# HUMAN RESEARCH PROTECTION PROGRAM

## HRPP

NOVEMBER 2024

UNIVERSITY of VIRGINIA

# Accreditation

- The University of Virginia School of Medicine and School of Nursing awards 1.0 contact hour for nurses who participate in the educational activity and complete the post activity evaluation.

- The University of Virginia School of Medicine and School of Nursing awards 1.0 hour of participation (consistent with the designated number of AMA PRA Category 1 Credit(s)TM or ANCC contact hours) to a participant who successfully completes this educational activity. The University of Virginia School of Medicine and School of Nursing maintains a record of participation for six (6) years.

# Disclosures

**Full Disclosure Policy Affecting CME Activities**: As a joint accredited provider, the University of Virginia Office of CME/CE requires attested and signed global disclosure of the existence of all financial interests or relationships with commercial interest from any individual in a position to control the content of a CME activity sponsored by OCME.

**Disclosure Summary**:

**No one in a position to control the content of this education activity has disclosed a relevant financial interest or relationship with any commercial interest**

# Activity Code

- The Activity Code: 24725
- Instructions for claiming credits/contact hours can be found here.

# Human Research Protection Program

OCTOBER 2024

UNIVERSITY of VIRGINIA

# Human Research Protection Program (HRPP)

***Help to ensure the protection of subjects, investigators and the institution through education, oversight and by promoting compliance with the federal regulations on Human Subject Research.***

- Protect participants and the rights and welfare of communities
- Promote socially valuable, scientifically valid, and ethical research
- Foster a culture of ethical awareness in the research community
- Maintain and promote public trust in the research enterprise

***https://hrpp.research.virginia.edu/***

# Human Research Protection Program (HRPP)

- ***The HRPP is overseen by the Office of the Vice President for Research.***
- ***UVA's HRPP is currently accredited and in good standing.***
- ***Our program is made up of four specialty teams to better serve the research community:***


- ***Education and Training***
- ***IRB for Health Sciences Research (IRB-HSR)***
- ***IRB for Social and Behavioral Sciences (IRB-SBS)***
- ***Post Approval Monitoring (PAM)***

# Human Research Protection Program (HRPP)

***Education and Training Team:***

- ***CITI Training modules***
- ***Virginia IRB Consortium***
- ***Microlearning videos***

https://hrpp.research.virginia.edu/teams/hrpp-education-and-citi-training

# Human Research Protection Program (HRPP)

***IRB for Health Sciences Research (IRB-HSR):***

- ***Specializes in serving medical studies***
- ***HIPAA Privacy Board for Research***
- ***IRB Full Board meets twice per month***
- ***Team is fully remote***
- ***Collaborates with the SOM Clinical Trials Unit***

https://hrpp.research.virginia.edu/teams/irb-hsr

# Human Research Protection Program (HRPP)

***IRB for Social and Behavioral Sciences (IRB-SBS):***

- ***Specializes in non-medical studies, including educational studies***
- ***IRB Full Board meets twice per month***
- ***Team is hybrid (3 days in office & 2 remote)***
- ***Many student projects with Faculty Advisors***

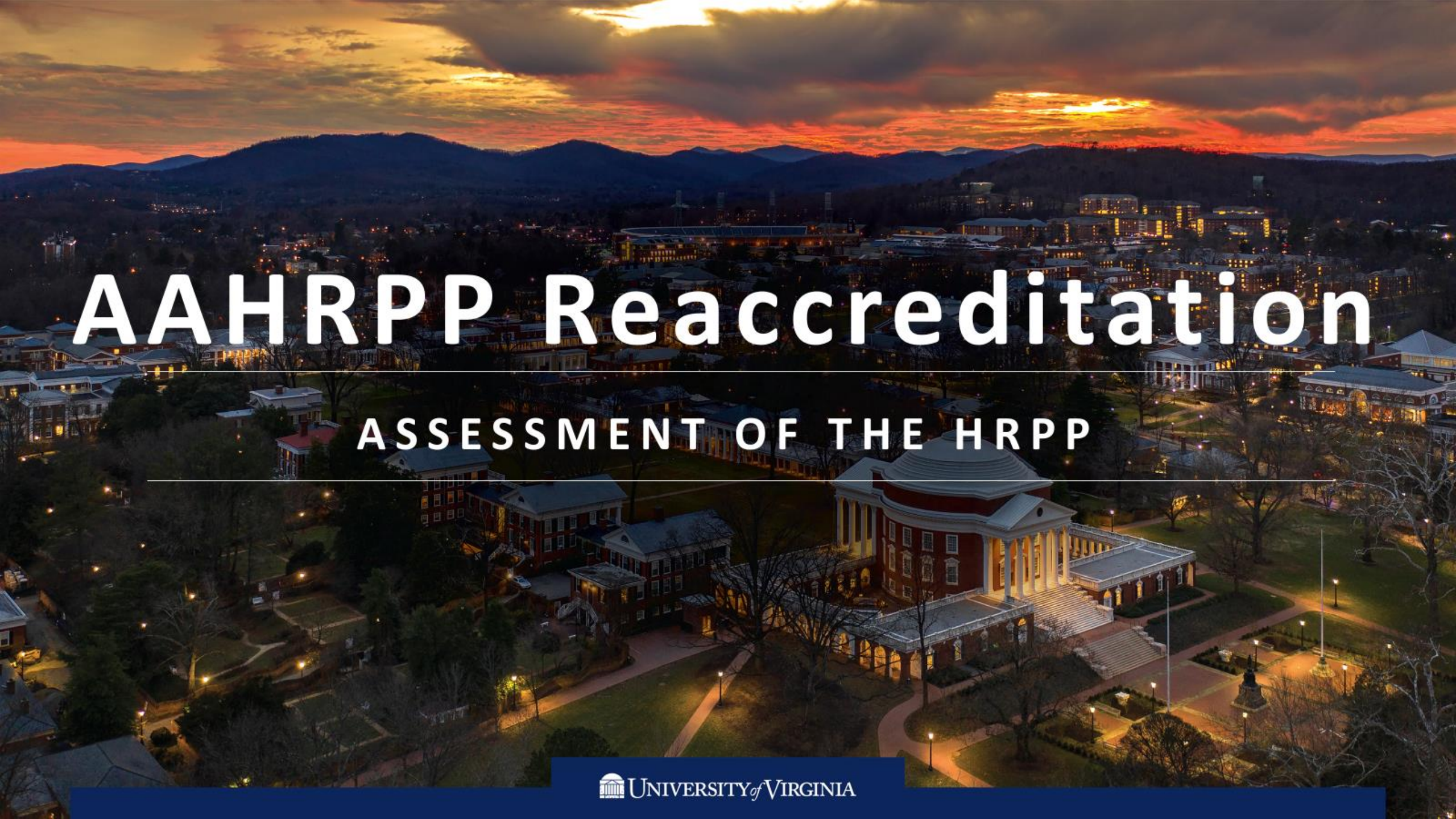
https://hrpp.research.virginia.edu/teams/irb-sbs

# Human Research Protection Program (HRPP)

***Post Approval Monitoring Team:***

- ***Confirm that studies are conducted responsibly***
- ***Specialize to the medical and academic sides of the IRB***
- ***Includes random and directed post approval monitoring (PAM) visits***

https://hrpp.research.virginia.edu/teams/hrpp-pam-ed


AAHRPP Reaccreditation
ASSESSMENT OF THE HRPP
UNIVERSITY of VIRGINIA

# What is AAHRPP?

The Human Research Protection Program (HRPP) at UVA is ***due for reaccreditation*** by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). This reaccreditation is essential to maintain the institution's commitment to high standards of ethical research and participant protection.

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An independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection. To earn accreditation, organizations must provide tangible evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement.

# What is the *Value* of AAHRPP Accreditation?

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The primary purpose of AAHRPP accreditation is to strengthen protections for research participants. Each accreditation advances that objective and helps build public trust and confidence in research. The benefits of AAHRPP's comprehensive approach ***extend beyond participants to the research enterprise as a whole***. Perhaps the greatest value is to those organizations that earn the privilege of displaying the AAHRPP seal. For them, attaining AAHRPP accreditation has proved to be both the right and the smart thing to do. ***The vast majority find that AAHRPP accreditation provides an excellent return on their investment.*** Equally important, the value of AAHRPP accreditation endures and is reinforced through reaccreditation.

# Who is AAHRPP reviewing as part of UVA's HRPP?

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***The accreditation process takes a broad view of the program and covers the entire HRPP at an institution.***

This includes higher administration (President, VPR office), researchers, IRB's (IRB-HSR and IRB-SBS), Office of Sponsored Programs, SOM Clinical Trials Unit, additional compliance committees/ offices including radiation safety, scientific pre-review committees, investigational drug services, etc.

# AAHRPP Standards

AAHRPP utilizes the following evaluation instrument for accreditation.

The evaluation instrument for the Human Research Protection Program contains three domains:

- Domain I: Organization
- Domain II: IRB (or Ethics Committee)
- Domain III: Researcher and Research Staff

Each domain is further broken down into Standards.

Standards are then broken down into Elements.

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- Domain I: Organization
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- Domain III: Researcher and Research Staff

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Standards are then broken down into Elements.

# Domain III: Researchers and Research Staff

**STANDARD III-1: In addition to following applicable laws and regulations, researchers and research staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, researchers and research staff have the protection of the rights and welfare of research participants as a primary concern.**

**STANDARD III-2: Researchers meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.**

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- ELEMENT III.1.A.: Researchers and research staff know which of the activities they conduct are overseen by the Human Research Protection Program, and they seek guidance when appropriate.
- ELEMENT III.1.B.: Researchers and research staff identify and disclose financial interests according to organizational policies and regulatory requirements and, with the organization, manage, minimize, or eliminate financial conflicts of interest.
- ELEMENT III.1.C.: Researchers employ sound study design in accordance with the standards of the discipline. Researchers design studies in a manner that minimizes risks to participants.
- ELEMENT III.1.D.: Researchers determine that the resources necessary to protect participants are present before conducting each research study.
- ELEMENT III.1.E.: Researchers and research staff recruit participants in a fair and equitable manner.
- ELEMENT III.1.F.: Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.
- ELEMENT III.1.G.: Researchers and research staff have a process to address participants' concerns, complaints, or requests for information.

**STANDARD III-2: Researchers meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.**

- ELEMENT III.2.A.: Researchers and research staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization's policies and procedures regarding the protection of research participants.
- ELEMENT III.2.B.: Researchers maintain appropriate oversight of each research study, as well as research staff and trainees, and appropriately delegate research responsibilities and functions.
- ELEMENT III.2.C.: Researchers and research staff follow the requirements of the research protocol or plan and adhere to the policies and procedures of the organization and to the requirements or determinations of the IRB or EC.
- ELEMENT III.2.D.: Researchers and research staff follow reporting requirements during a research study in accordance with applicable laws, regulations, codes, and guidance; the organization's policies and procedures; and the IRB's or EC's requirements.

# PROJECTED TIMELINE FOR AAHRPP

- **Winter 2024** — Formal Project Kickoff
- **Early 2025** — Step 1 AAHRPP Application
- **June 2025** — Deadline to submit Step 1
- **Fall 2025** — Step 2 AAHRPP Application
- **Early 2026** — Site Visit and Report
- **June 2026** — Review by Council for Accreditation

# PREPARING FOR AAHRPP

What changes can you expect to see in the IRB?

***We are working to align the process for the IRB-HSR & IRB-SBS as part of our unified Human Research Protection Program.***

We are really trying to be thoughtful in bringing these two sides of the IRB (medical and non-medical) together into a more cohesive program to make it easier for study teams and researchers to navigate the processes here at UVA.

# PREPARING FOR AAHRPP

What can you do as a Clinical Research Coordinators (CRCs)?

***Ways that you can help our institution as part of the research community:***

- Reach out to us with ideas and feedback so we can support your work
- Attend the CTU's CRC Education Series courses and keep up with CITI training
- Read our website to keep up to date on the process:
  - The initial AAHRPP application process in 2025 is document based
  - The AAHRPP site visit involves interviews with the research community, and we will help to provide coaching in preparation for that process beginning in the summer of 2025
- Continue following best practices and providing study patient focused quality work

# Suggestion Box


- Share your thoughts on what you like or any feedback for improvements with us here.
- Your ideas will help us to shape future plans for UVA's Human Research Protection Program.
- Note, for urgent matters, please see the Compliance Helpline.

# UVA's Human Research Protection Program

We are all in this together.

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