Volume 017 | April 2024

VIRGINIA COMMONWEALTH UNIVERSITY
Human Research Protection Program

NEWSLETTER

HRPP Transformation Project

The HRPP is thrilled to announce a significant leap forward in our commitment to protecting human research participants through the HRPP Transformation powered by the Huron Consulting Toolkit. This transformative initiative introduces new policies, procedures, work instructions, and an investigator's guide, reinforcing our dedication to excellence in research ethics and participant safety.

Key Components of the HRPP Transformation:

New Policies and Procedures

Our HRPP now boasts a comprehensive set of updated human research protection program plan, policies, and procedures aligned with the latest industry standards. These changes are designed to streamline processes, enhance clarity, and ensure the highest level of ethical conduct in human research.

Investigator's Guide

The introduction of an investigator's guide equips researchers with a valuable resource to navigate the complexities of the research process. This guide serves as a roadmap, providing step-by-step instructions and best practices to promote adherence to ethical standards and regulatory compliance.

Check out the recently updated HRPP Transformation Project web page for more information!

****If you receive an error message from the hyperlinks, please copy/paste the address into your browser.*

HRPP Toolkit Go-Live and Updates

The HRPP Toolkit has successfully been in active operation since *July 14, 2023*. This comprehensive toolkit comprises workflows, standard operating procedures, checklists, worksheets, and templates meticulously crafted to adeptly handle IRB submissions throughout the study lifecycle. Protocol and consent templates are included in the toolkit and have been designed to align, and emerge, with institutional expectations and industry standards.

We are committed to continuous improvement, actively refining and expanding the toolkit's elements. For a detailed overview of the HRPP toolkit components, please refer to the HRPP Toolkit Overview Deck.

****It is important to note that the previous VCU HRPP WPPs are now obsolete, and we are in the process of systematically replacing them with the new and enhanced HRPP Toolkit wherever applicable.*

Most recent Update

Exciting news! Post-Approval Monitoring and Quality Improvement (PAMQuIP) has evolved into a cutting-edge endeavor called Post-Approval Monitoring and Education (PAM&E).

The HRPP has embarked on an ambitious transformation, orchestrating a dynamic overhaul of our post-approval monitoring strategy. PAM&E is poised to deliver unparalleled excellence in research monitoring and education. This endeavor is dedicated to upholding VCU's commitment to regulatory compliance and industry-leading practices, ensuring that all human subject research conducted under our auspices achieves the highest standards of quality and integrity.

PAM&E guidance can be found on the HRPP website under Other Submissions and Monitoring.

Visit the PAM&E section of the HRPP website for information about the types

of post-approval visits that are conducted by the HRPP, an overview of the PAME process, preparation for visits, education and consulting, and the Study Conduct Toolkit.

The new email address is pame@vcu.edu.

HRPP Training for the Research Community

*****SAVE THE DATE*****

April 25, 2024

Upcoming training -

HRPP/IRB Research Community Training:
*****New IRB System Updates*****

Are you ready to revolutionize your research process?

Join us for an exclusive IRB System Training Event on Thursday, April 25, 2024, from 2:00 – 3:30 p.m. EST.

Unlock the power of our cutting-edge IRB system and streamline your research endeavors like never before! This comprehensive training session is tailored to equip you with all the tools and insights necessary to seamlessly integrate the new IRB system into your workflow.

Whether you're a seasoned researcher or just starting out, this event is your gateway to mastering the intricacies of the IRB system. Discover best practices, learn essential tips, and engage in interactive discussions to ensure a smooth transition for the entire research community.

The HRPP team will share updates, including a comprehensive plan of action for study teams.

Don't miss out on this invaluable opportunity to prepare for the future of research. Mark your calendars and reserve your spot today!

Date: Thursday, April 25, 2024

Time: 2:00 – 3:30 p.m. EST

Location: Zoom/Virtual

Registration Required

Register for the April 25th training here

Together, let's pave the way for innovation and excellence in research. See you there!

Please contact the VCU HRPP with any questions atirbeducation@vcu.edu.

Direct Registration Link for the April 25th Training Session:

https://us02web.zoom.us/meeting/register/tZ0qf-GorD0iHtRw_eRwdWDwNQpeLapdqu7d

HRPP Annual Conference

SAVE THE DATE

October 24, 2024

Mark your calendars and save the date for an exciting event you won't want to miss!

The Human Research Protection Program (HRPP) is thrilled to announce the upcoming VCU HRPP Conference: "Ensuring Ethical Excellence in Human Studies Research Compliance"

Hosted by the Human Research Protection Program at Virginia Commonwealth University, this conference promises to be an invaluable opportunity for researchers, ethicists, compliance professionals, and all stakeholders involved in human studies research.

Join us as we delve into critical topics surrounding ethical excellence in human studies research compliance. From best practices to emerging trends, our lineup of speakers and sessions will provide insight, inspiration, and practical guidance to enhance your work in this vital field.

Date: Thursday, October 24, 2024

Time: 9:00 am est- 4:00 pm est

Location: Virtual Event via Zoom

Registration link will be released at a later time

Conference Keynote Speaker Announced

Brie Haupt, PhD

In January 2024, Dr. Haupt was a featured guest on VCU CompassPoint podcast titled Finding support and success when navigating the IRB and shared insights into VCU's IRB process, common challenges and questions that students and faculty may have, and information on how to seek support from a Protocol Navigator Consultant (PNC) as you prepare your submission.

Brittany “Brie” Haupt, Ph.D., is an Assistant Professor at Virginia Commonwealth University in the Homeland Security & Emergency Preparedness Department. She is an expert in crisis communication, cultural competency, and emergency and crisis management. In 2021, Haupt's book, with Dr. Claire Connolly Knox, on *Cultural Competence for Emergency and Crisis Management: Concepts, Theories, and Case Studies* won the Book of the Year Award from the American Society of Public Administration’s Section on Democracy and Social Justice. This text has been utilized by numerous emergency management programs and incorporated into the Federal Emergency Management Agency's training programs. In 2022, Haupt published a textbook on *Crisis Communication Planning and Strategies for Nonprofit Leaders* with Dr. Lauren Azevedo. This text won the Network of Schools of Public Policy, Affairs and Administration's Outstanding Scholarship of Teaching and Learning award sponsored by the Journal of Public Affairs Education. Haupt has been sought out for her expertise and was even invited by Canada-Coalition for Police Reform to speak on Communicating during Crises: Strategies for Community Relations.

Haupt has also published in several peer-reviewed journals (i.e., Public Administration Review, Journal of Public Affairs Education, Disaster Prevention and Management, Risk, Hazards, and Crisis in Public Policy, Natural Hazards Review, Journal of Homeland Security and Emergency Management, Journal of Emergency Management, Frontiers in Communication section on Disaster communications and more). She also serves as a board member for the American Society of Public Administration's Section on Emergency and Crisis Management, co-chair for the Network of Schools of Public Policy, Affairs and Administration's Section on Emergency Management and Homeland Security Programs, a board member for Public Administration Theory Network, a committee member for the NASPAA's Diversity, Equity and Inclusion committee, an associate editor for Natural Hazards Review and associate editor for Frontiers-Disaster Communications.

Stay tuned for further details regarding conference speakers, agenda, and registration information. We look forward to your participation in this important

event as we strive to uphold the highest standards of research ethics and compliance.

Together, let's ensure ethical excellence in human studies research. Save the date and be part of the conversation on October 24, 2024!

Additional details will be released over the coming weeks through the HRPP blog and newsletter.

Update - HRPP/IRB Research Community Training: Criteria for IRB approval and the role of post-approval monitoring

*****Completed training - session materials now available*****

On March 28, 2024, the HRPP held an online session that focused on the criteria for IRB approval and the role of the post-approval monitoring process in the conduct of human subjects research. This session was brought to the VCU research community by the HRPP's Post-Approval Monitoring and Education staff.

The presentation addressed the IRB's purview and review process, specific criteria for approval of human subjects research, and the role of the post-approval monitoring process in human subjects research. The HRPP division greatly appreciates the research community's willingness to take time out of their schedule to attend this session!

All registrants received post-evaluation survey and session materials by email. We plan to hold community driven education on an ongoing basis. *Your* continued collaboration and support are integral to the success of VCU's human research protections program.

Recordings and materials HRPP trainings can be found in theHRPP's Kaltura MediaSpace. Slides for this session are uploaded into the *HRPP's Kaltura MediaSpace* in the *Attachments* section within the media recording.

Tools to Assist the Research Community with IRB Submissions

As part of the *HRPP Transformation Project*, we created a collection of training sessions designed to ease the community into changes made within the HRPP. Training topics include: review of the HRPP Toolkit, reportable new information, single and multi-site research, vulnerable populations, informed consent, clinical drug and device considerations, and minimal risk research

considerations.

Recordings and slides of past sessions are available on the HRPP Blog and VCU HRPP/IRB Kaltura channel.

Updates to HRPP web content

The HRPP and OVPRI staff have collaborated with external consultants to provide the research community with the most robust and transparent resources for human subjects research, and this included review of the current HRPP web content. The HRPP manages several web pages that provide support for human subjects research at VCU. Revisions to the webpages will be posted as they become available over the next few months and a full transformation for the OVPRI's website is planned for 2024!

Check out the most recent web page updates we have rolled out...

HRPP Transformation Project

IRB Reliance
Includes matrix outlining review pathway/fee applicability

HRPP Toolkit
Spotlight Documents

Introducing...

HRPP Toolkit guidance for the Consent Process and Consent Documentation

The HRPP Toolkit contains checklists, worksheets and SOP's that address the informed consent processes for human research, uses of specific consent processes, such as the Short form consent process, and requirements related to documentation of consent for research participation.

The IRB refers to HRP-090 - SOP - Informed consent process for research and HRP-091 - SOP - Written documentation of consent for review of consent processes and plans for documentation of consent in human research protocols.

The HRP-410 - CHECKLIST - Waiver or alteration of consent process and the HRP-411 - CHECKLIST - Waiver of written documentation of consentare used to supplement the IRB's review when determining whether criteria for waiver or

alteration of the consent process, or criteria for waiver of documentation of consent have been met.

The HRP-317-WORKSHEET Short form of consent documentation is used to supplement the IRB's review when reviewing research that proposes use of a short form consent process. Short form consent processes generally apply to situations when there is unexpected enrollment of a non-English speaking participant, or when a study population includes few to no non-English speaking individuals. Studies that utilize a short form consent process must follow applicable guidelines outlined by the IRB.

DHHS and FDA guidelines provide parameters for applicability of short form consent processes. A particular consideration requires all elements of consent be presented to the participant orally, such that a complete and equitable consent process is being conducted with non-English speaking participants and to assure autonomy over their agreement to participate.

The HRP - 507 TEMPLATE Consent Document - Short form consent has been translated into many languages. The main English version and all translated versions are posted under the HRPP Toolkit and IRB Forms page under Templates.

Refer to the HRP-103 - Investigator manual for detailed guidance about consent requirements and processes for enrollment of participants with limited English proficiency. Studies approved by Single IRB review should refer to the HRP-103p - Investigator manual - Single IRB review of multi-site research (pSite).

Designated IRB reviewers and consultants for the IRB use these worksheets during their review to help prepare a protocol for review against the HRP-314 - WORKSHEET - Criteria for approval.

Research teams must assure the aims and procedures specified in the human research protocol are scientifically sound and justified. This includes clear objectives, background, setting, procedures, data and safety monitoring (if applicable), risks, potential benefits and alternatives to participation.

The human research protocol and consent information must be consistent with one another for final approval by the IRB. All plans related to selection of subjects, recruitment, research procedures, data collection, data sharing and data dissemination must be clear and consistent across the protocol, consent and other supporting documents.

Institutional resources for human research protocol development and other research support for health studies, any research being conducted on the

medical campus, clinical trials and patient centered studies include:

C. Kenneth and Dianne Wright Center
For Clinical and Translational Research

VCU ONETRAC/PROCS

Massey Comprehensive Cancer Center Clinical Trials Office

The Protocol Navigator Consultant (PNC) project provides research support to the academic campus and is designed as a collaboration between the VCU HRPP and several participating academic departments. Current collaborating departments include VCU's School of the Arts, School of Education, College of Humanities and Sciences, the Wilder School, and the School of Social Work. The Protocol Navigator Consultant (PNC) project is considered a primary human research resource for the specified participating academic schools.

The HRPP Toolkit documents will be updated periodically and updated versions will be posted under the HRPP Toolkit and VCU HRPP/IRB Forms web pages.

*****HRPP SPOTLIGHT*****

Child Abuse Prevention Month

and

Sexual Assault Awareness

Month

As a matter of Human Rights and Research Ethics we must strongly consider the manner and purpose for the selection of human participants in research, the minimization of risks and undue burden to individuals and their community/s, and an individual's autonomy over their agreement to participate or have their data or other materials used in research...

There are (3) basic ethical considerations for human subjects research that are outlined under the Belmont report; respect for persons, beneficence, and justice. These principles speak to the autonomy of participants, minimization and balancing of risks/benefits, and fairness in the selection of subjects.

Click on each topic/article that is hyperlinked below to learn more.

****Columns are not organized in any particular order.*

Respect for Persons	*Beneficence*	*Justice*
Why Human Subjects Appendix B: Recommendations regarding risk in research involving children	**National Center for PTSD - Working with Trauma Survivors: What Workers Need to Know**	**Incorporating a Victim-Centered, Trauma-Informed Lens to Research - RTI International**
Virginia Bill Expands List of Mandated Reporters	**Center for Victim Research - Victim Protection in Research**	**Trauma and Violence - Substance Abuse and Mental Health Services Administration**
Virginia Code - Reporting of acts of sexual violence	**RAINN Campus Sexual Violence: Statistics**	**State of Privacy Laws in US (2021)** **State Privacy Legislation (2024)**
National Institutes of Justice - Overview of Rape and Sexual Violence	**Centers for Disease Control Fast Facts: Preventing Sexual Violence**	**VCU Libraries Research Guides** **VCU Libraries Research Guide: Drugs and Alcohol: Open Access to Research** **VCU Libraries Research Guide: Military Medicine**

Some federal investigations that speak to human research ethics and are currently on the radar...

Reproductive rights in America - NPR.org

***Update: Final opinion from SCOTUS expected by this summer. See all final opinions issued by SCOTUS over the years here.

American Academy of Dental Sleep Medicine Special Update: AGGA Investigation

***Update: Seems to have resulted in many class action lawsuits to date, with the inventor and other practitioners who prescribed the dental device levied under extensive scrutiny for the lack of a scientific process being used in the design and implementation of the medical device and apparent failure to obtain

FDA oversight for use of the experimental medical device. Professional organizations have posted comments voicing ethics concerns, as the medical device that was implemented may have caused undue harm to patients and appears to have been used without sufficient scientific support and without sufficient oversight to protect participants from potential harms.

The Patient First Podcast Episode 94: Just How Bad Is the "AGGA" Issue?

International Association for Dental, Oral, and Craniofacial Research Code of Ethics

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Did you know that the National Institutes of Health (NIH) has a center that is specifically dedicated to providing resources to research communities that are centered around research ethics and integrity? Check it out...

NIH Annual Review of Ethics Case Studies

Upcoming Human Subjects Research Events and Trainings

VCU and Other Local Events

VCU OVPRI Research Events

VCU Wright Center Research Events

National Events

May 16-17, 2024

SOCRA Program - Protecting Human Research Participants: Legal, Ethical, and Practical Considerations

May 21-23, 2024

2024 AAHRPP Annual Conference: Science and Standards in San Diego

September 16-18, 2024

NIJ Annual Conference: Advancing justice through science

Federal and State Human Research Resources

US Department of Health and Human Services (HHS) Human Research Protection Program Resources	**National Institutes of Health (NIH)** Human Subjects	**Food and Drug Administration (FDA)** FDA Meetings, Conferences and Workshops
Department of Defense (DOD) DoD Instruction DOHRP	**National Science Foundation (NSF)** Research Involving Human Subjects	**Environmental Protection Agency (EPA)** Human Subjects Research
World Health Organization (WHO) Ethical standards for research with human beings	**Department of Veterans Affairs (VA)** VA HRPP	**National Institutes of Justice (NIJ)** NIJ Human Subjects and Privacy Protections
Indian Health Service (IHS) Tribal governance and human subjects research	**United States Federal Register** Federal policy for the protection of human subjects in research	**Virginia State Code** Human Subjects Research **Virginia Department of Social Services** VDSS IRB

If you would like your research featured in one of our upcoming newsletters, please submit a request.

Submit a newsletter request