Join us for the UVA Research Open Forum Series!

To help keep the UVA Research community updated and gain feedback on future improvements, the Office of the Vice President for Research will host multiple hybrid **Open Forums** throughout the year at The Corner Building.

- October 30, 2024: **HRPP**
- November 6, 2024: **Research Integrity**
- November 13, 2024: **Compliance and Security**
- November 20, 2024: **OSP - Pre-Award**

UVA Research

ADVANCING DISCOVERIES

and

DRIVING INNOVATION

Sparking new ideas, building connections, and exploring interdisciplinary collaborations.

Presented in partnership with the UVA School of Data Science

Thursday, Nov. 7th | 5pm | 1919 Ivy Road

Human Research Protection Program (HRPP)

Kelly Hochstetler, AVP for Research Operations, Compliance & Policy

UPCOMING PROGRAM ENHANCEMENTS

- Executive Director HRPP
- New IRB System Project
- Training & Communications
- Community Hospitals & Riverside
- Reaccreditation

IRB-SBS & IRB-HSR

OBJECTIVES

THE IRB-HSR AND IRB-SBS WILL:

- **DISCUSS NEW IRB STAFFING & CONTACT INFO**
- **REVIEW IRB BOARD & PROCESS INFORMATION**
- **PROVIDE TIPS FOR EFFICIENT PROTOCOL**
- **REVIEW UPDATES & FUTURE PLANS SPECIFIC TO EACH IRB**

Institutional Review Board For The Social And Behavioral Sciences

or

(IRB-SBS)

Meet the IRB-SBS

Jeff Monroe
Associate Director
mjm6ny@virginia.edu
- Reliance Agreements
- Determinations
- Law, Medicine, Education

Tara Gaucher
Compliance Analyst
tlg2t@virginia.edu
- Education

Maizie Jackson
Administrator
- Protocol intake
- File management
- Business processes

Sandy Gardner
Assistant Director
slm6Q@virginia.edu
- Psychology
- Darden School of Business
- Nursing

Ashley Williams
Compliance Manager
amw9z@virginia.edu
- Undergraduate outreach
- Undergraduate research
- Anthropology
- Sociology
- Engineering

Meet the IRB-SBS

Primary Contact Information for the IRB-SBS

URL: https://hrpp.research.virginia.edu/teams/irb-sbs
EMAIL: irbsbshelp@virginia.edu
PHONE: 434-924-5999

Tonya R. Moon
Chair IRB-SBS, Professor of Education
trm2k@virginia.edu

Coby V. Meyers
Vice Chair IRB-SBS, Professor of Education, Chief of Research
cvm2x@virginia.edu

Bronwyn Blackwood
Director IRB-SBS
blb2u@virginia.edu

How to reach the IRB-SBS staff?

- Email irbsbshelp@virginia.edu
- Leave a voice mail at 434-924-5999
- Schedule a zoom meeting with your pre-reviewer
- Email your pre-reviewer
- Be patient
- You are always welcome to call my number directly at 434-243-2915 and I will return your call as soon as possible.

IRB-SBS Board Composition

- 21 IRB members and alternates
  - 5 Full Board members
  - 16 Alternate members
- Full board meetings are twice a month occurring on the 2nd and 4th Tuesday of the month (except for December)
- Board Is made up of scientists, physicians, nonscientific members, and community members
- Meetings take place virtually on zoom
- IRB-SBS has a relationship with a community board called Residents for Respectful Research (R3) under the Public Housing Association of Residents (PHAR)

SUBMISSION NUMBERS FOR IRB-SBS

Total Active Protocols for the IRB-SBS

- 1,554 active studies
  - 921 are exempt
  - 584 are expedited
  - 12 are full-board
  - 37 are reliance agreements

Annual Review of New Studies, Continuations, Modifications

- 1,221 new study submissions
  - 709 new exempt studies
  - 483 new expedited studies
  - 29 new full-board studies
- 652 modifications
- 17 continuations for full-board studies

TIPS FOR EFFICIENT PROTOCOL APPROVALS

In addition to the tips covered by Heather, some additional tips for improving SBS research submissions include:

- Make sure that you don't collect sensitive information unless it is essential for completion of your project.
- Don't collect identifying information unless necessary for your project.
- Work to protect people’s identities if it might be possible to deduce some participants in your research project.
- Make sure to present a thoughtful, yet reasonable analysis of risks to your participants.
- Make sure to elaborate on how you will protect participants from any risks resulting from participating in your research project.
- Confidentiality can never be assured for focus groups.
- Make sure to use the terms "confidential" and "anonymous" correctly and consistently in your protocol and on any consents.

HRPP TURN AROUND STATS

Approximate turn around times (based on 2023 numbers, and includes weekends and holidays):

- Exemptions in 18 days
- Expedited in 33 days
- Full board in 51 days

How can researchers improve these times?

- Follow our tips for success
- Respond to our pre-review and board member requirements as soon as possible

Protocol Review and Maintenance

Researcher Training

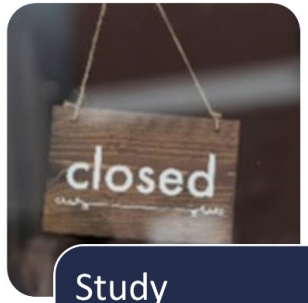
- CITI Training
- Investigator Agreement

Initial IRB Submission

- Protocol Development
- IRB Approval Process

Post Approval Maintenance

- Protocol Amendments
- Event Reporting



Study Completion

- Closure with IRB
- Record Retention

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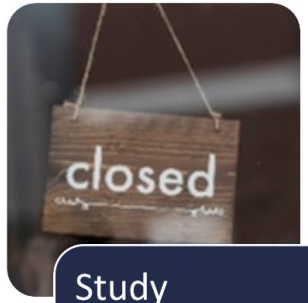

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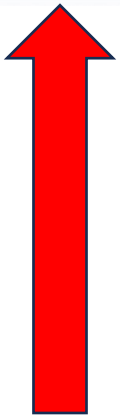

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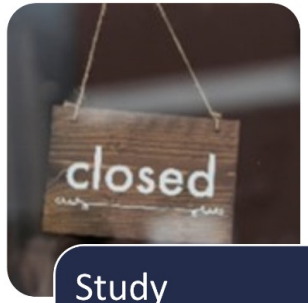

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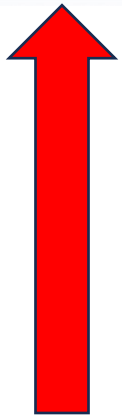

Protocol Review and Maintenance

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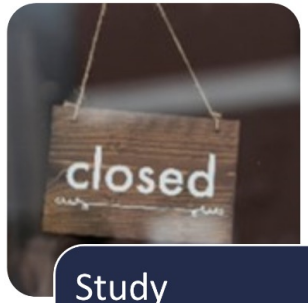

Study Completion

- Closure with IRB
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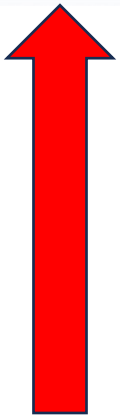

Protocol Review and Maintenance

Researcher Training

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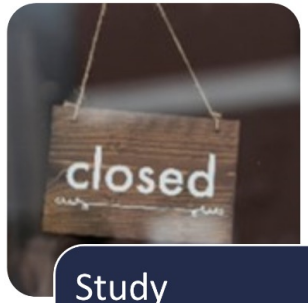

Study Completion

- Closure with IRB
- Record Retention

IRB-HSR

HEATHER FERRERI, MPH, CIP
DIRECTOR, IRB-HSR

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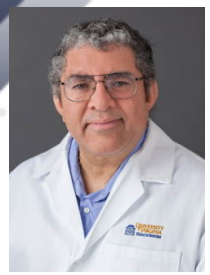
Meet the IRB-HSR



Gregory Townsend, MD
Chair
gct2r@virginia.edu

Stephen Caldwell, MD
Chair Emeritus
SHC5C@uvahealth.org

Lauren Dunn, MD, PhD
Vice Chair
LAK3R@uvahealth.org

Heather Ferreri, MPH, CIP
Director
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uzs6wf@virginia.edu

Sandy Borucki, RN, CIP
Associate Director
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Modifications
SAEs/UPs/Deviations

Joanna Faulconer
Associate Director
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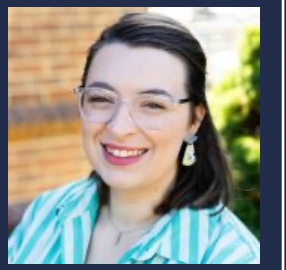
Jld6p@virginia.edu
Continuations / IRB #3
Reliance on Non-UVA IRB/sIRB
Non-Engaged, NHSR Determinations

MEET THE IRB-HSR

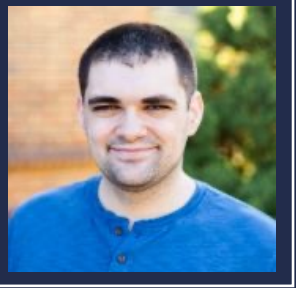
New Submissions

Sa'Mara Brooks
hph3qa@virginia.edu
Full Board Submissions



Amanda Bibb
acl3q@virginia.edu
Full Board Submissions
Modifications
Exempt Determinations

Mya Sherman, MA, MS
fmq2vz@virginia.edu
Expedited Submissions



Matthew DeHaai
xqj4vs@virginia.edu
Exempt Determinations

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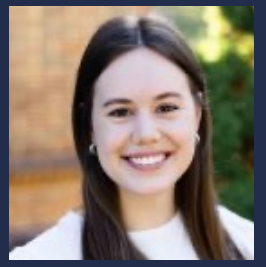
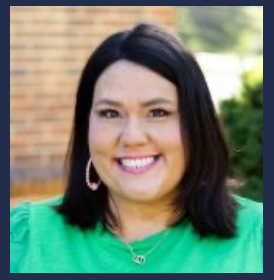
Modifications

Amber Kofman, MS, MPH
nsa2dq@virginia.edu



Kaylyn Wertz, MA
kaw3bu@virginia.edu



Continuations / IRB #3
Rachel Elrod
dgb4ky@virginia.edu

IRB #1 / Administrative
Beth Lane
kdt2vq@virginia.edu

IRB-HSR RESOURCES

Training
Marina Muchnik
huv9vq@virginia.edu
IRB Compliance Training Specialist

Protocol Development
Amy Warren, MS CCRC
434-243-4815
alh3p@virginia.edu
Protocol Development Administrator

Project Management
Andrea Ruhsam
alr8q@virginia.edu
HRPP Project Manager

IRB-HSR FULL BOARD

- 30 IRB MEMBERS ON IRB #1, 17 IRB MEMBERS ON IRB #3. SOME MEMBERS SERVE ON BOTH IRB #1 & IRB #3.
- FULL BOARD MEETINGS ARE TWICE A MONTH FOR BOTH IRB#1 & IRB #3 (EXCEPTION: ONLY ONE MEETING IN DECEMBER)
- BOARD IS MADE UP OF SCIENTISTS, PHYSICIANS, NONSCIENTIFIC MEMBERS, AND COMMUNITY MEMBERS
- MEETINGS TAKE PLACE VIRTUALLY ON ZOOM

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HOW TO REACH THE IRB-HSR STAFF?

- IRB Zoom Office Hours. Sign up on the IRB-HSR website
- Email! IRBHSR@virginia.edu or check staff directory
- Call! Leave a voice mail if needed
- Be patient

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NUMBERS / VOLUME OF SUBMISSIONS

For IRB-HSR (does not include IRB-SBS)

- ~4,000 active studies
- 500 are full-board
- 1450 are exempt
- 1050 are expedited
- 800 are CIRB
- 50 are multi-site sIRB

Annually

- New FB studies: ~100
- New Expedited Studies: ~100
- New Exempt Studies: ~300
- New Modifications: ~600
- Continuations: ~950

NUMBERS: TURNAROUND TIMES

APPROXIMATE TURN AROUND TIMES (BASED ON 2023 NUMBERS, AND INCLUDES WEEKENDS AND HOLIDAYS):

- **EXEMPTIONS IN 18 DAYS**
- **EXPEDITED IN 33 DAYS**
- **FULL BOARD IN 51 DAYS**

HOW CAN RESEARCHERS IMPROVE THESE TIMES?

- **FOLLOW OUR TIPS FOR SUCCESS**
- **RESPOND TO OUR PRE-REVIEW AND BOARD MEMBER REQUIREMENTS ASAP**

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TIPS FOR EFFICIENT PROTOCOL APPROVALS

- A lot of our studies in our queue are “pending resolution”, which means that we have conducted the administrative review and have asked for clarifications or updates to the study and have yet to received the requested materials.
    - Respond to email communication
    - Submit all necessary documents including all supporting documents: telephone script, email template, letters of support, data collection instruments (surveys/questionnaires), user’s manual, etc.
    - Make sure documents are consistent (protocol, consent form, application)
    - Answer Protocol Builder questions correctly, so that the sections that need to be completed populate and all necessary ancillary reviews are completed.
    - Make sure all CITI training is complete and current.

TIPS FOR EFFICIENT PROTOCOL APPROVALS

- Use lay language as much as possible in the consent form (6th-8th grade reading level).
- Provide complete responses with details (who, what, when, where, how, & why). Ask someone with no familiarity with the study if things make sense.
- Proofread your submission thoroughly.
- Don’t argue unnecessarily

THANK YOU!

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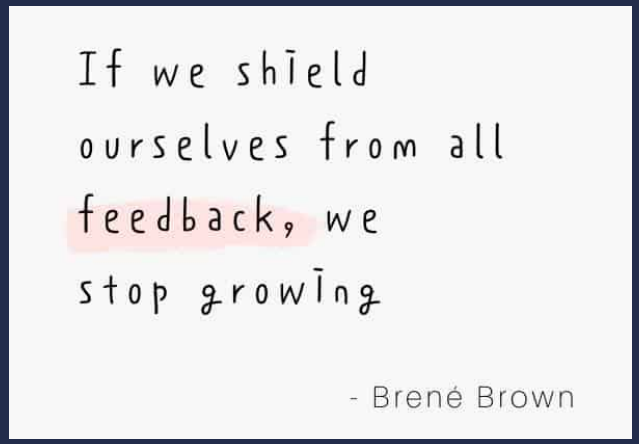
QUESTIONS? & FEEDBACK



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434-924-3167
uzs6wf@virginia.edu

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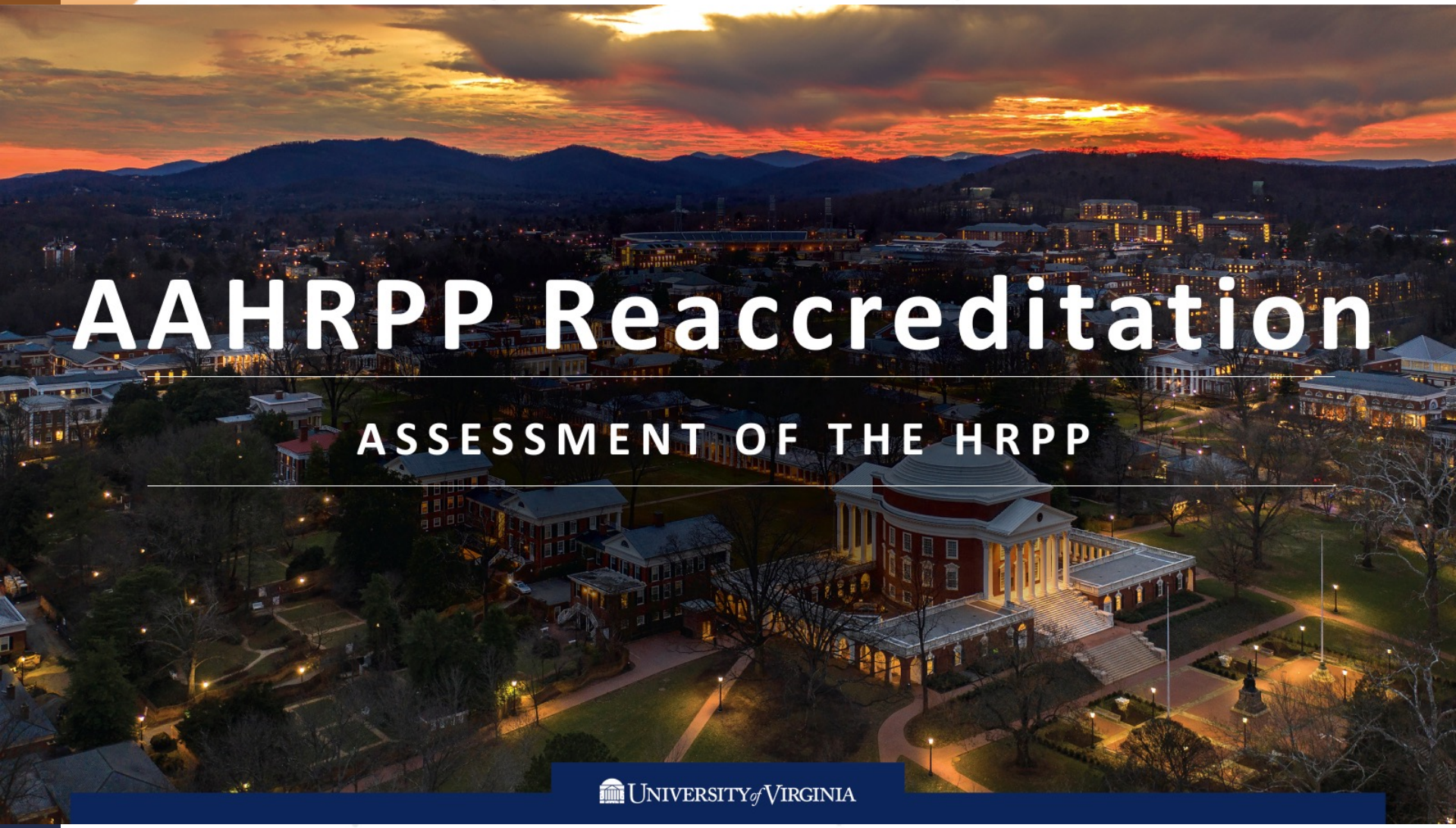
AAHRPP Reaccreditation
ASSESSMENT OF THE HRPP
UNIVERSITY of VIRGINIA

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.

AAHRPP

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.

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What is the *Value* of AAHRPP Accreditation?

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.

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.

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

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.

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.

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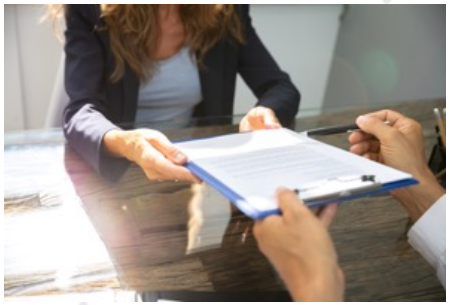
PROJECTED TIMELINE FOR AAHRPP

- **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

Where can I learn more?

Please visit our website to stay informed about the AAHRPP Reaccreditation process.

POST APPROVAL MONITORING & EDUCATION

JANE LEHMBECK, BSN, CCRC, CIP
DIRECTOR, POST APPROVAL MONITORING & EDUCATION PROGRAM

STEPHANIE KEISTER, ED.D., MS
POST APPROVAL MONITOR & EDUCATOR, IRB-SBS

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WHAT IS POST APPROVAL MONITORING?

- The HRPP Post Approval Monitoring & Education (PAM & Ed) program was initiated in 2002 and is managed by PAM & Ed groups in the IRB-HSR and IRB-SBS
- The purpose of the PAM & Ed program is to protect research participants and provide on-going support for investigators as they conduct human subject research
- The program provides internal oversight and ensures compliance with federal, state, local and institutional regulations

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POST APPROVAL MONITORING & EDUCATION

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Stephanie Keister, Ed.D., MS
Post Approval Monitor & Educator
IRB-SBS
qda4md@virginia.edu

Elaine Dube, BS, CCRP, CIP
Manager PAM & Ed
IRB-HSR
ed7y@virginia.edu

SOM CTU Educators

Katie Rea, RN, MSCR, CCRC
Clinical Research Manager
kaw3j@virginia.edu

Amy Smith, BS, MSHS Certificate
Research Education Coordinator
ajb6bb@virginia.edu

PAM WORKING GROUP (IRB-HSR)

The PAM Working Group is a collaborative group of research professionals at UVA who evaluate and discuss Post Approval Monitoring review findings of the studies audited.

- The group meets on the second Wednesday of each month and reviews all PAM audits completed the previous month.
- The group helps with corrective actions and reporting when needed and may make additional recommendations to those noted in the PAM report.

Members:

- Research Compliance Monitors (PAM Director & Manager)
- SOM CTU Educators, Director and Assistant Director
- Associate VP for Research Operations, Compliance & Policy
- IRB-HSR Director

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IRB PAM ADVISORY COMMITTEE (IRB-HSR)

The IRB PAM Advisory Committee (IRB-HSR) members provide a secondary review of the PAM audit findings and make the final determination regarding protocol deviations, reporting requirements and corrective action plans when required.

- The committee meets at the end of each month
- They review all PAM audits completed the previous month as well as the meeting minutes/recommendations from the PAM working group
- The IRB PAM Advisory Committee may refer studies to the IRB-HSR Full Committee if needed

Members:

- Research Compliance Monitors (PAM Director and Manager)
- IRB-HSR Chair and/or Vice Chair
- IRB-HSR Director and Associate Director

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PAM ADVISORY COMMITTEE (IRB-SBS)

The PAM Advisory Committee reviews PAM Reports and is responsible for discussing the PAM Report findings, determining if further action required by the study team, and recommending educational activities for the study team.

- The committee meets on the second Wednesday of each month.

Members:

- IRB-SBS Chair
- IRB-SBS Director
- IRB-SBS Associate Director
- IRB-SBS Community Member
- IRB-SBS PAM Monitor & Educator
- IRB-HSR PAM Director
- Associate VP for Research Operations, Compliance & Policy

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POST APPROVAL MONITORING SUMMARY JAN-DEC 2023

IRB-HSR PAM:

- 93 PAM reviews completed
- 67 studies were approved by IRB-HSR Full Committee review
- 15 studies were approved by IRB-HSR Expedited review
- 11 studies were approved by non-UVA IRB of record Full Board

IRB-SBS PAM:

- 34 PAM reviews completed
- 100% compliance with PAM deadlines
- 100% PI attendance at PAM visits
- 24% of studies were rated exceptional by the PAM Advisory Committee
- Created a variety research educational materials to support investigators

REASONS FOR AUDIT SELECTION

- Random selection
- Follow-up of previous audit findings
- Requested by IRB staff, IRB Chair, study team or other source
- Requested for assistance with FDA or sponsor audit preparation
- For cause or complaint from research participant
- New CRC or PI assessment
- Focus on non-UVA IRB of record or UVA sIRB of multi-site study

HOW TO PREPARE FOR YOUR PAM AUDIT

- **Provide access to regulatory files** (protocol and consent form versions, IRB assurance forms, advertisements, delegation of authority and training logs, etc)

- **Make sure original signed consent forms for subjects enrolled are available for review** (as well as any screen failures who signed consent)

- **Source documentation will be reviewed to verify adherence to approved protocol:**
  - Medical records
  - Eligibility checklists
  - Study flowsheets or data collection worksheets
  - Subject diaries
  - Study drug or devices accountability logs
  - Questionnaires, pain scales, quality of life assessments, other tools used
  - Recruitment materials

⇨SIGNED INFORMED CONSENT FORMS – MAKE SURE THERE IS PROPER USE AND DOCUMENTATION OF INFORMED CONSENT

AFTER THE PAM REVIEW

Read the PAM report

- Respond and ask questions if needed
- Carefully read the report and respond to the PAM report in writing with any correction to the content, your comments, clarifications and/or actions to resolve and prevent problems

Common findings

- Informed consent form discrepancies
- Missing documentation of subject eligibility
- Incomplete or no delegation of duties and/or protocol training log
- Subjects enrolled not entered in OnCore (IRB-HSR)
- Data storage inconsistencies

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WHAT'S GOING WELL

- **Most audits were completed remotely by review of electronic files**
  - EPIC medical records
  - REDCap database
  - OnCore database
  - Florence ebinders
  - Qualtrics
  - UVA Box
- **PI compliance with monitoring deadlines**
- **Most studies reviewed had only minor deviations noted**
- **Minor deviations were without significant problems or continuing non-compliance**
- **Studies where there were significant problems identified – the PI and study team completed required education and follow-up**

WHAT'S GOING WELL

Educational support to the UVA research community

- **Study teams have utilized the research education and mentoring services provided by the SOM CTU Educators**

- **Educational materials to support study team success**
  - Quarterly Investigator Newsletter
  - Compliance check-up tool for IRB-HSR and IRB-SBS researchers

- **Faculty Advisor resources**
  - IRB-SBS Guide for Faculty Advisors
  - IRB-SBS Canvas site to support faculty advisors work with student researchers

Request to be added to the IRB-SBS Faculty Advisor Canvas site

COMPLIANCE CHECK-UP

- The Compliance Check-up is an **optional** but important step to confirm you are conducting your study appropriately
- The tool is a Qualtrics survey that will help you evaluate your research to ensure you are compliant with federal regulations and your approved protocol
- The Compliance Check-up will take approximately 30 minutes to complete and includes an opportunity to provide feedback about IRB processes as well

IRB-HSR Compliance Check-up

IRB-SBS Compliance Check-up

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LOOKING FORWARD

- Increased collaboration with IRB-SBS and IRB-HSR Post Approval Monitoring & Education programs and with the HRPP overall
- Develop educational materials to support the needs of the UVA research community
- Continue working with SOM CTU Educators Katie Rea and Amy Smith to develop and expand research education and training opportunities
- Increased focus on multi-site studies with an sIRB of record (UVA and non-UVA IRB review)
- Focus on AAHRPP Re-Accreditation – IRB-SBS and IRB-HSR PAM & Ed programs are working with both IRBs and other UVA offices to ensure we achieve AAHRPP Re-Accreditation in 2025!

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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 maters, please see the Compliance Helpline.

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QUESTIONS?

PLEASE CONTACT US WITH ANY QUESTIONS OR FEEDBACK!

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