



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

On-Site Audits

“For Cause” Audits: CQI staff investigates allegations of misconduct, questionable activities in IRB submissions, or other concerns. Individual projects and/or all projects belonging to an investigator may be audited when justified.

“Not for Cause” Audits: CQI staff conducts internal assessments to improve the overall HSPP, assure researcher adherence to IRB policies, federal regulations, and the protocol. Outcomes include identifying and correcting noncompliance, working with researchers to adopt best practices, and offering training to researchers and staff.

Significant New Information/Findings (SNIF) Addendum: To follow up on implementation when the IRB has affirmed the need for a SNIF addendum. iStar questions will be added to continuing review to verify receipt of SNIF addendum by enrolled subjects.

Online IRB Application (iStar) Audits: Queries on application questions, and IRB processing time

Privacy and Confidentiality: Researchers conflate these two terms (AAHRPP finding). Initial corrective action will be through IRB staff sending inadequately answered explanations back to the PI for clarity.

Investigator-initiated: Investigators answer “yes” to this question erroneously, which creates inaccurate numbers when running reports on the volume of investigator-initiated studies. Oversight of investigator-initiated differs from sponsored research and necessitates increased attention by the IRB.

Data Safety and Monitoring Plans: Monitoring plans often lack details. Evaluate answers provided by researchers and check IRB review of the plan. Initial corrective action will be through IRB staff sending inadequately answered explanations back to the PI for clarity.

Consistency between Sponsor Contracts and Consent Document: Through the use of a checklist, the IRB staff works with the Health Research Association (HRA) staff to verify the contract language in the research agreement is consistent with language in the informed consent document. If the language is inconsistent, the IRB will not approve the study.

IRB Processing time (60+ days for IRB approval): Three times a year, review projects that took 60+ days to obtain IRB approval, investigate delays, and determine whether IRB related issues or investigator issues. Recent trends included inadequate initial screening, poorly worded iStar questions, and an IT glitch in iStar.

HSPP Outreach Activities

“Meet ‘N Greets”: Annual meetings are held with many of the University Park Campus schools/departments to listen to IRB concerns, discuss changes, and keep an open dialogue in both directions.

Faculty Meetings: The Office for the Protection of Research Subjects (OPRS) and IRB Directors are often invited to speak with faculty to address problems and work to correct. Recent issues included quality of student submissions, and lack of mentoring.

Monthly IRB Education Sessions: The OPRS office provides monthly training sessions on both campuses for researchers on human subject protections, research ethics, and the IRB submission process. These sessions are announced through the listserv.

Classroom Education: IRB Directors are often invited as guest lecturers to discuss human subjects protections with students (e.g. incoming PhD students, medical students, undergrad scholars, etc...).

Communication and Training on Current Changes: Changes to the HSPP (e.g. policies, systems, requirements, etc.) are communicated to the HSPP stakeholders through a listserv, website, and/or a newsletter. In person training sessions are provided when appropriate (e.g. research coordinators, IRB staff, and investigators).

Community IRB Member Luncheon: OPRS hosts annual meetings with community IRB members from many Southern California institutions to discuss emerging issues and to share information.

Quality Meeting with Grants and Contracts Department: Meet with Grants and Contracts staff to discuss and refine shared processes, provide IRB system training, and discuss IRB issues related to the various institutional systems.

IRB Video: The University Park IRB created an online video/tutorial with information about human subjects education, IRB applications, which is on the IRB website, School of Education website, and available to the public.

Listserv: New information, changes, and guidance documents are communicated to stakeholders through the listserv. Training sessions are publicized through the listserv.

Internal Evaluations and Surveys

Annual Evaluation of IRB members: IRB members are reviewed for their participation at IRB meetings, quality of their reviews, and IRB attendance.

Annual Evaluation of IRB Chair/Staff: the IRB Chair and staff efforts, turnaround time, and quality of review, is evaluated.

Annual Evaluation of the IRB Budget: the annual budget is reviewed to ensure resources are adequate to assure a productive work environment. This includes a review of the volume of studies and level of IRB staff.

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): Current iStar users are invited to complete an online survey of satisfaction with the IRB and HSPP systems. The survey is sent to 6000+ people, including active researchers and staff, IRB members, Department Chairs, Deans, and other school contacts. A Faculty Advisor brochure was one result of an 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.

University Park IRB (UPIRB) Subcommittee: A working group of UPIRB committee members was created to refine UPC IRB forms, discuss and propose changes to the iStar system, and review policies. The continuing review application was modified based on recommendations by this group.

Technical Systems/Resource Improvements

iStar (online IRB application) Development Group: Directors from the University Park and Health Sciences campuses meet bimonthly to propose, discuss, and implement iStar system improvements.

IRB Websites: The IRB websites are continually updated with current information and provide guidance materials, instructions, policies, regulations, links to related websites, and templates for IRB submissions. Recently, the website was upgraded by web designers to make the sites more user-friendly and navigable.

Internal Communication

Monthly HSPP Conference Call: OPRS hosts a monthly conference call to discuss issues of concern from all parties, share information, assign tasks, plan events, and discuss upcoming changes to all IRB Directors, Staff, IT Staff, HRA, and Office of Compliance.

IRB Staff Training and Improvement

Certified IRB Professional (CIP) Preparation Course: The OPRS office created classroom training for IRB staff preparing for the CIP certification exam. Activities included guest speakers, practice tests, and a thorough review of all relevant human subjects research regulations and state laws. Resources and binders were provided to all attendees. All IRB staff who attended passed the CIP exam.

Resources for Student Researchers

OPRS Student Mentors: OPRS provides graduate assistantships to students to serve as UPIRB liaisons by meeting with student researchers and by providing one-on-one assistance and training. The student mentors are full voting IRB members and represent USC students in IRB deliberations. The student mentors bring student concerns into policy meetings, they also review OPRS documents for student perspective.