University Administration: Prepare to be Interviewed! for AAHRPP Site Visit

As an Administrator, you are an integral part of the Human Subject Protection Program (HSPP) at USC. USC is preparing for re-accreditation of its HSPP. Achieving accreditation publicly affirms USC as a top-tier academic institution in its ethical and regulatory conduct of human subjects research.

USC’s HSPP accreditation largely depends on these interviews. You will be expected to:

- Know your role(s) in the Human Subjects Protection Program (HSPP) and the roles of the HSPP (e.g. IRBs, OPRS, Office of Compliance)
- Know where to obtain answers to ethical/regulatory questions about conducting research duties (e.g. IRB Chair/Director/staff/members, human subjects policies and procedures, HSPP website: oprs.usc.edu)
- Know how to access HSPP Policies and Procedures: oprs.usc.edu/rules
- Know how to report non-compliance, adverse events, unanticipated events, etc.
- Know how to maintain compliant research records and documentation, and be able to explain your research submission and rationale
- Know the regulatory standards that pertain to your research/discipline (e.g. OHRP, FDA, regulations for experimental drugs or devices)
- Know the ethical aspects and regulatory details applicable to research: what you are reviewing/performing is sound, purposeful, and has value
- Understand what constitutes a conflict of interest at all levels (e.g. staff, IRB, institution, administration)
- Familiarize yourself with the terminology contained in the iStar: https://oprs.usc.edu/review/istar/glossary/
- Describe the Human Subjects Education you’ve had: HSR, GCP, HIPAA training
- Know how to recruit subjects ethically and justly while adhering to inclusion/exclusion criteria

To obtain accreditation, all interviews must be successful. These materials and OPRS staff are available to help you succeed. The following guidance is intended to prepare you for the interview.

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1. **What is AAHRPP accreditation and why is it important for USC?**

AAHRPP accreditation is a gold standard recognizing adherence to a rigorous set of human subjects protection standards that surpass state and federal requirements. The accreditation process involves an evaluation of the USC Human Subjects Protection Program (HSPP) and a site visit focused on interviews with critical members of the HSPP, including IRB members. Accreditation largely depends on these interviews which involve tough questions about research policies, process, and training.

2. **What are the components of the USC Human Subjects Protection Program (HSPP)?**

The USC Human Subjects Protection Program (HSPP) is a team effort. It includes all the University Park and Health Sciences IRB staff, directors, chairs, vice chairs, members, as well as Office of Compliance officials, Office for the Protection of Research Subjects members and the Vice President of Research. IRB staff and reviewers are responsible for review and administration of IRB issues. OPRS is responsible for policy, education and outreach efforts. The Office of Compliance serves as a legal and ethical resource for OPRS and the IRBs.

3. **What does the IRB do?**

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The main mission of the Institutional Review Boards at USC is to protect the rights, safety and welfare of research subjects. The IRBs review and approve research in accordance with Department of Health and Human Services (HHS) regulations in 45 CFR 46. For studies involving products regulated by the Food and Drug Administration (FDA), the IRBs review research according to the requirements in 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812. The IRBs also comply with HIPAA and the regulations in 45CFR 160 and 164.

4. What is the guiding philosophy of the Human Subjects Protection Program at USC?

The University of Southern California is committed to conducting its biomedical and behavioral research involving human subjects under rigorous ethical principles. The IRBs have been established to comply with existing regulations of the federal government in accordance with U.S. Department of Health and Human Services (HHS) regulations (46 CFR Part 46), the Food and Drug Administration (FDA) regulations (21 CFR 50, 56), and with the Federalwide Assurance accepted by the DHHS. Office for Human Research Protections (OHRP). The University has also agreed to adhere to the statements of ethical principles as described in The Belmont Report: Ethical Principles and Guidelines for the Human Subjects of Research. Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The IRBs also meet the International Conference on Harmonization Good Clinical Practice Consolidated Guidelines regarding organization and operation of Institutional Review Boards.

This fundamental commitment to the protection of human subjects applies to all University of Southern California research involving human subjects regardless of whether the research is funded through Government, non-profit or industry sponsors, through University funds, or not funded at all, and regardless of the location of the research.

5. What does your administration do to support human subjects activities?

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

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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).

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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.

**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.

**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

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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 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
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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.

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.
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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).

6. What education must an investigator complete to be qualified to participate in a human subjects project?

The answer is person-specific but can include CITI Human Subjects Protection course, Good Clinical Practices, Responsible Conduct of Research, HIPAA training, Certified IRB Professional training, as applicable. Additional sources of ongoing education include: PRIM&R conferences (or equivalent professional meetings), monthly IRB member education during IRB meetings and additional educational opportunities offered at USC (Office of Research, Office of Compliance, IRB/OPRS).

7. Who should you contact for help with regulatory or ethical issues?

The first point of contact is normally the IRB and/or the Office for the Protection of Research Subjects. Additional follow-up may be necessary with the Office of Compliance, USC General Counsel, the FDA, or the Health and Human Services Office for Human Research Protections (OHRP).

8. In a dispute between IRB and a researcher, can an administrator overrule IRB’s decision? Why?

No, "Consistent with federal regulations, the university IRBs have the sole authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. [See 45 CFR 46.109; 45 CFR 46.113]." "

9. How do you handle complaints regarding the IRB system?

Subjects/participants, researchers, IRB members, and others who have human subjects

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research related complaints, concerns, recommendations, or reports of suspected violations are encouraged to contact one of the following offices:

- Office for the Protection of Research Subjects
- USC Office of Compliance
- University Park IRB (UPIRB)
- Health Sciences IRB (HSIRB)
- Office of the Vice President for Research

Visit https://oprs.usc.edu/about/complaints/ for the contact information for each department.

All inquiries are taken seriously and will be directed to the appropriate personnel. Where 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 Protection Program, due consideration will be given and changes made, as appropriate.

The USC Office of Compliance also maintains an anonymous Help and Hotline that can be used to confidentially report suspected violations of law, without fear of retribution. Anyone who has knowledge or a good faith belief that an applicable law, regulation, or university policy has been violated, should report such information to the Help and Hotline at (213) 740-2500.

10. How do you communicate University values and ethical messages to your associates and institution?

University values are communicated through policy choices such as the USC Code of Ethics:

At the University of Southern California, ethical behavior is predicated on two main pillars: a commitment to discharging our obligations to others in a fair and honest manner, and a commitment to respecting the rights and dignity of all persons. As faculty, staff, students, and trustees, we each bear responsibility not only for the ethics of our own behavior, but also for building USC's stature as an ethical institution.

We recognize that the fundamental relationships upon which our university is based are those between individual students and individual professors; thus, such relationships are especially sacred and deserve special care that they not be prostituted or exploited for base motives or personal gain.

When we make promises as an institution, or as individuals who are authorized to speak on behalf of USC, we keep those promises, including especially the promises expressed and

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implied in our Role and Mission Statement. We try to do what is right even if no one is watching us or compelling us to do the right thing.

We promptly and openly identify and disclose conflicts of interest on the part of faculty, staff, students, trustees, and the institution as a whole, and we take appropriate steps to either eliminate such conflicts or insure that they do not compromise the integrity of the individuals involved or that of the university.

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We nurture an environment of mutual respect and tolerance. As members of the USC community, we treat everyone with respect and dignity, even when the values, beliefs, behavior, or background of a person or group is repugnant to us. This last is one of the bedrocks of ethical behavior at USC and the basis of civil discourse within our academic community. Because we are responsible not only for ourselves but also for others, we speak out against hatred and bigotry whenever and wherever we find them.

We do not harass, mistreat, belittle, harm, or take unfair advantage of anyone. We do not tolerate plagiarism, lying, deliberate misrepresentation, theft, scientific fraud, cheating, invidious discrimination, or ill use of our fellow human beings — whether such persons be volunteer subjects of scientific research, peers, patients, superiors, subordinates, students, professors, trustees, parents, alumni, donors, or members of the public.

We do not misappropriate the university's resources, or resources belonging to others which are entrusted to our care, nor do we permit any such misappropriation to go unchallenged.

We are careful to distinguish between legal behavior on the one hand and ethical behavior on the other, knowing that, while the two overlap in many areas, they are at bottom quite distinct from each other. While we follow legal requirements, we must never lose sight of ethical considerations.

Because of the special bonds that bind us together as members of the Trojan Family, we have a familial duty as well as a fiduciary duty to one another. Our faculty and staff are attentive to the well-being of students and others who are entrusted to our care or who are especially vulnerable, including patients, volunteer subjects of research, and the children in our daycare and community outreach programs.

By respecting the rights and dignity of others, and by striving for fairness and honesty in our dealings with others, we create an ethical university of which we can all be proud, and which will serve as a bright beacon for all peoples in our day and in the centuries to come.

- Adopted by the Board of Trustees of the University of Southern California, March 28, 2004

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11. Is the HSPP budget sufficient? How are HSPP budget decisions made?

Yes. Annually, the IRB budget will be reviewed by the IRB Chairs, the Executive Director of OPRS, and the Vice Provost for Research Advancement and modified as necessary to accommodate the volume and type of research reviewed, including appropriate space, facilities, and staff. The budget then undergoes a thorough review process by the Office of the Provost.

12. What is the “process” of consent?

Obtaining informed consent is a basic ethical obligation for researchers. The process of consent should ensure that potential subjects are provided with information about the study in a way that is understandable to them (written in “lay language” and in the subject’s language) allowing them to make an informed and voluntary decision about participation. The amount of information and the manner of presentation can vary depending on the complexity and risk involved in the study. The consent form serves to document that the subject agreed to participate in the study and also serves for the subject’s future reference.

Subjects should sign the consent form after the investigator has verbally explained the purpose and procedures involved in the study, answered questions, and provided information that permits the subject to make an informed decision. The consent form must be signed before any study data collection procedures begin. The consent process should be an ongoing educational interaction between the investigator and the research subject that is ongoing throughout the study.

Only legally competent adults can give legally effective informed consent. Minors and those individuals who are not competent to provide consent should be given the opportunity to assent to participate in the research project. Assent is an affirmative, knowledgeable agreement to participate in the project. Adequate provisions should be made for soliciting the independent, non-coerced assent from minors or cognitively-impaired persons who are capable of a knowledgeable agreement. In general, the IRB recommends that children ages seven and older, and most cognitively-impaired adults, be given the opportunity to assent. In cases where assent is obtained from a minor or cognitively-impaired subject, permission must also be obtained from an authorized representative. In studies involving minors, the authorized representative may be:

- a parent
- court-appointed guardian
- the court

13. What is ethical research?

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- Research must have sound design and not unnecessarily expose subjects to risk (45 CFR 46.111)
- It is unethical to put subjects at risk or even to inconvenience them in a flawed study.
- Research should advance scientific understanding and promote human welfare.

14. What is the Nuremberg Code? the Belmont Report? the “Common Rule”? 

**Nuremberg Code**

Modern human subjects protections began with the Nuremberg Code which was developed for the Nuremberg Military Tribunal as standards by which to judge human experimentation conducted by the Nazis. The Code captures many of what are now considered basic principles governing the ethical conduct of research involving human subjects. The first provision of the Code states that “the voluntary consent of the human subject is absolutely essential”, which is the cornerstone of ethical experimentation involving human subjects.

The Nuremberg Code also discusses capacity to consent, freedom from coercion, and comprehension of the risks and benefits involved. Other provisions include: minimization of risk and harm, favorable risk/benefit ratio, qualified investigators using appropriate research designs, and freedom for the subject to withdraw at any time.

**Belmont Report**

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research presented *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The Report sets forth three basic ethical principles: respect for persons, beneficence, and justice. These principles are now accepted as the three quintessential requirements for the ethical conduct of research involving human subjects. The Report describes how these principles apply to the conduct of research. Specifically, the principle of respect for persons underlies the need to obtain informed consent; the principle of beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of justice requires that subjects be fairly selected.

The Report also provides a distinction between “practice” and “research”:

- *practice* is described as medical or behavioral interventions to diagnose, treat, or provide therapy to particular individuals.
- *research* is described as an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge.

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The Report recognizes that “experimental” procedures do not necessarily constitute research, and that research and practice may occur simultaneously.

The “Common Rule”

In 1991, 16 federal departments and agencies adopted a common set of regulations (hence the term “Common Rule”) governing human subjects research sponsored by the federal government. The Rule is designed to create a uniform human subjects protections system for all relevant federal agencies and departments. The Rule consists of Subpart A of the Department of Health and Human Services (DHHS) regulations for the protection of human subjects. The authority and function of the IRB are defined in the Common Rule. Additional protections for vulnerable populations have also been adopted by DHHS:

- Subpart C, “Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects”
- Subpart D, “Additional Protections for Children Involved as Subjects in Research”

15. What is OHRP, FDA, and HIPAA?

OHRP

The Office for Human Research Protections (OHRP) is the federal office overseeing the system that protects the rights, welfare, and well-being of subjects involved in research and helping to ensure that research is carried out in accordance with Department of Health and Human Services (DHHS) regulations.

FDA

The Food and Drug Administration is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, US food supply, cosmetics, and products that emit radiation. FDA regulations for research with drugs, devices, and biologics are contained in Title 21 Parts 50 and 56 of the Code of Federal Regulations. Additional FDA regulations that are relevant to IRB review of research are Parts 312 (Investigational New Drug Application), 812 (Investigational Device Exemptions) and 860 (Medical Device Classification Procedures).

HIPAA

The Health Insurance Portability and Accountability Act (HIPAA), also known as the “Privacy Office for the Protection of Research Subjects (OPRS)

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Rule” (effective April 14, 2003), establishes minimum Federal standards for safeguarding the privacy of individual’s identifiable health information. The law generally prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from using or disclosing “protected health information” without written authorization from the individual.

16. Are there additional requirements for studies sponsored by the DoD, NSF or DOE? How are studies tracked when federal sponsors have unique requirements?

Many agencies such as the Department of Defense (DOD), the National Science Foundation (NSF) and the Department of Energy (DOE) have requirements that differ from those set out by the U.S. Department of Health & Human Services (HHS) or privately-funded research. Consult the sponsor’s website, the project officer, or the IRB for additional information.

These projects are identified both through the iStar system and when they are flagged by the Department of Contracts and Grants (DCG). Depending on the funding source, DGC (federally, departmentally or foundation-funded projects), the Clinical Trials Office (industry-sponsored projects) and the Principal Investigator are responsible for ensuring that the requirements of the funding agency are met so that funding can be obtained.

17. What is your role in managing conflicts of interest and institutional conflicts of interest?

This is role-specific.

18. What is your involvement/role in USC’s HSPP? What research is under your purview?

This is role-specific.