human subjects research.

I. Lead Researcher (LR) Responsibilities

- A. It is the responsibility of the LR to notify the IRB via the AE/UP Reporting process of any complaint by a subject that indicates an unexpected risk or which cannot be resolved by the UCI LR. The reporting timeframe is within 10 working days of the researcher becoming aware of the problem. (See HRP Policy # 19.)
- B. It is the responsibility of the LR to report to the IRB at the time of continuing review any complaint made by a participant that was resolved and did not involve an unexpected risk (e.g., a participant complains that he/she did not receive compensation in a timely manner).
- C. Lead Researchers are to cooperate with the IRB by making documents accessible, responding to written requests within the designated time frame, and being available for questions by the IRB.

II. IRB Committee Responsibilities

- A. Initial Concern or Complaint
 - 1. The assigned IRB Chair or his/her designee will be notified by the HRP staff member conducting the investigation or directed audit of planned activities.
 - 2. The IRB Chair or his/her designee may request revisions or additions to the planned investigation or directed audit activities.
- B. Committee Review
 - 1. At the completion of the investigation or directed audit, the findings (if warranted) will be taken to full Committee for review.
 - 2. A determination will be made by the Committee of any further actions that are to be taken.

III. IRB Administrator Responsibilities

- A. Initial concern or complaint
 - 1. When an IRB staff member receives a verbal concern or complaint, he/she will collect as much information as possible while completing the IRB Complaint Information Form.
 - 2. All written concerns or complaints and completed complaint forms are to be forwarded to the Director of Research Protections or designee for investigation into the nature of the concern or complaint.
- B. Review and Follow-up
 - 1. When a concern or complaint is substantiated, the Director of Research Protections or designee will forward the complaint to the IRB Education and Quality Improvement Team for further investigation or a directed audit.

2. When the concern or complaint involves sensitive issues, the complaint may be forwarded to the IRB Working Group for discussion and recommendations prior to initiating any activity.
 3. The results of the investigation will be reported to the Director of Research Protections or designee. If the concern or complaint is study-related, the appropriate IRB Committee will also be notified of the results. If warranted, the results of the investigation will be forwarded to the IRB full Committee for further determinations and/or recommendations.
 4. The Administrator will forward Committee determinations and/or recommendations regarding the investigation to the Executive Director of Research Protections or designee.
 5. If warranted, the Director of Research Protections or designee will notify the Vice Chancellor for Research of the investigation or directed audit outcomes. (See HRP Policy # 53.)
 6. The Administrator will update the IRB database accordingly.
 7. Records of the concern or complaint and subsequent investigation will be kept in a separate encrypted electronic location on the HRP intranet.
- C. Results from the IRB Surveys are monitored for HRP feedback and suggestions, as well as any concerns or complaints that require investigation.