



Continuous Quality Improvement (CQI) Efforts for the Human Subjects Protection Program (HSPP)

The University of Southern California is committed to conducting its biomedical and social behavioral human subjects research while adhering faithfully to ethical and regulatory standards. At USC this obligation to research subjects is a commitment undertaken to maintain the USC Human Subjects Protection Program (HSPP) as a nationally recognized leader. The Office for the Protection of Research Subjects (OPRS) and the USC IRBs have undertaken the following activities in order to achieve this goal and to maintain full accreditation from the Association for the Accreditation of Human Subjects Protection Programs (AAHRPP).

On-Site Audits

- “For Cause” Audits: IRB staff investigate allegations of misconduct, questionable activities identified in IRB submissions, or other concerns. Individual projects and/or all projects belonging to an investigator may be audited when the IRB identifies or confirms a concern.
- “Not for Cause” Audits: CQI staff conduct assessments to improve the overall HSPP, assure researcher adherence to IRB policies, federal regulations, and that research is conducted according to IRB approved protocol. Outcomes include identifying and correcting noncompliance, working with researchers to adopt best practices, offering training to researchers and staff, and making changes to the HSPP if appropriate.
- Significant New Information/Findings (SNIF) Audits: Random SNIFs will be checked to assure proper communication with subjects when the IRB has affirmed the need for a report of SNIF. iStar questions have been included in continuing reviews to verify SNIFs were given to enrolled subjects and revised consents were given to new subjects.

Online (iStar) Audits:

- Privacy and Confidentiality: Researchers often fail to include adequate subject protections in their proposed protocols. Initial corrective action will be through IRB staff seeking clarification from PIs for any inadequately answered explanations submitted on an IRB application.
- Investigator-initiated: Investigators answer “yes” to this question erroneously, which creates inaccurate reports of the volume of investigator-initiated studies. Oversight of investigators who held IND/IDE differs from oversight of sponsored research and calls for increased monitoring by the IRB.
- Data Safety and Monitoring Plans: Monitoring plans submitted to the IRB often lack details. Answers provided by researchers will be evaluated during IRB review of the protocol. Initial

corrective action will be through IRB staff seeking clarification from the PI for any inadequately answered explanations found on an IRB application.

- Consistency between Sponsor Contracts and Consent Document: Using the electronic IRB application system, IRB staff work with Clinical Trials Office (CTO) staff to verify that the contract language in the research agreement is consistent with the language in the informed consent document. If the language is not consistent, the IRB will not approve the study.
- IRB Processing time (90+ days for IRB approval): Staff will review projects that took 90+ days to obtain IRB approval, investigate delays, and determine whether IRB related issues or investigator issues were the cause. Recent causes for delay of IRB review include; inadequate initial screening, poorly worded iStar questions, and a technical glitch found in the online IRB submission System (iStar).
- Accreditation Requested iStar Monitoring: The electronic IRB submission system is used to monitor any issues or study types identified by AAHRPP during the accreditation renew process.

HSPP Outreach Activities

- Faculty Meetings: OPRS and IRB Directors are often invited to speak with faculty to address problems related to IRB submission and work to correct them and their students. Recent issues included quality of student submissions, and lack of mentoring.
- Classroom Education: OPRS and IRB are often invited to discuss human subjects protections with incoming PhD students, medical students, undergrad scholars, etc. These presentations are designed to give students a better understanding of human subject protections, research ethics, and the IRB submission process as they relate to the students' discipline.
- Communication and Training on Current Changes: Changes to the HSPP (e.g. policies, systems, requirements, etc.) are communicated to HSPP stakeholders through a listserv, website, and a newsletter. In person training sessions are provided to research coordinators, IRB staff, and investigators when appropriate.
- Communication with schools/depts: In order to ease the IRB review process for students, feedback is regularly sought from schools and departments (social work, education, gerontology) who frequently submit studies to the IRB.
- Community IRB Member Bi-Annual Teleconference: OPRS hosts bi-annual teleconferences with community IRB members from several Southern California institutions to discuss emerging issues and to share information.
- Listserv: HSPP information, updates, policy changes, and guidance documents are communicated to stakeholders through a listserv. Training sessions are also announced through the listserv. <http://oprs.usc.edu/about/listserv-2/>
- Research Coordinator Bulletin: Information specific for coordinators and research support staff is communicated through a coordinator bulletin. Featured topics include educational sessions,

coordinator events and networking opportunities, coordinator FAQs, national coordinator resources and articles of interest.

<http://oprs.usc.edu/initiatives/research-coordinators/bulletin/>

- **National Networks and Collaboration:** OPRS and IRB network and collaborate with other institutions to share information, discuss best practices, implement changes in policies and interpret changing regulations. USC is nationally recognized for HSPP leadership and excellence and engages in speaking roles at local, regional and national events.

User Help Desks

- **IRB Administrative Staff:** Administrators for both IRBs are available via phone or email to all investigators who have questions regarding applications and subsequent submissions to the IRB.
- **iStar Help Desk:** In addition to the IRB staff, IT staff are also available via to phone or email to help investigators and IRB staff manage IRB applications as they are processed through the online IRB submission and review system (iStar). The iStar helpdesk staff meets regularly with the IRB, OPRS and CHLA to discuss users' concerns as well as opportunities for, and implementations of, improvements to the system.
- **CITI Help Desk:** USC provides online training on the responsible conduct of research, good clinical practices, and human subjects via the Collaborative Institutional Training Initiative (CITI). Although the CITI organization is an external organization, USC provides a helpdesk for USC investigators and their affiliates who need assistance in establishing accounts and completing CITI training.
- **OPRS:** The Office for the Protection of Research Subjects has provided a phone number online and in educational materials, for subjects/participants, researchers, and IRB members to report concerns, complaints, or recommendations related to human subjects research.

Evaluations and Surveys

- **Annual Evaluation of IRB members:** IRB members are reviewed for their participation, quality of their reviews, and IRB attendance. Members' contributions and attendance are evaluated before reappointments are made.
- **Annual Evaluation of IRB Chair/Staff:** IRB Chair and staff efforts, turnaround time, and quality of review, is evaluated annually and salaries are determined.
- **Annual Justification of the IRB Budget:** the annual budget is reviewed to ensure resources are adequate to maintain a productive work environment. This includes a review of the volume of studies, time until approval, number of IRB staff, and feedback from faculty.
- **iStar User survey:** Once a study application is submitted through the online system (iStar), users are asked to complete a voluntary survey.
- **Annual HSPP Survey (IRAT):** PIs on all active studies in iStar are invited to complete an online survey of satisfaction with the IRB, HSPP, and iStar systems. The survey is sent to 6000+ people, including active researchers and staff, IRB members, Department Chairs, Deans, and other university

contacts. The creation of a Faculty Advisor brochure and in-person iStar training are some of the results of the IRAT survey.

Policies and Procedures Evaluation and Updates

- Policies and Procedures (P&P) Review: A working group was formed to continually update and evaluate the Human Subjects Protection Program (HSPP) policies and procedures manual to ensure it reflects current practices, relevant regulations, federal guidance, and best practices.

Technical Systems/Resource Improvements

- iStar (online IRB application) Development Group: Directors from the USC University Park and Health Sciences campuses and Children's Hospital of Los Angeles meet bimonthly to propose, discuss, and implement iStar system improvements.
- IRB/OPRS Websites: The IRB websites are continually updated with current information, guidance materials, instructions, policies, regulations, links to related websites, and templates for IRB submissions. Recently, the website was upgraded to make the sites more user-friendly and navigable.
<http://oprs.usc.edu/>

Internal Communication

- Monthly HSPP Conference Call: OPRS hosts a monthly conference call to discuss issues of concern related to human subjects protection, share information, assign tasks, plan events, and discuss upcoming changes. IRB directors, staff and IT staff are included in the conference call.
- Executive Committee Meeting: Monthly meeting amongst OPRS Executive Director and IRB Chairs and Directors from both campuses to discuss updates to regulations, implementation of new procedures and best research practices.

Staff Training and Improvement

- IRB Staff Education: OPRS arranges biannual educational sessions for IRB members and staff during IRB meetings. Topics include updates to regulations and best practices, considerations for specialized research, and journal articles about IRB review. Guest speakers are invited to lead discussions as well as members of the USC HSSP team.

Resources for Student Researchers

- OPRS Student Mentor: OPRS has a graduate assistantship for a student who serves as UPIRB liaison to student IRB applicants by meeting with student researchers and by providing one-on-one assistance and training. The student mentor is a full voting IRB member. The student mentors bring student concerns into policy meetings and also reviews OPRS documents from a student's perspective. Each holder of the assistantship joins OPRS in conducting education sessions and creating educational materials.

- Human Subjects Research Brochures and Booklets: OPRS creates and updates a plethora of human subjects research education booklets and pamphlets. These are distributed during classroom education sessions, meetings, and online. OPRS recently completed a series of nine booklets on the Responsible Conduct of Research (RCR).
<http://opr.usc.edu/education/booklets/>