Volume 021 New Year January 2025

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NEWSLETTER

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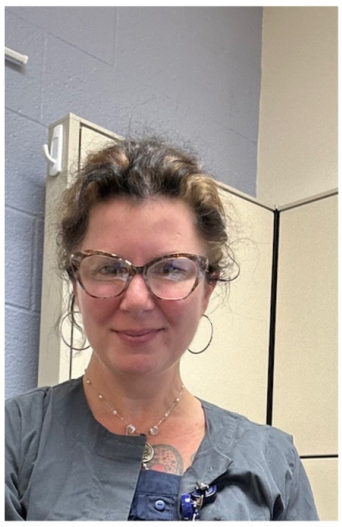
Dear UNSTOPPABLE colleagues,

Welcome to the 2025 New Year! This year, the HRPP will be focusing efforts towards restructuring of the Post-Approval Monitoring and Education (PAM&E) areas of our program, with particular emphasis on changes to the HRPP website, educational offerings and ongoing monitoring for human research at VCU. To start the year off, we have hired two new staff members to our crew. Please give a warm welcome to Amanda Hasuly and Ita Fischer.

Warm regards,

VCU HRPP/the UNLIMITED HRPP

Amanda's transition out of the RN Research field occurred when she was recruited by Walter Reed Army Institute's Human Research Protections Board. She continued to work in HRPP for the Department of Defense including oversite of HRP programs for several



Amanda Hasuly

Amanda Hasuly, originally from the Mid-Atlantic portion of the Virginia/DC area is coming to us from Oneonta, NY. Throughout her career in nursing and research management, she helped medical institutions set up nursing-centered research programs, convened, assisted, and established HRPP programs, established Institutional Review Boards, and brought regulatory, human research protections, and research ethics experience and education to many folks involved in the multidisciplinary roles it takes to engage in ethical and relevant research projects.

divisions of the Army and Navy under their respective Surgeon Generals. She will be exiting her senior regulatory/HRPP scientist, clinical research project manager, and IRB member at Bassett Medical Networks Research Institute.

Her favorite part of working in HRPP is the opportunity to teach, mentor, and continue to learn and serve the needs of a variety of communities and ensure that the research undertaken is relevant to communities of research foci. Amanda holds a master's Degree in Clinical Research Management and Regulatory Science and a Bachelor in Nursing. She is also experienced with the Huron toolkit.

Before this position, Ida was involved with the Colorado Multiple Institutional Review Board at the University of Colorado Denver - Anschutz Medical Campus, where she reviewed human subjects research protocols and advised researchers on preparing their submissions.

Ita Fischer

Ita Fischer comes to us from Rhode Island where she has worked at the Human Research Protection Program at Brown University for over 10 years, most recently serving as the Associate Director. In this role, she oversaw the implementation of Huron, supported the IRB, and presented on research ethics as part of the Office of Research Integrity's education program.

She is a certified IRB professional and holds a M.A. in Anthropology from the University of Denver. Ita comes to us with a wealth of knowledge and experience as a proactive, collaborative partner in research. She is passionate about HRPP. She loves working with stakeholders and is a good educator as well as analyst. It has been noted that she is collaborative and proactive in her work.

HRPP Training and Events for the Research Community

*****Stay tuned for upcoming educational offerings from the HRPP*****

Upcoming Human Subjects Research Events and Trainings

VCU and Other Local Events

VCU OVPRI Research Events

VCU Wright Center Research Events

National Events

January 28-29, 2025

FDA Conference: Knowledge Management and Modernization of Regulatory Quality Assessment and Submissions at FDA

January 29, 2025

WCG: ICH E6 (R3) is Here – What You Need to Know

February 18, 2025

2025 NIJ Forensic Science Research and Development Symposium

February 19, 2025

FDA Public Webinar: FDA Review of Biologics License Applications for Blood and Source Plasma

February 19- 20, 2025

OHRP and Augusta University Research Community Forum 2025

February 27-28, 2025

FDA - NIH Rare Disease Day Workshop

February 27-28, 2025

FDA Generic Drugs Forum (GDF) 2025

January - November 2025

Full Listing of SOCRA Events

Tools to Assist the Research Community with IRB Submissions

Unpacking the IRB review process...

1) The IRB's review process begins when a submission has been received in the RAMS-IRB system.

2) Once a submission is received, the IRB staff will conduct a pre-review screening to assure that all required documents have been uploaded and necessary regulatory considerations have been addressed.

3) When a submission is considered review ready, the study will head down the appropriate review pathway. There are two main review pathways that apply for VCU IRB review:

a) Full-board reviews are generally reserved for studies that pose greater than minimal risk, studies that require formal risk assessment prior to approval (such as specific FDA regulated studies or research activities that fall outside of the scope of 'minimal risk' that is defined by HHS), studies that include prospective enrollment of prisoners/interactions with prisoners as research participants, and reportable events that require formal action by the IRB. Full board studies require review by the convened IRB panel that includes designated IRB reviewers to formally vote and record meeting minutes.

b) Expedited/Exempt reviews include categories that are predefined by the federal regulations and allow the IRB staff or designated IRB reviewers to review and approve research outside of a convened meeting. The IRB refers to the HRP-313 - WORKSHEET - Expedited review and HRP-312 - WORKSHEET - Exemption determination when making expedited/exempt determinations.

4) In addition to the IRB's full board and expedited/exempt review processes, the VCU IRB has processes in place to defer review of research to external IRB's (IRB Reliance) and review of 'Not Human Subjects Research' (NHSR):

a) The IRB Reliance process is in place to allow research teams to establish formal agreements between VCU IRB and non-VCU IRB's for conduct of collaborating research. Refer to the IRB Reliance webpage for all information related to collaborating studies.

b) The 'Not human subjects research' (NHSR) review process is in place to allow the IRB to formally review projects that fall outside of the scope of the IRB and to provide a formal letter to the research team that explains why the research does not require VCU IRB oversight. When making NHSR determinations, the IRB refers to the HRP-310 - WORKSHEET - Human research determination and HRP-311 - WORKSHEET - Engagement determination. The IRB staff only issue formal NHSR determinations through the RAMS-IRB review process. The HRP-503b - TEMPLATE NHSR needs to be uploaded for NHSR IRB reviews.

General Reminders...

- **For a listing of all ancillary reviews that must occur prior to implementation of research at VCU, refer to the HRP-309 - WORKSHEET - Ancillary review matrix.**

- For all research supported under the VCU Health System, research teams will need to first reach out to their applicable PROC for guidance prior to submitting to the IRB.

- Researchers who plan to separate from VCU must close or amend studies prior to separation to assure there are no gaps in study oversight.

- 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...

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) projectis considered a primary human research resource for the specified participating academic schools.

*** *The HRPP Toolkit documents are updated periodically and updated versions can be found under the HRPP Toolkit.*

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

Contact us with your questions

HRPP SPOTLIGHT

January is...

National Blood Donor Month

and

National Month for Prevention of Slavery and Human Trafficking

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
NIH Blood Bank	HHS Donate Blood and Help Save Lives	Red Cross: Virginia
Research on Trafficking in Persons - United Nations	Association for the Advancement of Blood and Biotherapies (AABB)	Human Trafficking Resources and Research - Office for Victims of Crimes
Human Trafficking - National Library of Medicine (2023)	Walter Reed National Military Medical Center National Blood Donor Month	Human Trafficking - National Institutes of Justice (NIJ) Topics

Historical guidance for human research ethics...

The Belmont Report	Nuremberg Code	World Medical Association Declaration of Geneva (1948)

The Declaration of Helsinki was developed ~1964 with consideration of the ethical principles outlined in both the Nuremberg Code and Declaration of Geneva and is centered on medical research. Whereas, the Nuremberg code is written more broadly in terms of its applicability for During the Nuremberg trials it was particularly noted that ethical principles must be strongly applied to non-therapeutic experimentation because risks may outweigh the prospect of benefit to the individual participant or where there may be unknown risk of harm.

PRIM&R Interactive Research Ethics Timeline

Federal decisions and investigations and central resources that speak to human research ethics...

Update on Medication Abortion - Reproductive rights.gov
See all final opinions issued by SCOTUS over the years here.

The FDA has a safety and adverse event reporting program called MedWatch that is in place to track and facilitate consumer and industry

awareness of new safety information and adverse events for FDA regulated products.

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

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The FDA also maintains a webpage designated to public awareness of ongoing criminal investigations and case activity that falls under their jurisdiction.

FDA Database for Criminal Investigations Case Activity

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...

NIH Annual Review of Ethics Case Studies

OHRP provides guidance for research volunteers and a process for submitting complaints about research involving humans...

Office for Human Research Protections - Submitting a Complaint About Research Involving Humans

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VCU Libraries provides access to the Journal of Empirical Research on Human Research Ethics...

Empirical Research on Human Research Ethics

Federal and State Human Research Resources Table

******Full table of federal and state resources now available to the community on the HRPP website under HRPP Policies and Guidance --> Special Guidance --> Regulations, Laws and Federal Guidance.***

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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