AAHRPP Site Visit 2020:
Interview Guide for Researchers and Research Staff

Accreditation
AAHRPP, or the Association for the Accreditation of Human Research Protection Programs, will conduct a reaccreditation site visit at the University of Southern California spring of 2020. AAHRPP is an international, independent nonprofit organization that reviews and accredits an institution’s human research protections program. “AAHRPP accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that an Human Research Protection Program is focused first and foremost on excellence.” USC has been AAHRPP accredited since 2007.

AAHRPP has been provided with a written description of the USC Human Subjects Protection Program (HSPP) Policies and Procedures, and resources, as well as with a list of all active IRB protocols. During the site visit, representatives from AAHRPP will conduct interviews and review records to ensure that those policies and procedures have been implemented effectively and are being adhered to throughout the university.

As a researcher or research team member, you are an integral part of the USC HSPP. During the site visit, AAHRPP will select approximately 75 individuals to be interviewed. Anyone who has a role in human research may be selected for an interview. A number of researchers and research staff will be interviewed.

AAHRPP will provide a list of individuals selected for interviews approximately three weeks prior to the site visit. If selected for an interview by AAHRPP, you will be notified closer to the visit date and provided with additional information.

We anticipate each session will take between 20-45 minutes. Sessions will be in the form of individual or group interviews. We expect questions to be focused on regulatory and ethical issues related to research with human participants, but questions may also relate to the conduct of your research, as well as your impressions of the USC HSPP and the USC IRBs. If you were selected for an interview based on a specific type of protocol (e.g., international, device, etc.), please review your procedures for conducting that type of research.

Preparing for the Site Visit
This document is provided to help you prepare should the visit team select you for an interview. You may be familiar with the information included however, this guide is intended to refresh your understanding. Information is also available on the OPRS website: AAHRPP Reaccreditation Visit. Each section of this document is followed by a list of questions that you may be asked. This document includes sections on the following topics:

- Section 1: General Tips
- Section 2: USC HSPP Policies and Procedures
- Section 3: Roles and Responsibilities of Investigators and Research Staff
- Section 4: Minimizing Risks and Protecting Participants’ Rights and Welfare
- Section 5: Compliance with IRB and Other Review Unit Requirements
- Section 6: Obtaining and Documenting Informed Consent
- Section 7: Conflict of Interest Disclosure
Section 1: General Tips

USC reaccreditation depends largely on these interviews. You will be expected to:

- Understand the USC Human Subjects Protection Program's structure
- Clearly describe your role in supporting the protection of research participants
- Be familiar with the USC HSPP Policies and Procedures and where to access them
- Understand the purpose of the AAHRPP accreditation process
- Know how to report non-compliance and Unanticipated Problems Involving Risks to Subjects or Others (UPX)
- Understand and describe the ethical aspects, the purpose, and the value of your work
- Know the regulatory standards that apply to your research
- Know IRB application (iStar) submission terminology, and describe your IRB submissions
- Understand what constitutes conflict of interest
- Know how a potential conflict of interest is disclosed and reviewed at USC
- Describe the humans research training that you had: (e.g., CITI Training)
- Know how to recruit participants ethically and in an equitable manner while adhering to inclusion/exclusion criteria

If interviewed, we recommend that you respond directly to the question asked. If a question seems unrelated to the type of work you do, please let the interviewer(s) know. For example, if a question regarding Food and Drug Administration (FDA) regulations is asked, a social/behavioral researcher should let the interviewer(s) know that drugs or medical devices are not part of their research. Below are examples of the type of general questions you might be asked.

### Possible General Questions

#### About Your Own Project(s)

- Describe your study. What are the procedures? How do you recruit? What is the consent process?
- What kinds of harms can occur in your study? How do you minimize those harms?
- Do you communicate results with your participants after the completion of your research?
- How did you interact with the IRB on this study?

#### Relationship with the IRB

- What is AAHRPP accreditation and why is it important to USC?
- What is the IRB’s reputation on campus?
- What are typical turnaround times?
- How did the IRB prepare you to conduct your research?
- How do you feel about the IRB?
- Do you think IRB reviews are fair?
- What do you think about the IRB and their efforts to protect human research participants?
- Do you know how often the convened (full board) IRB meets?
Section 2: USC HSPP Policies and Procedures

The following sections are taken from the USC HSPP Policies and Procedures available on the Office for the Protection of Human Subjects (OPRS) website. The USC University President, Carol L Folt, has provided a memorandum that designates responsibility to Maja Mataric, Interim Vice President of Research as the Institutional Official. Key elements of policy are provided for your review.

The Interim Vice President for Research, Maja Mataric, serves as the Institutional Official (IO) for USC and is responsible for the overall conduct of research at the University. The USC IRB is responsible for the review of all human subjects research conducted at USC. The IO has the authority, but is not limited, to take the following actions:

- Suspend or terminate research
- Place administrative sanctions on investigators for non-compliance, such as
  - Suspending or terminating of research privileges
  - Requiring investigators or research staff to undergo additional training as condition of continuing research
  - Appointing an independent person to monitor ongoing research

The Vice President for Research may delegate duties to University representatives including the Office for the Protection of Research Subjects, IRB Chairs, and the Office of Compliance, as appropriate.

Julie Slayton is the Director for the USC Office for the Protection of Research Subjects. She has the authority to take the following actions or delegate these authorities to a designee:

- Ensure that the HSPP has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner
- Determine what IRBs the Institution will rely upon
- Ensure that the research review process is independent and free of undue influence.

The USC HSPP is supported by:

- The USC Office for Research, the Office for the Protection of Research Subjects, the USC Institutional Review Boards (IRB) Office, the Clinical Trials Office (CTO), the Office of Ethics and Compliance, the Office of Research Integrity, and the Department of Contracts and Grants
- Academic units, including schools, colleges, and other units to which faculty, staff, and trainees engaged in human research are appointed
- The Biomedical IRBs 1, 2, and 3 and the Social Behavioral IRB
- Key executive and administrative offices, including the Office of General Counsel.

The mission of USC’s Human Subjects Protection Program plan is to protect the rights and welfare of participants involved in human research that is overseen by this Institution.
### Possible Questions About HSPP Policies and Procedures

- Who is the institutional official responsible for research at USC?
- Who is the organizational official responsible for the USC Human Subjects Protection Program?
- What are the components of the USC HSPP?
- What is the mission of the HSPP at USC?

### Section 3: Roles and Responsibilities of Investigators and Research Staff

Investigators have primary responsibility for protecting the rights and welfare of humans participating in research. Safeguarding human research participants takes precedence over the goals and requirements of any research endeavor. The principal investigator (PI), co-investigator (CO-I), and other members of the study team are expected to be knowledgeable about and adhere to:

- **The Belmont Report** identifies and summarizes three main ethical principles that should govern human research:
  - **Respect for persons** (autonomy/voluntary participation/adequate information)
  - **Beneficence** (risks of research are reasonable in relation to the benefits the research may provide to subjects or science)
  - **Justice** (selection of subjects is equitable and is representative)

- **The Common Rule (45 CFR 46)** is the federal regulatory framework that governs federally funded research with human subjects and codifies the ethical principles of the Belmont Report. Under the Common Rule, research with human subjects is defined as follows:
  - **Research**: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
  - **Human Subject**: A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) information or biospecimens through interaction or intervention with the individual, and uses, studies or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- **21 CFR 50** and **21 CFR 56** serve as the regulatory framework for research regulated by the FDA (i.e., research involving drugs, devices, biologics). This set of regulations is derived from the Common Rule, but the FDA and HHS regulations have some **notable differences in their content**. Research that is sponsored by the Department of Defense (DOD), Environmental Protection Agency (EPA), Department of Energy (DOE), and Department of Education (ED) hold additional regulatory requirements.

- Other federal and state laws and regulations that apply to research include the Mental Health and Developmental Disabilities Confidentiality Act [MHDDCA], Family Educational Rights and Privacy Act [FERPA], Health Insurance Portability and Accountability Act [HIPAA], 21st Century Cures Act, General Data Protection Regulation [GDPR], and National Institutes of Health Policy on the Use of a Single Institutional Review Board for Multi-Site Research. (Guidance and clarification of regulations are provided by the Office for Human Research Protection [OHRP].)
### Possible Questions About Roles/Responsibilities of Investigators and Research Staff

- What is the PI’s primary responsibility in conducting the research?
- What is the Common Rule?
- What are the Belmont Principles and when did you first hear of them?
- Are there additional requirements for studies sponsored by the DOD, EPA, DOE, or ED?

### Section 4: Minimizing Risks and Protecting Participants’ Rights and Welfare

Minimizing risks to participants and ensuring participants rights and welfare are key components of human research protections. Below are some strategies through which these goals can be accomplished.

- Design and implement protocols that comply with applicable regulatory and institutional policies, as well as the principles of the Belmont Report
- Verify procedures are consistent with sound research design by ensuring that the research is reasonably expected to answer the proposed question and that the resulting knowledge is expected to be sufficiently important to justify the research
- Ensure that recruitment procedures foster the equitable selection of participants
- Utilize procedures already being performed for diagnostic or treatment purposes, when possible
- Ensure that appropriate resources are available to conduct the research (e.g., personnel, facilities, equipment, etc.)
- Keep in mind that “minimal risk” to subjects means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is adequately protected
- Establish adequate provisions for monitoring participants to identify adverse events and to review data collected to ensure participant safety, when appropriate
- Develop plans for protecting participant privacy and the confidentiality of data. In human research, these terms are defined as follows:
  - **Privacy**—Relates to an *individual* having control over the extent, timing, and circumstances regarding the sharing of information about themselves with others
  - **Confidentiality**—Relates to the protection of a participant’s *data* that has been shared with the researcher with the expectation that it will be protected and not disclosed
- Ensure enhanced protection for participants vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or those economically or educationally disadvantaged)

The process for evaluation of scientific merit of a study can be found in the [USC HSPP Policies and Procedures – Chapter 7: Review of Scientific Merit](#).
Possible Questions About Minimizing Risks & Protecting Participants’ Rights and Welfare

- What is the process of scientific review for your research?
- Do you know the difference between minimal and more-than-minimal risk?
- What is the difference between privacy and confidentiality?
- How do you protect participant privacy and confidentiality of data?
- How/who do you recruit for your research?
- How do you ensure that only participants meeting the inclusion criteria are enrolled?
- What additional mechanisms do you have in place to protect your research participants?

Section 5: Compliance with IRB and Other Review Unit Requirements

Investigators and research staff have a responsibility for ensuring research is conducted in compliance with IRB, as well as other institutional and applicable regulatory requirements. Below are some requirements that investigators and research staff should be aware of related to this responsibility.

- All research with human participants must obtain IRB review and approval before work can begin.
- The requirements of the IRB (i.e., submission of initial review, continuing review, modifications, and reporting of adverse events and unanticipated problems) must be met.
- Research must be conducted as specified in the IRB approved protocol.
- All proposed changes to the research, no matter how minor, must be approved by the IRB prior to implementation unless necessary to eliminate immediate hazard to participants – in which case a report to the IRB must follow.
- PI's are responsible for the content of all submissions to the IRB (e.g., iStar application, supporting documents, etc.)
- Materials must be submitted to the IRB in a timely fashion (e.g., requests for changes, continuing review applications, etc.)
- Information regarding reportable events is available in USC HSPP Policies and Procedures – Chapter 18: Reportable Events and Non-compliance, and includes Unanticipated Problems Involving Risks to Subjects or Others (UPX) which must be reported to the IRB as soon as possible but no later than 10 working days after the investigator becomes aware of the event.

- UPX – Any information, including any incident, experience, or outcome that meets ALL of the following conditions:
  - unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.
  - related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research), and
  - suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognize.
Potential non-compliance with laws, regulations, or IRB requirements by the research team or others must be reported, even if this non-compliance was unintentional or discovered during the course of quality assurance activities. Participants being exposed to unnecessary risk may also be reported as potential non-compliance.

Reports of research misconduct, complaints or concerns can be forwarded to:
- USC Office of Research Integrity
- USC Office of Ethics and Compliance
- USC Office for the Protection of Research Subjects
- The Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services (HHS)

More information is available on the OPRS website: Complaints, Concerns and Report of Misconduct

OPRS and the IRB office conducts for-cause and not-for-cause audits in order to ensure the research complies with the federal and applicable regulations, guidelines and institutional policies that govern research. Clinical trial self-monitoring education is available to all research personnel from the USC International Center for Regulatory Science/Southern California Clinical and Translational Science Institute (SC CTSI). The Clinical Trial Quality Training Series offers instruction modules along with document templates, tools and SOP samples. These activities aim to ensure that rights of participants are protected; that researchers and staff have educational resources that enables them to fulfill their roles; and that the research community has access to study support tools and other compliance related resources.

### Possible Questions About Compliance with IRB and Other Review Unit Requirements

- How do you notify the IRB about proposed changes to your research?
- What would you do if you lost your research data and who would you tell?
- Do you know how to report a participant complaint or a problem with your study?
- What is a UPX? Have you ever had one on a study?
- How would you report an adverse event or a UPX?
- Do you know what non-compliance is and when and how to report it?

### Section 6: Obtaining and Documenting Informed Consent / Waiver of Document of Informed consent

#### Documentation of Informed Consent

Informed consent is the voluntary choice of an individual to participate in research based on a complete and accurate understanding of the study. Informed consent is not a single event or document, but rather an ongoing process involving the investigator and/or study team and the research participant. Informed consent requires full disclosure of the nature of the research and the participant’s role in that research, understanding of that role by the potential participant, and the participant’s voluntary choice to join the study. For more information on obtaining and documenting informed consent, please visit Informed Consent, on OPRS website and USC HSPP Policies and Procedures – Chapter 9: The Process of Consent.

- Investigators are responsible for ensuring proper informed consent is obtained and documented before the research begins unless the IRB waives this requirement.
Informed consent must be conveyed in language that is understandable to participants or their legally authorized representative.

Consent must be sought under circumstances that minimize potential for coercion or undue influence.

The participant will be given answers to questions and an adequate amount of time to consider participation in the study relative to the initiation of study procedures.

It must be made clear to participants that their participation is voluntary and that they may withdraw at any time with no penalty.

The recruitment and consent process will not promise participants a certainty of cure or benefit beyond what is outlined in the informed consent document/informed consent script.

The recruitment and consent process will take place in an area in which it is possible to maintain privacy and confidentiality.

Consent is documented by use of a consent form approved by the IRB unless a waiver of informed consent or a waiver of documentation of informed consent is granted.

The Common Rule (45 CFR 46.116 (a)) requires that the informed consent includes:

- A statement that the study involves research;
- Information on the purpose of the research;
- The expected duration of subject participation;
- A description of the procedures (identification of experimental procedures);
- A description of reasonably foreseeable risks or harms;
- A description of any benefits to subjects or others;
- Disclosure of appropriate alternative treatments/procedures, if the research involves clinical treatment;
- A description of how the confidentiality of records will be maintained
- A description of procedures related to compensation for injury, if the research is more than minimal risk;
- Contact information for the PI and IRB
- A statement that participation is voluntary and that the subject may withdraw at any time with no penalty or loss of benefits.

One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

2. A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

The participant (or their legally authorized representative) should be provided with a copy of the consent document at the time of consent.
Investigators are responsible for retaining signed consent documents for at least three years after completion of the research (six years if protected health information will be used or disclosed in connection with the study) or longer if required by the institution or research sponsor.

**Waiver of Document of Informed Consent**
The IRB may waive the requirement for the Investigator to obtain signed (documented) informed consent for some or all participants [45 CFR 46.117(c)] if it finds that:

- The only record linking the participant to the research would be the consent form, and the principal risk to the participant is the potential harm resulting from a breach of confidentiality. In that event, each participant (or legally authorized representative) should be asked if he/she wishes to have documentation linking the participant with the research. The participant’s wishes will govern.

- The research presents no more than a minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, or asking shoppers in a mall about the ambient lighting or temperature).

- If the participant (or legally authorized representative) is a member of a distinct cultural group in which signing forms is not the norm, that the research presents no more than minimal risk of harm, and there is an appropriate alternative for documenting that informed consent was obtained.

Where documentation of informed consent has been waived, the IRB may require investigators to provide participants with a written statement regarding the research.

In order to grant a waiver of signed (documented) consent, the IRB (Full Committee or Chair/Designee) must document that it believes the request meets the following criteria: 1) The research involves no more than minimal risk to the participants; 2) The waiver will not adversely affect the rights and welfare of the participants; 3) The research could not be practicably carried out without the waiver; 4) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; 5) Whenever appropriate, the participants will be provided with additional pertinent information after participation.

**Possible Questions About Obtaining and Documenting Informed Consent**
- What are the required elements of informed consent?
- Describe your consenting process. Does the participant get a copy? If yes, when do they get it?
- What is the process for obtaining consent? Who does it? Where are participants approached? Do participants have time to think about it before they agree to participate?
- What would you do if you recruited a non-English speaking participant? How would you consent?
- How do you know if the participant understands the consent document?
- Who answers questions about the research?
- What is a waiver of informed consent?
Section 7: Conflict of Interest Disclosure

A Conflict of Interest (COI) is a situation in which financial or other personal considerations compromise, or have the appearance of compromising, an individual’s professional judgment in proposing, conducting, supervising or reporting research. Conflicts of interest include non-financial as well as financial conflicts, because non-financial interests can also come into conflict with a researcher’s primary commitment to maintain scientific objectivity.

The following relationships are examples of situations that may raise questions regarding an apparent or actual conflict of interest in research:

a) An investigator or study staff member has a consulting or other relationship with a company sponsoring a research project, or a company that manufactures or markets a product under evaluation in the research.

b) An investigator, study staff member, and or the university has intellectual property interests in a product or method under evaluation in the research.

c) An investigator or study staff member is a founder and has equity interests in a start-up company that owns intellectual property under evaluation in the research.

Potential COIs are identified through annual and continual disclosure requirements for investigators in USC’s diSClose system. Disclosures of investigators are reviewed by the Conflict of Interest in Research Committee (CIRC) in the context of each research project in which an investigator is engaged to determine whether or not a COI exists, and if so, how it will be reduced, managed, or eliminated in the interest of preserving research objectivity and protecting the rights and welfare of human research participants. For research involving human participants for which a COI determination is made, a management plan is developed by the CIRC and is provided to the IRB for assessment as to whether or not the management strategies adequately protect the rights and welfare of human research participants.

The following are examples of COI management strategies often instituted when an investigator is determined to have a COI related to a specific research project:

1. Disclosure of the related interest to research team members and collaborators
2. Disclosure of the related interest to human research participants in the informed consent document
3. Disclosure of the related interest in press releases, presentations, and publications arising from the research
4. Reduced role of investigator in the research project (e.g., cannot serve as PI, no involvement in enrollment or consent processes, etc.)
5. Independent review of data/independent data analysis

Institutional Conflict of Interest (ICOI) exists when the financial interests of the university have the potential to cause bias in the conduct of research. Such conflicts occur most frequently in situations where a research project provides a direct benefit to an outside entity through evaluation, validation, trial or test of an invention, product, drug, service or technology, and the university holds a financial interest in the outside entity. A university-held financial interest in an outside entity includes, but is not limited to, receipt of royalties from the outside entity or an ownership interest in the outside entity.

USC has specific policies and processes governing conflict of interest in research, both on the individual and institutional level. Please take some time to review the full policies:
Policy on Conflict of Interest in Research

Institutional Conflict of Interest in Research

Possible Questions About Conflict of Interest Disclosure

- What do you know about conflict of interest?
- What do you disclose to participants regarding a financial conflict of interest?

Section 8: Accountability and Additional Administrative Requirements

Principal investigators must perform or delegate to authorized research staff all necessary tasks to carry out research, including specifically:

- Obtaining IRB approval before research begins;
- Obtaining informed consent of participants prior to study enrollment;
- Conducting continuing review in a timely manner;
- Informing the IRB of any disapprovals, suspensions, or terminations to active research studies;
- Creating and maintaining accurate records and
- that sufficient resources are available to meet the needs of study.

The PI is also ultimately responsible for proper conduct of the study and fulfillment of related obligations, including specifically:

- Ensuring that all study team members have the appropriate experience and training required on protocol and safety issues;
- Cooperating with investigations/inspections by authorized internal oversight activities as well as external reviews; and
- Supporting student researchers and the protection of human participants in the students’ research, if applicable.

The negotiations of research contracts and management of grants takes place through the Clinical Trials Office (CTO) and the Department of Contracts and Grants (DCG).

Assistance with research development, services and support can be obtained from the Southern California Clinical and Translational Science Institute (SC CTSI).

Information regarding the reporting of any research misconduct can be found on the OPRS website: Complaints, Concerns and Report of Misconduct

Researchers may contact Maya Mataric, Interim Vice President of Research, Julie Slayton, Director of the Office for the Protection of Research Subjects, or the Interim Director of the IRB, RoseAnn Fleming to obtain answers to questions, express concerns, or share suggestions regarding the USC HSPP. Email: oprs@usc.edu or irb@usc.edu

Possible Questions About Accountability and Additional Administrative Requirements

- Who prepares the IRB application and who submits the application?
- Who communicates with the IRB?
- What are the qualifications of your study team?
- How does your study team work together (delineation of roles)?
- How do you communicate within your team?
Section 9: Education
The Collaborative Institutional Training Initiative (CITI) Program provides research ethics education to the research community. The CITI program offers both initial and refresher courses covering human subjects protections. Information regarding research education requirements and training certification can be found at the OPRS website under Training. HIPAA Privacy Education is available online from the USC Office of Ethics and Compliance. In-person educational sessions for researchers, students, and staff are provided through the Office of Research, OPRS, SC CTSI, Clinical Trials Office, Department of Contracts and Grants, and the administrators of the iStar Online IRB submission system. The iStar system contains required certification(s) and status of each member on the study team, and also provides individuals with notification of impending expirations.

Possible Questions About Education
- What kind of training have you receive?
- What training do you require/provide for your research team?
- Were you trained in human research, ethics, and carrying out your research duties?
- How do you verify CITI certification status for yourself and other study team members?

Section 10: Additional Resources
- OPRS website: AAHRPP Reaccreditation Visit
- USC IRB Webpage
- USC HSPP Policies and Procedures
- AAHRPP

OPRS and USC IRB Office staff are available to answer your questions and to help you have a successful interview. If you have any questions, don’t hesitate to contact us at: oprs@usc.edu and irb@usc.edu