UCLA Research Administration
Human Research Protection Program

Policy and Guidance: Complaints, Concerns and Suggestions, and Reports of Undue Influence Regarding the Conduct of Human Participants Research (last updated February 20, 2020)

Overview

Complaints, concerns and suggestions about the conduct of specific human research studies or about the UCLA Human Research Protection Program are taken very seriously. This guidance addresses how complaints, concerns and suggestions that are reported directly or indirectly to the UCLA Institutional Review Board (IRB) or the UCLA Office of the Human Research Protection Program (OHRPP) are responded to. Complaints and concerns might also include reports of any attempts to unduly influence individuals responsible for the oversight of human research (e.g., IRB chairs and members, OHRPP staff).

Complaints, concerns or suggestions may be received by the Principal Investigator, other researchers on the study, IRB members, OHRPP Director or staff, the UC whistleblower hotline/website, or the Office of Patient Experience (UCLA Health). These reports may also be received by other individuals or offices within the University, including the Vice Chancellor for Research or the Associate Vice Chancellor for Research. They may also be received by study sponsors or federal agencies.

There are several methods for participants or others to contact the OHRPP office, including:

- All UCLA IRB-approved consent forms provide OHRPP contact information and advise participants to contact the researcher and/or the OHRPP with any questions, concerns, or suggestions.
- All UCLA Research Participants Bill of Rights provide OHRPP contact information and advise participants to contact the researchers and/or the OHRPP with any questions or concerns.
- The UCLA OHRPP home page links to a section called “Information for Research Participants”. This link is available in English and Spanish and includes instructions for filing complaints or concerns with OHRPP.
- The OHRPP home page links to a “Survey” for research participants that provides participants with an easy way to provide feedback about their participation in a specific study.
- There is also a link on the OHRPP “contact us” page called “Program Feedback” that provides OHRPP contact information for both researchers and participants.

Policy

- All complaints, concerns or suggestions regarding the conduct of human research at UCLA are brought to the attention of the OHRPP Director and an IRB Chair and/or the Vice Chancellor for Research. The complaints or concerns will be investigated and handled appropriately as described below in "IRB/OHRPP Responsibilities". Suggestions will be evaluated and implemented as appropriate.
- Complainants may include but are not limited to the following: participants (past, present, or potential), participant 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.
- Reports of attempts to unduly influence IRB chairs, members and OHRPP staff will be investigated and handled appropriately as described below in "IRB/OHRPP Responsibilities".
- If the concern or complaint is an allegation of noncompliance, the matter will be handled and investigated as described in OHRPP Policy: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Participants Research.

Principal Investigator Responsibilities

- During the consent process and before the study begins, the Principal Investigator, other investigators on the study as well as research staff are required to answer any and all questions of the research participants and provide contact information if future questions or concerns arise.
- Once the participant agrees to be in the study, the PI is responsible for responding as quickly as possible to any questions, concerns or complaints which he or she receives from participants or any other individuals.
    - Any complaint or concern that involves potential risks to participants or others, negatively impacts the rights of participants or others, results in a change in the risk-potential benefit profile of the study must be reported via PAR application to the IRB as described in the OHRPP Guidance and Procedure: Post Approval Reporting.
    - Any complaint or concern received and resolved by the investigator that does not involve risk to participants or others, or does not change the risk-potential benefit profile of the study should be submitted in a summary format to the IRB for consideration at continuing review, for those studies with continuing review. For studies without continuing review, investigators should maintain the summary of complaints in their research files.
- The Principal Investigator is responsible for the inclusion of contact information for the PI and the OHRPP in the IRB-approved informed consent documents as indicated in the UCLA consent templates posted on the OHRPP website. Participants may contact the researchers directly, and/or the OHRPP about their rights as a research participant or any questions or concerns about the study. They may contact OHRPP if they wish to speak with someone other than the study researchers.
- For medical studies conducted in California that meet the definition of medical experiment in the CA Health and Safety code, the Principal Investigator is responsible for assuring

that the research participant has been given a copy of the UCLA Research Participants Bill of Rights in a language that the participant can understand. The Bill of Rights contains OHRPP contact information and informs participants to contact the OHRPP if they have questions or concerns about the study.

- When the investigator receives a complaint directly or is made aware of a complaint made to another entity, they should work to resolve it whenever possible. If the investigator receives a number of complaints of the same type, the investigator is encouraged to conduct a root cause analysis in order to develop a CAPA (Corrective Action Preventive Action) plan. For guidance on these activities, please see OHRPP Guidance and Procedure: Post Approval Reporting.

- Investigators and research staff should consider and evaluate any suggestions that participants may have, and make improvements as appropriate.

- Investigators who receive any complaints or concerns should review available guidance to determine if the complaint meets the threshold for reporting to the IRB. As part of this assessment, the investigator should review Guidance and Procedure: Post-Approval Reporting (PAR).

IRB/OHRPP Responsibilities

- The OHRPP Director and Associate/Assistant Directors, 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/OHRPP 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.

- The IRB is responsible for making sure that the IRB-approved consent documents contain contact information for the Principal Investigator and the OHRPP.

- The OHRPP Director 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 OHRPP or to the Vice Chancellor for Research is posted on the OHRPP website. The Director is also responsible for including OHRPP contact information in the consent templates and on the UCLA Research Participants Bill of Rights.

OHRPP Procedures

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

- All complaints and concerns will be handled in a confidential manner, and all information will be kept as confidential as possible within the law.

- Upon receipt of a complaint or concern from a research participant or other individual, the OHRPP Director, or Associate/Assistant Director will assure that sufficient information is available to conduct an inquiry and obtain and record the following information, as appropriate (if not already in written form from the complainant). A “Human Participants Research Complaint/Concern Report Form” is available for this purpose.

    - Complainant’s name and contact information (i.e., address, phone number, e-mail

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, the complainant's name will not be disclosed.

- Research protocol IRB number and name of Principal Investigator, if applicable.
- A detailed description of the complaint or concern.
- Whether the complainant has contacted the PI/research staff, if applicable, or anyone else regarding the concern.
- A description of complainant's proposed resolution of the complaint or concern, if the complainant has such a proposal.

- The OHRPP Director or designee will formally acknowledge receipt of the complaint or concern with the complainant either verbally or in writing. The OHRPP Director or designee 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.
- The OHRPP Director or designee 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 OHRPP Director or Associate/Assistant Director may query the study investigator, either verbally or in writing, to obtain additional information regarding the complaint or concern.

- Complaints and concerns will undergo an initial inquiry at an administrative level by the OHRPP Director or designee. The reported complaint/concern and the outcome of the initial OHRPP inquiry will be forwarded to the appropriate IRB Chair or Vice Chair for review. Complaints or concerns that become suggestions about the conduct of the study will be discussed with and forwarded to the Principal Investigator for consideration and evaluation and may potentially result in modifications to the study
  - If the IRB Chair or Vice Chair determines at review that the event requires review by a higher level of authority (e.g., Vice Chancellor; School Dean, Academic Senate), the report will be forwarded to the appropriate campus office for a higher level of review.

- If the concern or complaint is an allegation of noncompliance, then the complaints or concerns will handled as possible noncompliance according to OHRPP Policy: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research.

IRB Review Procedures

- Complaints or concerns reported to the IRB by the investigator as a post approval report will be processed and reviewed according to OHRPP Guidance and Procedure: Post Approval Reporting.
- Complaints or concerns that are reported to the OHRPP or IRB by the complainant directly or forwarded from a complaint received by another entity (other than the PI) will be entered (redacted) into a post approval report will be processed and reviewed according to OHRPP

Guidance and Procedure: Post Approval Reporting.

- The IRB Chair or Vice Chair will decide whether or not the complaint/concern appears to represent an unanticipated problem.
    - If it does ***not*** represent an unanticipated problem (i.e., poses risks to participants 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.
    - If it ***does*** represent an unanticipated problem (i.e., appears to involve unexpected risk to participants or others, or results in a change in the risk/benefit profile of the study), the IRB Chair or Vice Chair will forward the complaint or concern to a convened IRB for review for a final determination and recommendations.
- The IRB Chair or Vice Chair will decide whether the complaint/concern appears to represent continuing non-compliance and/or serious non-compliance per OHRPP Policy: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Participants Research .
    - If it does ***not*** represent continuing or serious non-compliance, the report may be accepted and signed by the IRB Chair or Vice Chair.
    - If it ***does*** represent continuing or serious non-compliance, the IRB Chair or Vice Chair will forward the complaint or concern to a convened IRB for review for a final determination and recommendations.
- If the complaint or concern is of the nature that the safety, rights and welfare of participants 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 participants pending formal inquiry and review by the full Committee. This measure may include a suspension of some or all of the study (see OHRPP Policy and Guidance: Suspension and Termination of Research).
- If the complains or concerns represent a pattern of participant complaints, the IRB may request additional information from the PI and/or amendments to the protocol or ask that the QIU conduct an on-site review of the study or monitor the consent process.
- The OHRPP Director or designee 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.

Complaints about the Human Research Protection Program

- General or specific concerns, complaints or suggestions about the HRPP that do not involve a possible risk to participants or others will be considered and handled on a case-by-case basis. These will be addressed by the OHRPP Director, the Vice Chancellor for Research, the Associate Vice Chancellor for Research, or a designee, as appropriate. Any complaints, concerns, or suggestions that can be addressed by improving systems or procedures to the overall program will be implemented.
- General or specific complaints about the OHRPP or the Human Research Protection Program that may involve a possible risk to participants or others will be processed according to other sections of this guidance ("OHRPP Procedures" and "IRB Review Process"). The Vice Chancellor for Research or his or her designee may also investigate or be involved in the resolution of any complaints or may appoint an ad hoc committee to investigate the concerns.

- General or specific complaints about the OHRPP that are allegations of noncompliance will be processed according to OHRPP Policy: Noncompliance and Allegation of Noncompliance Regarding the Conduct of Human Participants Research.

IRB Reporting Requirements

Unanticipated problems involving risks to participants 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 OHRPP Guidance and Procedures: IRB Reporting Procedures for Unanticipated Problems, Noncompliance, Suspension, or Termination **.**

Regulations and References

DHHS Regulations

- Written procedures for prompt reporting to IRB 45 CFR 46.108(b)(5)
- Requirements for informed consent (obtain further information) 45 CFR 46.116(a)(6)
- Requirements for informed consent (whom to contact for questions) 45 CFR 46.116(a)(7)

FDA Regulations and Guidance

- Requirements for informed consent (obtain further information) 21 CFR 50.25(a)(6)
- Requirements for informed consent (whom to contact for questions) 21 CFR 50.25 (a)(7)
- Written procedures for prompt reporting to IRB 21 CFR 56.108(b)
- FDA Guidance for IRBs and Clinical Investigators – A Guide to Informed Consent – Information Sheet (1998, updated June 10, 2019)

AAHRPP Standards & Elements

Element I.1.C.
Element I.4.A
Element III.1.G

Change history:
2/20/2020: Update to include standard UCLA and UC mechanisms for filing complaints; correct broken links; reflect current content on OHRPP website; revise the process for complaint processing to reflect the current thinking of IRB Chairs; provide consistent formatting; and ensure content agrees with revised PAR guidance.