Interview Guide for UF Investigators and Research Staff
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 on January 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, 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 an Investigator or research team member, 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 regulatory issues related to research with human subjects, but questions may also relate to the conduct of your research, as well as your impressions of the HRPP component offices and UF IRBs. If you are selected for an interview based on a specific type of protocol (e.g., drug, device, community research etc.), please review your procedures for conducting that kind of research.

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. Information is also available on the UF HRPP webpage – 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

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 regulatory standards that apply to your research
- Know IRB application (myIRB) 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 UF
- Describe the human research training that you had: (e.g., IRB803)
- 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 Project(s)

- Describe your study. What are the procedures? How do you recruit? What is the consent process?
- What kinds of risk or potential harms can occur in your study? How do you minimize those risk or potential harm?
- 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 UF?
- 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: UF HRPP AND IRB POLICIES AND PROCEDURES

The following sections summarizes 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?

SECTION 3: ROLES AND RESPONSIBILITIES OF INVESTIGATORS AND RESEARCH STAFF

Investigators and Research Staff 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, 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 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, 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.
- 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

- Do you know the difference between minimal and greater than minimal risk?
- 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 – is which case a report to the IRB must follow
- PI's are responsible for the content of all submissions to the IRB (e.g., myIRB application, supporting documents, etc.)
- 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

- 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 UPR? Have you ever had one on a study?
- How would you report an adverse event or a UPR?
- 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 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)) 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.

<u>Waiver of Document of Informed Consent</u>

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 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

- 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 REQUIREMENT

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 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

- 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?
- How are you trained in the details of the study protocol?
- How are new member to the study team trained?
- How do you ensure that study protocols are followed?
- Do you maintain a regulatory file for the study? Where is it?
- Where are your research records maintained?
- What kind of workload do you have?
- Do you have the appropriate resources to conduct the research properly?
- Do you work on any other studies?
- To whom do you go for help on issues, be they regulatory or ethical?

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 may provide through UF Research as part of UF's HRPP components offices: IRB, DSP, Research Integrity/COI, OCR, CSTI, etc.

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:
gailinemccaslin@ufl.edu