Reaccreditation of the NIH Intramural Research Program Human Research Protection Program by AAHRPP

OHSRP August 5, 2021

Presentation Outline

- AAHRPP accreditation
- Re-accreditation process
- Describe NIH application progress
- Discuss the upcoming site visit
- Describe interviews and how to prepare

OHSRP Vision Statement

We will promote the safe and ethical conduct of human subjects research by:

- providing timely, consistent and compliant reviews
- educating our community
- communicating effectively and responsively
- collaborating with stakeholders

and thus, will be recognized as national leaders in human subjects protections.

Why Accredit the NIH HRPP?

"To earn the AAHRPP gold seal, organizations must demonstrate that the entire HRPP meets accreditation standards—and that protecting research participants is a shared organizational priority."*

- As federal agency, and the largest dedicated research institution in the US, the NIH should be a leader not only in scientific advancement for human health and health conditions, but a leader in human subjects protections as well
- In order to promote trust and to foster scientific collaborations with other research institutions, it is imperative that NIH demonstrate that we have a high-quality human research protection program, and
- When serving as the Institutional Review Board, that the NIH is a trusted partner capable of providing robust ethical oversight of clinical research
- Accreditation demonstrates to our stakeholders that "protecting research participants is a shared organizational priority" at the NIH that involves all of us

*"20 Years of Protecting Participants, Advancing Research", AAHRPP Advance, Summer 2021, accessed 7/20/21 https://admin.aahrpp.org/Website%20Documents/AAHRPP_Advance_Summer%202021%20FINAL.pdf

Background - Accreditation of the NIH HRPP

- Initial Accreditation – March 2014
- First Reaccreditation – March 2017
- NIH is seeking the second re-accreditation of its Human Research Protection Program (HRPP)
- Why accredit our HRPP?
  - Accreditation establishes that the NIH has a high-quality HRPP and IRB based on common standards
  - These standards are based on US federal regulations and ethical principles
  - Being accredited promotes trust in our human research protection program and in our IRB.
  - When we seek to collaborate with other institutions, we look to see if they are accredited. (See Policy 105 IRB Reliance for more information)

Association for Accreditation of Human Research Protection Programs (AAHRPP)

- The Association for Accreditation of Human Research Protection Programs (AAHRPP) is our accrediting body
- It establishes common standards for human research protection programs (over 600 institutions worldwide are accredited based on these standards)
- The Accreditation Standards fall into three (3) domains:
  - Domain I – The Institution
  - Domain II – The IRB
  - Domain III – Investigators
- These domains make up the key components of an HRPP - It takes the entire HRPP to protect the rights, safety and welfare of research participants
- Being an accredited institution with AAHRPP is a priority for the NIH IRP, and indicates that our HRPP has the “Gold Seal” of approval

Why we are excited about the Site Visit

- The NIH IRP HRPP has undergone some big changes since our last Site Visit, we have:
  - Consolidated our IRBs
  - Centralized IRB operations
  - One (1) electronic IRB system
  - Streamlined HRPP policies and processes
- We are proud of the strides the NIH HRPP has made the last several years
- We are striving to be recognized as a national leader in human subjects protections
- Accreditation is one method to confirm we are going in the right direction to achieve our goal

The Status of NIH Accreditation So Far

- NIH has already:
  - Submitted the Step 1 Application which provided AAHRPP an overview of the NIH IRP HRPP and the HRPP policies
  - Submitted the Step 2 Application which also included:
    - Names of NIH HRPP staff listed by AAHRPP-specified roles
    - The IRB Roster
    - List of active protocols and study PIs
    - Certain documents specified by AAHRPP (e.g., IRB Minutes, policies, QAQI summaries)
- We are now preparing for the site visit this Fall, which consists of:
  - In-person interviews
  - Records review

AAHRPP next steps

AAHRPP will:

- Set the agenda for the site visit
- Select the Site Visitors
- Provide NIH materials to site visitors to pre-review

What is the Purpose of the Site Visit?

- The site visit is not:
  - An assessment of individuals, its an assessment of our institution's HRPP
  - An audit
- AAHRPP has already confirmed that HRPP policies meet the accreditation standards
- The site visit is a confirmatory process, site visitors are verifying that:
  - Our processes, (institutional, investigator and IRB), demonstrate the implementation of our policies
  - Our documents (protocols, consents, IRB minutes, etc.) reflect the policy requirements
  - NIH staff are knowledgeable about the HRPP policies and processes

What Happens During the Site Visit?

- The Site Visitors will conduct:
  - A program overview, focusing on how well we have integrated the various components of our organization
  - A records review of a list of selected records (e.g., iRIS, protocols, consents and IRB minutes)
  - Interviews of selected institutional leadership, IRB staff, IRB members, investigators and research staff

Site Visit Agenda

- Usually, the site visit is in person. However, due to COVID, the site visit could be virtual
- HRPP senior leadership will conduct an opening session with the site visitors:
  - Introductions
  - NIH will present an overview of the NIH IRP HRPP and some unique features of our program
- Each day will be comprised of records review and interviews, ending with a daily closeout meeting
- At the end of the site visit there will be a presentation by the site visitors to HRPP senior leadership, providing an overview of site visit findings and observations

Overview of Interview Process

- Interviews are grouped by function/roles that comprise the NIH HRPP:
  - Senior HRPP Leaders are interviewed individually
  - All other interviews are group interviews of 3-4 staff/IRB members
  - Investigators are selected by protocol titles (e.g., the PI and research staff working on an interesting protocol)
- Site visitors:
  - Are assessing core competencies related to human subject protection roles
  - Ask questions based on a particular role or function; and
  - Verify that the processes described by interviewees match those described in written materials (e.g., checklists, policies, or templates)

Who are our Site Visitors?

- They are our peers, they come from other AAHRPP accredited institutions
- They are led by an experienced site visitor who is usually a member of the AAHRPP Council (i.e., the body that approves accreditation of an institution)
- They are knowledgeable about research and IRB procedures based on their own experience
- They are collegial, respectful and open
- They don’t mind clarifying if you don’t understand their questions
- They don’t expect everyone to know the answer to every question or scenario

Who are the interviewees?

AAHRPP specifies who will be interviewed during the site visit based on key roles in the HRPP based on the three (3) domains:

- Domain I – Key institutional leadership roles, e.g., IC Directors, Scientific Directors or Clinical Directors, Institutional Official, OHSRP Director, Ancillary Review Committee Chairs
- Domain II – IRBO Director, IRB Chairs and Members, IRBO staff and OHSRP staff, etc.
- Domain III – Principal Investigators, Associate Investigators and research staff, QAQI staff, protocol navigators, etc.

What will happen if you are selected?

- If you are selected to be interviewed:
  - We will send you a notice informing you that have been selected and which group you fall into. We will ask for your phone number.
  - We will ask you to sign up and attend a prep session
  - We will send you a calendar invite for your interview session
  - You are expected to show up/be available 10 minutes earlier than your interview session
  - We will debrief you after your interview for an additional 10 minutes

What do we expect from interviewees?

- If selected to be interviewed, you must participate unless excused for travel, a health or other emergency.
- You must attend a prep session
- If you are a researcher, IRB member or HRPP staff, you should know some basics:
  - When you conduct, or review, clinical research, you must comply with human subjects protections regulations, the Common Rule (45 CFR 46) and, when applicable, FDA regulation (e.g., 21 CFR parts 50, 56, 312 or 812), NIH policy and other applicable regulations
  - Where to find HRPP policies on the IRBO website (or in Manual Chapter 3014)

It’s gonna be okay if you are selected

If you are selected to be interviewed, relax:

- It’s not about you, it’s about your role or function in the HRPP
- OHSRP will prepare you for your site visit interview
- You won’t be interviewed alone, you’ll likely be with a small group of your peers
- AAHRPP is focused on how you do your job, arrive at outcomes, and the processes that get you there
- So, you don’t have to cram or learn something new - You should already be familiar with your function/role, your responsibilities and written materials (e.g., protocol, consents, minutes, or determinations)

During the interview

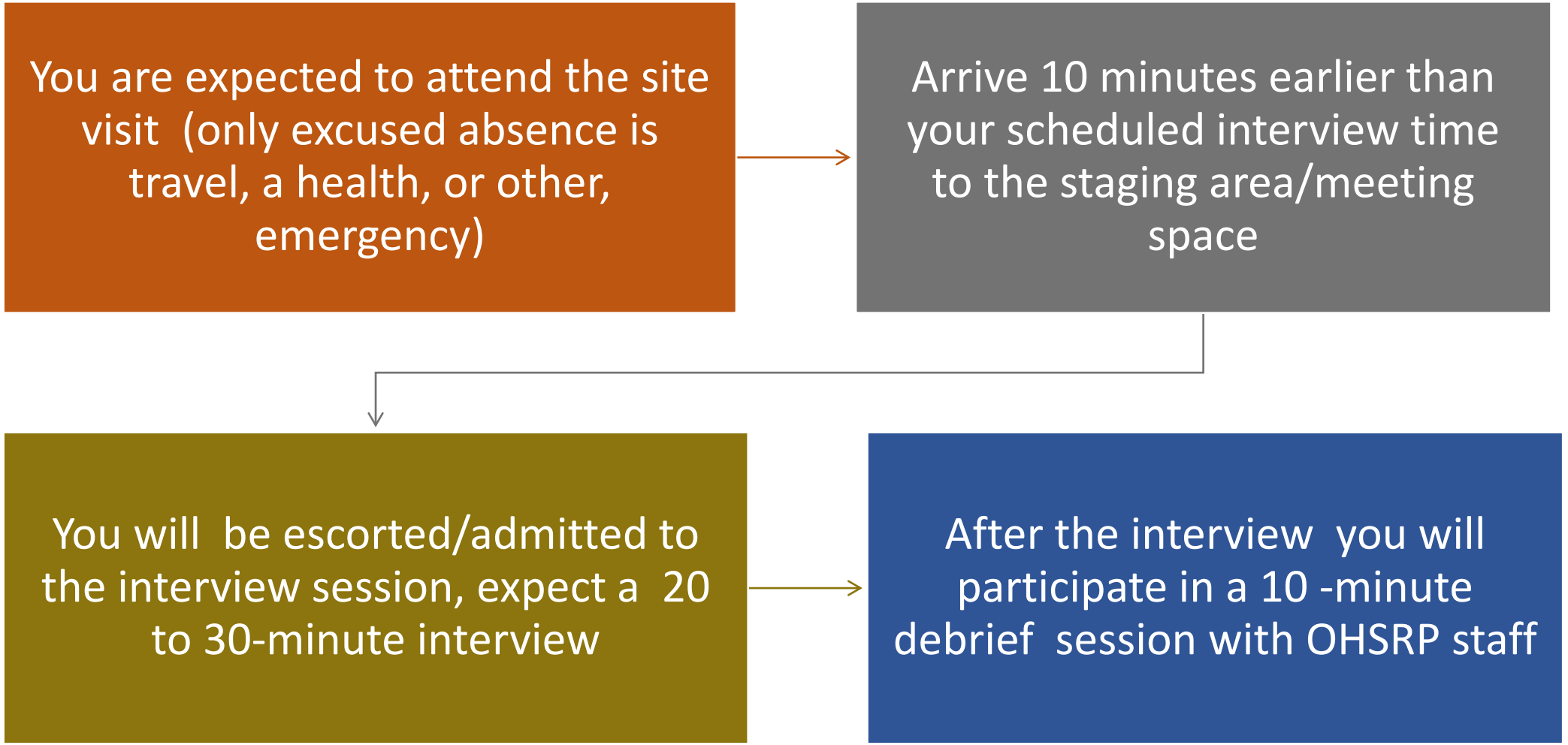
- If you are in a group session, anyone in the group can answer any question
- If it gets very quiet and someone is struggling, help them out, feel free to jump in and say something if you know the answer
- It's okay to be honest. If you can't answer based on your experience, someone else in your group can probably answer that question or speak to that experience
- Even if you don't get the answer exactly right, it's okay. AAHRP is looking at the totality of our HRPP and one wrong answer won't prevent us from being accredited
- AAHRPP provides the NIH the opportunity to clarify any areas of confusion when we address any site visit concerns

Take away for interviewees

You don’t have to have all the answers or know all the HRPP policies, but - you should be able to demonstrate that you know:

- When to ask a question
- Where to look for answers (e.g., policies, guidelines, FAQs, checklists, iRIS) and
- Who to ask for help when you can’t find the answer (IRB@od.nih.gov)

Day of Site Visit Process Flow



Basic Information Everyone Should Know

- YOU are part of the NIH Human Research Protection Program (HRPP)
- Dr. Gottesman is the Institutional Official: He is the highest HRPP official and the signatory on the NIH Federalwide Assurance (FWA)
- We have 2 Institutional Review Boards (IRBs):
  - NIH Intramural IRB
  - Research Compliance Review Committee
- The NIH Relies on other IRBs and has signed onto the SMART IRB Agreement
- We comply with the HHS Common Rule (45 CFR 46) and the Food and Drug Administration Requirements (e.g., 21 CFR parts 50, 56, 312 and 812)
- Only NIH Institutes/Centers can be IND/IDE Sponsors
- Some government rules are different than rules other research institutions are subject to, for example: Privacy Act of 1974, Conflict of Interest, Royalties, Research Related Injuries, how subjects are compensated

Basic Questions Site Visitors Ask

What do you do, how do you do it?

How do you find information ? Where do you go if you have questions?

Do you have access to training? See [Education and Training webpages]

Study team – Do you have ready access to the PI if you have a question?

Topics likely to be covered

- Differences between Privacy and Confidentiality (Policy 107 and the HRPP Policy Glossary)
- Requirements for reportable event reporting (Policy 801)
- If you Chair an ancillary review committee, be able to explain the committee's function, how you communicate your requirements and how you ensure compliance
- QAQI and monitoring staff should be able to explain how priorities are set, how results are shared and with whom, and what actions are taken in response to findings
- Senior leadership should be able to explain how you assess needed resources to support safe and compliant human subjects research, how you provide oversight over researchers, how you communicate with investigators, and how you respond to findings from QAQI activities and audits
- Everyone, how do you stay current with IRB requirements

How did COVID-19 Affect Your Research?

You may be asked how COVID-19 impacted your ongoing research or your research participants

- Did you have to change how you conducted your research?
- How did this impact your participants? How did you inform them?
- How did you work with the IRB when these changes happened?
- What about new research priorities did COVID -19 change them?
- Any special review processes or policies? **303 - Intramural Research Program Telehealth Requirements**
- Where did you find information?
- COVID-19 Information Hub

We thank you for representing the NIH HRPP

- We are excited to show how far our program has come to AAHRPP
- We've got a great HRPP, and you play an important role
- If selected, be proud that you get to represent the NIH to our peers
- Be prepared to talk about what you do and how you do it
- Prepare by reviewing any HRPP policies, guidance and checklists you are rusty on
- If you have any questions, reach out to the IRB and OHSRP. We're here to help you. Points of contact:
  - Heather Bridge bridgeh@od.nih.gov
  - Chris Witwer chris.witwer@nih.gov
  - IRBO irb@od.nih.gov