



NEWSLETTER

[VCU HRPP statement about Winter Break](#)

For detailed information regarding VCU HRPP operations during the winter break, we invite readers to visit our HRPP [blog](#). We will be providing updates and insights to ensure a comprehensive understanding of our operations during this period. Thank you for staying informed about VCU HRPP.

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.

HRPP Toolkit Go-Live and Updates

As of July 14, 2023, the HRPP Toolkit has successfully been in active operation for a continuous six-month period. We are proud to announce that the core components of the Huron toolkit are now fully operational and available for exploration by the research community. This comprehensive toolkit comprises workflows, standard operating procedures, checklists, worksheets, and templates meticulously crafted to adeptly handle IRB submissions throughout the study lifecycle. Additionally, the toolkit includes protocol templates that assist research teams in developing protocols that align with compliance 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.

HRPP Toolkit Training for the Community

Update on the November 14, 2023, VCU HRPP Toolkit Training – Reporting Requirements (IRB and Other Offices)

On November 14, 2023, the collaborative training initiative between VCU HRPP and Huron proved to be a success, drawing the active participation of numerous members from the VCU research community. The training session covered essential topics such as human subjects research reporting requirements, the reporting process, and expectations for VCU researchers. Access the recorded session on the VCU HRPP Kaltura page for valuable insights and resources. [Reportable New Information Training 11.14.23.](#)

Stay tuned to the [HRPP blog](#) for 2024 training(s) offered through the VCU HRPP

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](#).

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

***HRPP Toolkit Spotlight Documents ***

HRP - 309 - WORKSHEET - Ancillary Reviews

Ancillary reviews are reviews by other compliance groups or individuals that inform the IRB's review of a new study or a modification to an existing study. The VCU HRPP has developed a comprehensive listing of ancillary reviews that outlines each type of ancillary review and the documentation required for IRB approval.

See the [HRP-309 - WORKSHEET - Ancillary review matrix](#) for all current information about ancillary review processes! This worksheet will be updated periodically and updated versions will be posted under the [HRPP Toolkit](#).

HRP-103 Investigator manual and HRP-321 - WORKSHEET - Review of information items

The IRB is responsible for determining whether reportable new information that is received by a research team qualifies as noncompliance and/or rises to the level of an unanticipated problem. Unanticipated problems and serious and continuing noncompliance must be reported to the federal entities directly by the institution and there are very strict reporting timelines that apply to both the research team and the IRB.

For guidance on the expectations for review of reportable new information to the IRB, refer to the [HRP-103 - Investigator manual](#) or [HRP-103p - Investigator manual - Single IRB review of multi-site research \(pSite\)](#), section 'What are my obligations after IRB approval?'

The VCU HRPP team refers to the [HRP-321 - WORKSHEET - Review of information items](#) for review of information that is received by the IRB. This worksheet also provides the framework for the types of actions that may be

taken by the IRB following receipt of new information.

For more information and videos, visit the VCU HRPP Kaltura page for the recorded [Reportable New Information Training 11.14.23](#).

*****Call for VCU IRB Membership Nominations*****

Join the Institutional Review Board in Fiscal Year
2024-2025

*****Application deadline: Extended to March 1, 2024*****

The HRPP is pleased to announce that the deadline for VCU IRB nominations has been extended until March 1, 2023. This extension provides an additional opportunity for individuals interested in contributing to the Institutional Review Board's important work in overseeing human research to submit their nominations. We encourage all qualified candidates to take advantage of this extended deadline and submit their nominations by the new date. Thank you for your interest in supporting the ethical conduct of research at VCU.

VCU community and non-VCU affiliated community members are highly encouraged to apply.

Visit our most recent call for nominations on the HRPP [blog post](#)

VCU's HRPP Shines at PRIM&R 2023 Conference

The VCU's Human Research Protection Program is thrilled to share the exciting news that Virginia Commonwealth University's HRPP took center stage at the Public Responsibility in Medicine and Research (PRIM&R) 2023 Conference, leaving a lasting impact on the audience.

PRIM&R serves as a vital platform for the HRPP community, fostering collaboration, knowledge exchange, and the exploration of ethical principles, thereby playing a crucial role in advancing best practices and ensuring the highest standards in human research protection.

To kick off the conference, Dr. Gerry Moeller, Deputy Institutional Official, dedicated a full day to engage with his fellow institutional officials, discussing the latest news and fostering partnerships to enhance our collective

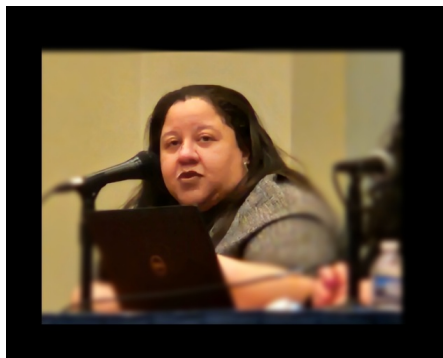
commitment to research ethics.

In addition, our esteemed Director, Dr. Sandy Brooks, of the HRPP played a pivotal role as the moderator for the Ethics of Data Sharing plenary session, delving into critical discussions on the ethical considerations surrounding data sharing. This plenary session, which drew over 1100 registrants both in person and virtually, sparked meaningful conversations and contributed significantly to the conference's overall success.

Also, our Director showcased expertise and leadership as a panelist in the breakout session titled "When You're the New Kid in Town: Taking Over as an HRPP/IRB Leader." This session provided valuable insights into the challenges and strategies associated with assuming leadership roles within an HRPP/IRB.

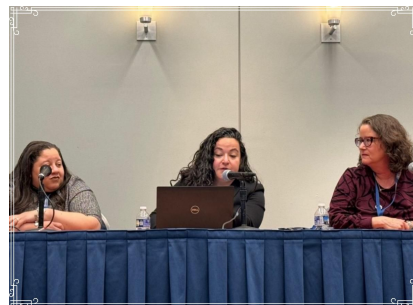
Additionally, the entire HRPP staff actively participated in various sessions, ensuring continuous education and contributing to the renewal of their Certified IRB Professional certification.

VCU's HRPP continues to be at the forefront of advancing ethical standards and best practices in human research protection and Institutional Review Board operations, and the active participation of our Director in these prominent roles underscores our commitment to excellence in human subject research.



Dr. Brooks, VCU HRPP Director, attended the 2023 PRIM&R Annual Conference and participated as a moderator during the **Ethics of Data Sharing** plenary session.

This session focused on federal data-sharing mandates and ethical considerations for sharing research data and specimens. Specific resources referenced during this session: **White House Office of Science and Tech Policy**, **NIH Data Sharing page**, and **NIH DMS policy**.



Some **hot topics** discussed at the PRIM&R conference:

- Impact of emerging AI technologies, such as ChatGPT, on the human subjects research landscape.
- Legal and ethical expectations for privacy and confidentiality.
- Emerging clinical research with psychedelic substances and FDA applicability for clinical research.
- Diversity and inclusion in

human subjects research:
LGBTQIA+, BIPOC,
persons with special needs
and of situational
vulnerability.

- Requirements for conduct of collaborative research with native populations and tribal sovereignties.

Acknowledging Outstanding Contributions-A Spotlight on Dr. Hollee McGinnis during PRIM&R Conference 2023:

A special acknowledgment goes to Dr. Hollee McGinnis, a distinguished faculty member in the VCU School of Social Work, for her valuable participation in the "Decolonizing Science for Justice: Closing the Research Loop" session. We appreciate Dr. McGinnis's insightful contributions to this crucial discussion, further enriching our understanding and commitment to equitable and just research practices!

HRPP SPOTLIGHT: Student Researcher

Class of 2023: Alaina Holt's research into vaping and THC-related products is helping keep the public safe

Alaina Holt from the Class of 2023, whose groundbreaking research on vaping and THC-related products is making a significant contribution to public safety. Through her dedicated efforts, Alaina is actively advancing our understanding of these products, shedding light on potential risks, and playing a crucial role in promoting the well-being of the community. Her commitment to research excellence exemplifies the positive impact that our students can have on critical issues affecting public health.

Upcoming Human Subjects Research Events and Trainings

[VCU and Other Local Events](#)

[VCU OVPRI Research Events](#)

[VCU Wright Center Research Events](#)

National Events

April 10-11, 2024

[OHRP Research Community Forum \(RCF\) with the University of Miami](#)

May 21-23, 2024

[2024 AAHRPP Annual Conference: Science and Standards in San Diego](#)

Federal and State Human Research Resources

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

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

Submit a newsletter request

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