

Chapter 22:
**Complaints
Regarding
Human
Subjects
Research**

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Subjects Research

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Complaints Regarding Human Subjects Research

A well run and well documented HSPP has mechanisms in place to receive and address complaints from any concerned party. This chapter contains information about participant complaints, undue influence, and the IRB/HSPP.

22.1 Handling Complaints Regarding Human Subjects Research

Participant Complaints

A participant complaint is an expression of dissatisfaction by the participant (or his/her representative) that may or may not involve a breach in human subjects rights or research ethics. Participants may choose to report complaints to the study team or to a third party. Therefore, it is important that during the consent process, subjects receive consent forms and information sheets that include investigator and IRB contact information so that participants have resources to ask questions about the study and report complaints.

At USC, participants can also address their complaints to the Office for the Protection of Research Subjects (OPRS) and the Office of Compliance (OOC).

OPRS Resources for Participant Complaints

The OPRS website contains contact information for OPRS, IRBs, and OOC, a webpage specific to participant complaints and a brochure for participants considering study participation with contact information for questions or complaints.

- OPRS and IRB contact information:
<http://oprs.usc.edu/about/complaints/>
- Participant brochure:
[Should I Participate in Research?](#)

OOO Resources for Participant Complaints

The USC Office of Compliance Help and Hotline can be utilized by participants to report complaints or ask questions about applicable laws, regulations and USC policies. Complaints may be made anonymously by calling the OOC Help and Hotline at (213)740-2500.

- OOC contact information:
<http://ooc.usc.edu/contact-us>
- OOC Help and Hotline:
<http://ooc.usc.edu/help-hotline>

At USC, subject complaints should be reported by the study team in iStar using the “Participant Complaint” form in the “Reportable Events” application. The report should be specific and include: date of the complaint, event description, relation to the study, determination of whether the complaint involves increased risk to study participants, explanation of how a similar event will be prevented in the future and supporting documentation if applicable. Alternatively, the study team can choose to contact the IRB directly to discuss the participant complaint. Additionally, complaints reported to OPRS, OOC or third parties will be subsequently reported to the IRB. When the IRB receives a participant complaint, the IRB staff or Director will be responsible for documenting the complaint in iStar.

Once a subject complaint is received, the IRB, along with OPRS or OOC as applicable, will attempt to substantiate the complaint in a timely manner. This process involves reviewing the study in which the subject is enrolled to ensure that the study has received and maintains active IRB approval and ensure compliance with pertinent federal and state regulations. The IRB office may contact the Principal Investigator (PI) and/or research staff for additional information to assist with the validation and/or dismissal of the complaint. Once all the information is received, the IRB will determine if any further action is necessary. The IRB will then provide written correspondence to the subject and PI with their determination and justification for actions taken. The determination and outcome of the complaint will be documented in iStar by the IRB.

If the IRB/OPRS office suspects there may be potential non-compliance, the IRB will initiate the process as outlined in the policy on handling allegations of non-compliance. Refer to [Section 20.8 – Procedure for Handling Reports of Noncompliance](#) for more information.

Complaints Regarding Undue Influence

Undue influence is a situation in which one person takes advantage of a position of power over another person. Any IRB staff member, IRB member, or other individual involved in the review of research, who believes they have been the target of undue influence by an investigator or other individual should report the incident to the IRB Director, Chair, or call the Office of the Compliance Help and Hotline **(213)740-2500**.

If the IRB is contacted, the Director or Chair will attempt to get all available information and, if warranted, forward the validated allegation to the Office of Compliance, where corrective action will be undertaken.

Complaints Regarding the IRB or HSPP

Subjects/participants, researchers, IRB members, and others who have human subjects research related complaints, concerns, recommendations, or reports of violations are encouraged to contact one of the following offices listed below. Aspects of the HSPP unrelated to the IRB may also be directed to these offices. All inquiries are taken seriously and will be directed to the appropriate personnel. When a complaint, concern, recommendation, or report of violation made to any one of the offices listed below reveals the need to consider modifying any aspect of USC's Human Subjects Research Protection Program, due consideration will be given and changes made as appropriate.

Complaints regarding the IRB or aspects of the non-IRB HSPP should be made to the nearest organization entity independent of the IRB. This could be the OPRS, Office of Compliance, or the Vice President of Research (Institutional Official). Attempts to get adequate information to validate the circumstances of the complaint will be sought by one or all of these entities. The contact information for these entities is found at <http://oprs.usc.edu/about/complaints/>. Complaints may be made anonymously by calling the OOC Help and Hotline at (213)740-2500.