

Interview Guide for UF Research Administrators

AAHRPP Site Visit: January 13 -15, 2021

ACCREDITATION

AAHRPP (*pronounced A-HARP*), or the Association for the Accreditation of Human Research Protection Programs, will conduct a reaccreditation site visit at the University of Florida January on 13 -15, 2021. AAHRPP is an international, independent nonprofit organization that reviews and accredits an institution's human research protections program (HRPP).



UF has been AAHRPP accredited since March 2018.

AAHRPP has been provided with a written description of the UF's Human Research Protection Program (HRPP) policies, guidances, and guidelines and other 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 regulatory documents have been implemented effectively and are being adhered to throughout the university.

As Research Administrators, you are an integral part of the UF HRPP. During the site visit, AAHRPP will select approximately 75 (or more) individuals to be interviewed. Each interview session will take between 20-45 minutes. We expect questions to be focused on human research protection practices at UF and regulatory issues related to research with human subjects, as well as your impressions of the HRPP component offices and UF IRBs.

AAHRPP will provide a list of individuals selected for interviews a few 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.

PREPARING FOR THE SITE VISIT

Early preparation is key and this document is intended to help you prepare. You may be familiar with the information included however, this guide is provided so that you can refresh your understanding. 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: UF HRPP Policies and Procedures
- Section 3: Ethical Conduct of Research and Federal Regulations
- 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 8: Accountability and Additional Administrative Requirements
- Section 9: Education
- Section 10: Additional Resources

SECTION 1: GENERAL TIPS

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

- Understand the UF Human Research Protection Program's structure
- Clearly describe your role in supporting the protection of research participants
- Be familiar with the UF HRPP 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 (UPRs)
- Understand and describe the ethical aspects, the purpose, and the value of your work
- Know the process for non-compliance reporting at UF
- Know IRB application (myIRB) submission terminology
- Understand what constitutes conflict of interest
- Know how a potential conflict of interest is disclosed and reviewed at UF

If interviewed, we recommend that you respond directly to the question asked. If a question seems unrelated to the type of work you do or your role in UF HRPP, please let the interviewer(s) know. Below are examples of the type of general questions you might be asked.

Possible General Questions

- What is AAHRPP accreditation and why is it important to UF?
- What is your role in the protection of human research protection?
- What does the IRB do?
- What is the IRB's reputation on campus?

SECTION 2: UF HRPP AND IRB POLICIES AND PROCEDURES

The following sections summarize UF's HRPP policy and procedures with which you should be familiar for your interview. The source of this information can be found on UF's HRPP webpage: <https://research.ufl.edu/research-operations-services/hrpp.html>

The Vice President for Research, Dr. David Norton, serves as the Institutional Official (IO) for UF and is responsible for the overall conduct of research at the University.

The UF HRPP is supported by:

- UF Research: The Division of Research Operations and Services, the UF Institutional Review Boards (IRBs), UF Research Integrity/ Conflict of Interest Program, Division of Sponsored Programs, the Office of Clinical Research (OCR) and UF Clinical and Translational Science Institute (CTSI).
- Academic units, including schools, colleges, and other units to which faculty, staff, and trainees engaged in human research
- Key executive and administrative offices, including the Office of General Counsel.

The purpose of UF's Human Research Protection Program is to protect the rights and welfare of participants involved in human research that is overseen by this Institution; promote compliance with relevant legal requirements and ethical standards at all levels; and support investigators in their research activities.

Additionally, UF IRBs Policies, Guidelines and Guidances can be found on the IRB webpage:

<http://irb.ufl.edu/index/irb-policies-guidelines-and-guidances.html>

Possible Questions About HRPP Policies and Procedures

- Who is the institutional official responsible for research at UF?
- Who is the institutional official responsible for the UF Human Research Protection Program?
- What are the components of the UF HRPP?
- What is the purpose of the HRPP at UF?
- What is your role in UF HRPP? What research function is under your purview?
- What does your division/department/office do to support human research activities?

SECTION 3: Ethical Conduct of Research and Federal Regulations

UF fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of UF. All members of the UF research community involved in human research are expected to comply with the highest standards of ethical and professional conduct in accordance with applicable federal and state regulations as well as the institutional and IRB policies governing research involving humans.

The review and conduct of research at UF is guided by principles set forth in the following:

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, and 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), and Department of Education (ED) hold additional regulatory requirements. PLEASE NOTE: UF does not review or approve Human research supported by the Department of Energy (DOE) AND UF IRB reviews Department of Justice (DOJ) research that continues to follow pre 2018 common rule only.

Other federal and state laws and regulations that apply to research include, Family Educational Rights and Privacy Act [FERPA], Health Insurance Portability and Accountability Act [HIPAA], 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 ethical human subjects research?
- How do you communicate the University values and ethical messages to your associates, colleagues and other institutional administrators?
- What are the Belmont Principles and when did you first hear of them?
- What is the Common Rule (45 CFR 46)?
- What are OHRP, FDA, and HIPAA?

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.
- 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.
 - **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)

Possible Questions About Minimizing Risks & Protecting Participants' Rights and Welfare

- How do you protect participant privacy and confidentiality of data?
- What additional mechanisms do you have in place to protect your research participants?
- What are the different possible levels of risk associated with a study? How is risk levels assigned?
- Can sensitive information affect the risk level?

SECTION 5: COMPLIANCE WITH IRB AND OTHER REVIEW UNIT REQUIREMENTS

Research at UF must be conducted in compliance with the IRB, as well as other institutional and regulatory requirements. Below are some requirements that you 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
- Materials must be submitted to the IRB in a timely fashion (e.g., requests for changes, status reports, etc.)
- Information regarding reportable events is available in *UF IRB Policy on Reportable Events (HRP -112)*, *Investigator Guideline on Event Reporting and, the Investigator Guideline on Unanticipated Event Reporting and Procedures*–, which includes *Unanticipated Problems Involving Risks to Subjects or Others (UPRs)* that must be reported to the IRB as soon as possible but no later than 5 working days of the event occurring or after the investigator becomes aware of the event
 - **UPR** – 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:

- UF Research Integrity
- UF Institutional Review Boards (IRBs)
- The Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services (HHS)

UF 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.

Possible Questions About Compliance with IRB and Other Review Unit Requirements

- In a dispute between the IRB and a researcher, can an administrator overrule IRB's decision?
Note: IRB disapproval and other decisions of the IRB cannot be overruled by the Health Sciences Center administration. However, approvals may be overruled by the Chancellor's office if in the best interest of the institution. Project directors or principal investigators (PI) may appeal IRB disapprovals or restrictions on approvals to the IRB. If the PI wishes to further challenge any decisions made by the IRB, the PI must initiate the process through the Institutional Official, the Vice-Chancellor for Academic Affairs. Such appeals must be filed by the PI within 30 days of action by the IRB.
- How do you handle complaints regarding the IRB?
- To whom do you go to for help on issues, be it regulatory or ethical?

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 the **IRB Informed Consent Forms**, on IRB website and the **UF Investigator Guideline on Informed Consent and Which Template Should I use**.

- 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)) outlines the required elements of the informed 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.

Possible Questions About Obtaining and Documenting Informed Consent

- What is the process or characteristics of obtaining consent?
- How can a participant obtain information about human research protections at UF?

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 UF's UFOLIO system. Disclosures of investigators are reviewed by the UF Research Integrity Conflict of Interest (COI-R) Administrator 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 COI-R 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.

UF has specific policies and processes governing conflict of interest in research and, both on the individual and institutional level. Please take some time to review the following website and policy:

- ❑ [UF Research Integrity - Conflict of Interest in Research](#)
- ❑ [UF Regulation on Conflict of Interest](#)

Possible Questions About Conflict of Interest Disclosure

- Do you understand the UF COI Policies and how COIs may influence the protection of human research participants?
- What is your role, if any, in managing conflict of interest and institutional conflict of interest?

SECTION 8: ACCOUNTABILITY AND ADDITIONAL ADMINISTRATIVE REQUIREMENT

Principal investigators must perform or delegate to qualified research staff all necessary tasks to carry out research, including specifically, obtaining IRB approval before research begins; securing informed consent of participants prior to study enrollment; conducting continuing review in a timely manner; informing the IRB of any disapprovals, suspensions or terminations by other review units; the creation and maintenance of accurate records; and that sufficient resources are available to meet the needs of study. The PI is ultimately responsible for proper conduct of the study and fulfillment of related obligations.

The negotiations of research contracts and management of grants takes place through the Office of Clinical Research (OCR) and the Division of Sponsored Programs (DSP).

Assistance with research development, services and support can be obtained from UF's Clinical and Translational Science Institute (CTSI).

Information regarding the reporting of any research misconduct can be found on the UF Research Integrity website: <https://research.ufl.edu/compliance/research-integrity.html>

Information regarding the reporting of research noncompliance can be found on UF IRBs website: <http://irb.ufl.edu/index/noncompliance.html>

Researchers may contact Dr. David Norton, Vice President of Research or Michael Mahoney, Director of the Research Operations and Services and HRPP Administrator to obtain answers to questions, express concerns, or share suggestions regarding the UF's HRPP.

Possible Questions About Accountability and Additional Administrative Requirements

- Do you have access to adequate resources to perform your duties related to human research?
- Does the institution provide support for review and negotiation of contracts?

SECTION 9: EDUCATION

UF has a variety of training and education opportunities and platforms available and sometimes required for all individuals conducting and supporting research within the institution and its affiliates. UF Research has developed the Research Training Utility as a tool to help faculty, staff, and students identify what mandatory training must be completed in order to conduct research at the University of Florida.

UF Research Training Utility: <https://research.ufl.edu/research-operations-services/rtu.html>

Additionally, there are various In-person educational sessions for researchers, students, and staff -- provided through UF Research as part of UF's HRPP components offices: IRB, DSP, Research Integrity/COI, OCR, CSTI, etc.

Possible Questions About Education

- How do university officials keep you informed of new developments in human research regulations?
- If applicable, were you trained in human research/ethics/carrying out research duties, etc.?
- If applicable, how do you train your staff?

SECTION 10: ADDITIONAL RESOURCES

- [UF Research – HRPP webpage: AAHRPP Reaccreditation Visit](#)
- [UF IRB Webpage](#)
- [AAHRPP](#)

The HRPP Administrator and Accreditation Coordinator 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:

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