Upcoming Visit of the Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP) at NIH

AAHRPP is the body that accredits our NIH Intramural Human Research Protection Program (HRPP).

- Primary purpose of AAHRPP accreditation is to strengthen protections for research participants.
- Accreditation establishes that the NIH has a high-quality HRPP and Institutional Review Boards (IRBs) based on common standards.
- The NIH IRP was initially accredited in 2014, was reaccredited in 2017 and 2022, and will have the next site visit in the Fall of 2026.
- HRPPs must have mechanisms in place to ensure the independence of its ethics review (e.g., protocol review by the IRB) and oversight functions from other units within the organization.
- Accreditation demonstrates to our stakeholders that protecting research participants is a shared organizational priority at the NIH that involves all of us.
- AAHRPP has set standards for HRPPs within three domains that are intended to advance the highest ethical research.
  - Domain I – The Institution
  - Domain II – The IRB
  - Domain III – Investigators
- When serving as the NIH IRB, we want to demonstrate that the IRB is a trusted partner capable of providing robust ethical oversight of clinical research.

Standards that relate to the IRB

- Structure of the IRB is appropriate for the type of research reviewed.
- IRB evaluates each protocol to optimize protection of participants.
- IRB approves protocols based on applicable regulations (e.g., 45 CFR 46.111 criteria), policy and guidance.
- IRB ensures there are additional protections for participants vulnerable to coercion or undue influence.
- IRB maintains documentation of its activities (i.e. IRB meeting minutes).

Reaccreditation process

- **Prior to the site visit**, OHSRP provides many documents to AAHRPP as part of our application for reaccreditation. For example, information about our HRPP, supporting documents, our NIH HRPP policies, IRB rosters and documents, and lists of protocols and personnel are submitted.
- **AAHRPP site visitors** are:
  - Our peers from other AAHRPP accredited institutions and led by an experienced site visitor.
  - Knowledgeable about research and IRB procedures based on their own experience.
- **Activities** conducted by site visitors:
  - Conduct a program overview, focusing on how well the various components of our organization are integrated.
  - Evaluate how our HRPP policies and procedures are operationalized at our organization through document review and interviews with members of the HRPP.
    - Review a list of selected records (e.g., specific protocols, consents and IRB minutes).
    - Conduct interviews with institutional leadership, key personnel, and others in the HRPP (e.g., IRB staff/members, investigators, study team members, DEC and ancillary review committee Chairs).
  - Common questions for IRB members:
    - What is your role on the IRB?
    - What training occurred before you became an IRB member? Ongoing training resources?
    - What do you do if you have a question about the IRB review process or review of a specific protocol?