

Working Together Towards AAHRPP Reaccreditation



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Objectives of Presentation

- Introductions
- AAHRPP
- UF's Human Research Protection Program (HRPP)
- Accreditation Process
- IRB Prep and Common Interview Topics
- Questions



AAHRPP ACCREDITATION



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What is AAHRPP?

- AAHRPP (*pronounced A-HARP*) is the Association for the Accreditation of Human Research Protection Programs.
- Nonprofit organization, Independent, International
- Founded in 2001
- Seeks to accredit HRPPs and ensure compliance with regulations and enhance protection standards.
 - ✓ “Gold Seal” accreditation signifies commitment to the most comprehensive human subject protections.



AAHRPP Standards

Federal Regulations



Vs.

AAHRPP



- 3 Domains of Standards
 - Organization
 - IRBs
 - Researcher and Research Staff
- Each Standard is divided into Elements (~77)
- These standards meet and in some cases exceed the usual federal requirements. AAHRPP evaluates structure, process, and outcomes via our policies, forms, checklists, websites, application system, etc.

Source for Accreditation Standards

- **Based on U.S. federal regulations for conducting human research**
- **Department of Health and Human Services**
 - 45 CFR 46
- **Food and Drug Administration**
 - 21 CFR 50, 56
- **ICH Good Clinical Practice Guidelines**
- **Various other regulatory based guidances & practices**

AAHRPP Mission & Method

☐ **Mission:**

- Protect the rights and welfare of research participants.
- Seeks to accredit high quality human research protection programs in order to promote excellent and ethically sound research.

☐ **Achieves mission by using an accreditation process based on:**

- Self-assessment
- Peer-review
- Education

What AAHRPP Does NOT Do:

- “Audit” decisions made by the IRB
- Critique researcher’s proposals
- Report “findings” to regulatory agencies
- The entire accreditation process is confidential!



Why is AAHRPP Accreditation Important to UF?

- **Mandated by the Vice President for Research**
- **Many of our peers are accredited**

- **Over 600 Institutions AAHRPP Accredited, Nationally**

- **70% of Universities AAHRPP Accredited**
- **85% of Medical Schools AAHRPP Accredited**

- **11 Florida Institutions are AAHRPP Accredited (including UM, USF, UCF, FDOH, etc.)**

- **Most importantly: Emphasis is on a comprehensive protection program**
 - ✓ *Shared responsibility*
 - ✓ Outside verification that all requirements are met at the highest standards
 - ✓ Enhances culture of compliance

UF Human Research Protection Program (HRPP)



- UF Research: the Division of Research Operations and Services, the UF Institutional Review Boards (**IRB**), UF Research Integrity/ Conflict of Interest Program (**COI**), the Division of Sponsored Programs (**DSP**), the Office of Clinical **Research (OCR)**, UF Clinical and Translational Science Institute (**CTSI**) and other compliance offices.
- Academic units, including schools, colleges, and other units to which faculty, staff, and trainees engaged in human research and associated project sponsors.
- Key executive and administrative offices, including General Counsel, Privacy Office, IT Security, etc.
- **UF has been AAHRPP accredited since March 2018.**

UNIVERSITY OF FLORIDA HUMAN RESEARCH PROTECTION PROGRAM (HRPP)



INSTITUTIONAL OFFICIAL
Dr. David Norton, Vice President for Research

Institutional Review Board (IRB) Chairs
Peter Iafrate, PharmD – IRB01
Ira Fischler, PhD – IRB02

IRB Board Members

Ancillary Committees/Services

**Research Operation & Services Director
HRPP Administrator**
Michael Mahoney, BA

Component Units

Investigational Drug Services
Susan Beltz, PharmD

Radiation Safety Committee
Walter E. Drane, MD

Biosafety Committee
Paul Gulig, PhD

Scientific Review Committee
Paul Crispen, MD

Conflict of Interest
Amber Moore, MPA

COVID-19 Scientific Review Committee
Duane Mitchell, MD

Assistant Director of IRBs
Ivana Simic, PhD

HRPP Accreditation Coordinator
Gailine McCaslin, MS

IRB Staff

Division of Sponsored Programs
Stephanie Gray, MBA

Office of Clinical Research
Brian Sevier, PhD

Research Integrity
Cassandra Farley, MBA

UF CTSI
Duane Mitchell, MD

UF Innovate (formally OTL)
Jim O'Connell, MS

General Counsel

Privacy Office

IT Security

NF/SG VA

Accreditation Process

Self-assessment

Evaluation and improvement of UF's Human Research Protection Program

On-site evaluation

A team of experts reviews UF's materials and schedules an on-site visit.

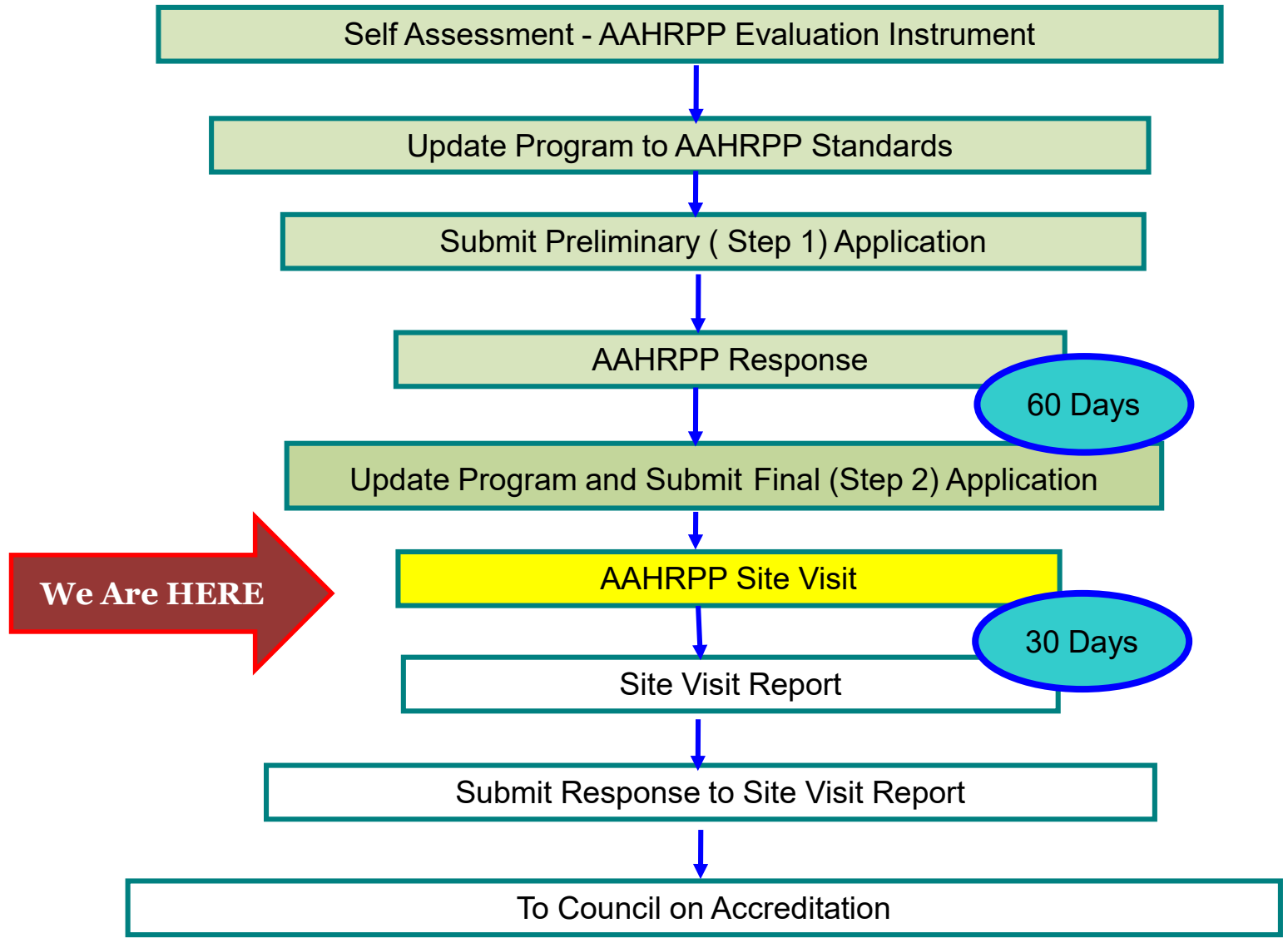
Council review

AAHRPP's Council of Accreditation reviews the report, deliberates on the team's findings and determines your accreditation status.

Notification of accreditation status

Organizations that achieve accreditation must be re-evaluated initially every three years and then every 5 years in order to remain accredited.

Where is UF in the Accreditation Process?



Nature of AAHRPP Site Visit

- 3 Day Visit begins: January 13-15, 2021
- **Representation from stakeholders:**
 - Institution
 - IRB
 - Investigators
 - Other HRPP Component Units/Entities
- **Interviews with:**
 - Institutional Official
 - Administrators
 - ***IRB Chairs, Board Members, and Staff (that's you!)***
 - HRPP Based Compliance Units (DSP, OCR, COI, CTSI)
 - Investigators and Research Staff

AAHRPP Site Visit – Expectations

- **Visible institutional awareness and support**
- **Clear lines of communication, authority and responsibility**
- **Policies, Guidances, and Guidelines:**
 - Meet regulatory requirements
 - Appropriate for program needs
 - Clearly documented, communicated, implemented, and enforced
 - [Adhered to in actual practice](#)

IRB MEMBER AND STAFF PREPARATION



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IRB Preparation: So What New?

- Common rule changes
- Limited IRB review
- sIRB (Single IRB)
- FDA waiver of consent for minimal risk clinical trials
- IRB registration
- Reporting to AAHRPP
- Removing some Dept of ED requirements

IRB Preparation

- **Initial Accreditation *2018* Site Visit Findings:**
 - Board Member Continuing Education
 - IRB Board Member Evaluations/Feedback
 - Unanticipated Problems involving Risks (UPRs)
 - IRB members review of Protocol application
 - Documented Protocol Specific Findings
 - Vulnerable Populations Reps and Equivalent Protections
 - Consenting Non-English Speaking Participants



Common IRB Interview Topics

- ✓ IRB Education Resources and Training
- ✓ IRB Membership
- ✓ IRB Member and Conflict of Interest
- ✓ What activities that need IRB Review
- ✓ IRB Review to Ensure Protection of subjects
- ✓ IRB Authorization Agreements
- ✓ Criteria for IRB Approval (Common Rule)
- ✓ Study Design & Safeguards to Minimize Risk
- ✓ Confidentiality and Privacy
- ✓ Recruitment Methods and Vulnerable Populations
- ✓ Evaluating Informed Consent Process
- ✓ Reporting requirements to regulatory Agencies



➤ AAHRPP Topics for IRB Members and Staff

IRB Education Resources and Training (Element I.1.E. Education)

IRB Training:

- Review of the Belmont Report, 45 CFR 46, Chapter 3 of the OHRP Guidebook, OHRP's Informed Consent Tips, UF's FWA, NIH Board Member training, and a review of UF IRB's Policies, Guidelines, and Guidances. Trainings with IRB Educator and Chair.
- Review and training of the myIRB electronic IRB submission and review software
- Reviewing Minutes & Submissions: Points to Consider Guide, Full Board Rules of the Game
- Continuing Education: Updates on regulatory and review process topics during IRB meetings, IRB retreats, monthly Brown Bag, IRB Forum, PRIM&R, AAHRPP, UF CTSI, Research Integrity/Compliance, etc.

➤ AAHRPP Topics for IRB Members and Staff

IRB Membership (Element II.1.B & II.1.E)

- The membership of the IRB or EC must be qualified through the experience and expertise, or the use of consultants

The formal appointments of IRB members are made by the Vice President of Research.

➤ AAHRPP Topics for IRB Members and Staff

IRB Member and Conflict of Interest (Element II.1.D)

Conflict of Interest (COI)

- set of circumstances that creates a risk that one's professional judgment or actions regarding a primary interest (e.g., the integrity of research, the welfare of human research subjects) will be unduly influenced by a secondary interest (e.g., financial gain, other personal interest).

- IRB members **must not** participate in the review of any protocol in which they have a conflict, except to provide information requested by the IRB.

➤ AAHRPP Topics for IRB Members and Staff

What activities need IRB Review?

- **Who provides an official determination whether an activity needs IRB review?**
 - ✓ IRB Chair, Designee, DROS Director, IRB Asst. Director
- **Upon what is the determination based?**
 - ✓ Common Rule Definition of Research & Human Subjects
 - ✓ FDA Definition – Human Subjects & Clinical Investigation
 - ✓ OHRP Guidance
 - ✓ DoD Definition of Experimental Subjects

➤ AAHRPP Topics for IRB Members and Staff

IRB Review to Ensure Protection of participants (Standard II.2)

The IRB decides on a study-by-study basis whether there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. The IRB decision is based on the sensitivity of the information obtained in the research and the protections promised to participants.

- **Full Board Reviews**
- **Exemptions and Limited Reviews**
- **Expedited Reviews**
- **Addressing unanticipated problems involving risks to participants or others (UPRs)**
- **Suspending or Terminating Studies**
- **Managing Multi-site Research**

➤ AAHRPP Topics for IRB Members and Staff

What are IRB Authorization Agreements (IAA)?

Describes the respective authorities, roles, responsibilities, and communications between an institution providing IRB review and participating site relying on the IRB.

➤ AAHRPP Topics for IRB Members and Staff

Refresher: Fundamental for IRB Approval

Criteria for IRB Approval

- ☑ Risks are reasonable in relation to anticipated benefits.
- ☑ Risks to subjects are minimized.
- ☑ Confidentiality is maintained
- ☑ Privacy is protected
- ☑ Selection of subjects is equitable
- ☑ Additional safeguards are included for vulnerable populations
- ☑ Data collection is monitored to ensure subject safety
- ☑ Informed consent is sought from each subject.
- ☑ Informed consent is appropriately documents.



*Common Rule
Regulation
45 CFR 46.111*

➤ AAHRPP Topics for IRB Members and Staff

Refresher: Safeguards to Minimize Risks

Study Design & Safeguards to Minimize RISKS

- Utilize procedures already being conducted
- Screening to rule out “at risk” subjects
- Professional Counseling Services
- Increased oversight
- Data security measures
- Create stopping rules
- Choose least intrusive design the yields valid data (e.g. Sequential Multiple Assignment Randomize Trial or SMART)
- Certificate of Confidentiality for legal risks



➤ AAHRPP Topics for IRB Members and Staff

Refresher: Confidentiality vs. Privacy

Confidentiality & Privacy

Data & how it is Protected

How data will be maintained, stored, transferred, etc.



People & their Expectations

Individual concept shaped by situation, experience, values, culture, beliefs, etc.



➤ AAHRPP Topics for IRB Members and Staff

Refresher: Recruitment Methods

RECRUITMENT METHODS



- **Equitable Selection –**

Proportionate Distribution; not targeting or excluding based on convenience

- **Undue Influence –**

No finders fees or recruitment bonus to study staff; appropriate IRB-approved ads; 3rd party if PI is an authority figure

- **No Cold Contacts –**

contact by personnel with legitimate access or through individuals with established relationships

- **Compensation –**

appropriate amount, method, and timing

➤ AAHRPP Topics for IRB Members and Staff

Refresher: Vulnerable Populations

Populations with special regulatory or institutional protections

- Pregnant Women
- Human Fetus
- Neonates
- Children
- Prisoners
- Decisionally Impaired/Comatose Individuals
- Institutional Residents
- Terminally Ill Patients
- UF/Shands/VA/OneFlorida Institution Staff
- UF/OneFlorida Institution Students

➤ AAHRPP Topics for IRB Members and Staff

Refresher: Informed Consent

Be prepared to describe how you evaluate whether consent form is :

- Is understandable,
- Is concise, or
- Provides key information that meets the **reasonable** person standard?



➤ AAHRPP Topics for IRB Members and Staff

Refresher: Informed Consent Process

Be prepared to describe how you evaluate the researcher's consent process!

- What suggestion would you or have you made to improve researcher's process?
- Giving feedback to researchers

➤ AAHRPP Topics for IRB Members and Staff

Refresher: Waiver or Alter Informed Consent

What Criteria does IRB consider for **Waiver or Alter** Informed Consent?

1. The Research Presents No More than Minimal Risk;
2. Research Could Not Practicably be Conducted without the Requested Waiver or Alteration;
3. If Using Identifiable Private Information or Identifiable Biospecimens, Research Count Not Practicably be Carried Out without Using Such Information or Biospecimens in an Identifiable Format;
4. Waiver or Alteration Will Not Adversely Affect Rights & Welfare of Subjects;
5. Whenever Appropriate, the Subjects or Legally Authorized Representative Will be Provided with Additional Pertinent Information After Participation.

➤ AAHRPP Topics for IRB Members and Staff

Refresher: Waiver of Consent Documentation

Waiver of Consent Documentation

requires an oral or written process to include all required applicable elements of consent.

What is waived?



➤ AAHRPP Topics for IRB Members and Staff

Reporting Required to Regulatory Agencies

1. Continuing or Serious Noncompliance
2. Unanticipated Problems involving Risk to Subjects or Others (UPRs)
3. Suspensions or Terminations.



➤ AAHRPP Topics for IRB Members and Staff

(NEW) What does UF IRBs Promptly Report to AAHRPP?



- Any negative actions taken by a government oversight office (OHRP Determination Letters, FDA Warning Letters or restriction);
- Any lawsuits (i.e., litigation, arbitration, or settlements initiated) related to human subjects research protections; or
- Press coverage (TV, newspaper, online publications) of negative nature regarding the UF HRPP

Key Things to Remember!

If you do not know the answer to a question, know where you can go to find it!

UF | Institutional Review Board
Protecting *the* rights and welfare *of* human research subjects

UF | Research

- IRB Policies, Guidelines and Guidances: <http://irb.ufl.edu/index/irb-policies-guidelines-and-guidances.html>
- UF HRPP: <https://research.ufl.edu/research-operations-services/hrpp.html>

Protection, NOT perfection!



Important Issues

- **Unanticipated Problems**

- Unexpected; Related to the protocol; New or increased risks to subjects or others

- Guideline: [Unanticipated Problems Involving Risks to Subjects or Others](#)

- **Consenting subjects who don't speak/read English**

- Translated consent for targeted populations

- **IRB Short form process (translator alone is insufficient)**

- Guideline: [Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak or Read English](#)

What Happens After Site Visit

- **UF receives written report**
- **Thirty day response period to address questions or gaps**
- **Site Visit Team Report and UF response submitted to AAHRPP Council on Accreditation**
- **AAHRPP Council renders a decision**

QUESTIONS ????



Interacting with AAHRPP Site Visitors



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Interacting with Site Visitors

- **Listen to the question that is being asked**
- **If you do not understand a question, ask for a clarification or to have the question repeated.**
- **Don't answer unless you fully understand the question**

Interacting with Site Visitors

- **ONLY answer the question being asked.**
 - Do NOT volunteer any unnecessary or unrelated information
- **If you do not know the answer,**
 - Admit you do not know
 - BUT you would find out
 - Ask IRB chair
 - Ask IRB staff
 - Review IRB website / policies / guidance

Interacting with Site Visitors

- **If you think you know a little bit / can make an educated guess:**
 - Admit that it is a guess
 - Stress you would never act on a guess without first confirming the correct answer.
- **If the question is about something outside your area of expertise:**
 - If appropriate, you can give an answer that is appropriate in your area of expertise
 - Do NOT allude to or attempt to address areas outside your area of expertise.

Interacting with Site Visitors

- NEVER lie to a site visitor.
- Do NOT argue with site visitors
- Don't be defensive with site visitors.
 - Remember, just like the IRB did not enact regulations, the site visitors did not set AAHRPP standards.
- Speak positively about our program and what you believe meets the standards.
 - The site visitors do not need our help identifying any deficiencies.

IRB Special Meeting – 11.2.2020

