Volume 020 Year End 2024

NEWSLETTER

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VCU Winter Break Edition

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VCU Winter Break HRPP Coverage

The VCU Human Research Protection Program (HRPP/IRB) office will be closed for the holidays beginning **December 23, 2024**, and will resume operations on **Thursday, January 2, 2025**.

With the exception of urgent reports for unanticipated problems or other emergencies, the office will not be processing or reviewing submissions during the closing, and the full board of the IRB will not convene between December 19, 2024 and January 7, 2025. Investigators may therefore experience a delay in the review turnaround time for submissions received around the holidays.

PLEASE NOTE: Investigators remain responsible for reporting to the IRB any unanticipated problems involving risk to subjects or others that occur during this time.

For guidance on what constitutes an unanticipated problem, refer to HRP-001 in the General Documents section of the VCU HRPP Toolkit, available on our website at **https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/**.

In addition, as always, investigators are responsible for taking any actions necessary to ensure the ongoing safety of research participants.

- To report an unanticipated problem involving risk to subjects or others: Follow the normal procedure for submitting the Report within **RAMS-IRB**.

- To seek guidance regarding an unanticipated problem or any emergency situation during the holiday closure: Alert our on-call staff via email to **hrpp@vcu.edu** and/or via voicemail to 804-828-0868. Please be sure to monitor your email or phone after your submission – a response may take up to 24 hours.

HRPP Transformation Project

Dear colleagues,

Over the past two years, the Human Research Protection Program and Institutional Review Board have engaged in a transformation project to streamline operations and respond to the needs and requests of the VCU research community. This project also ensures our compliance with all federal regulations, state laws, institutional policies and aligns VCU's human research with national best practices.

To date, the HRPP team has introduced a new investigator guide to navigate the complexities of the research process and updated our plans, policies and procedures. The streamlining of various processes and administrative processes has already produced a significant reduction in turnaround time for protocol reviews and approvals - this includes a 50% reduction in total review cycle time.

The next step in our transformation is underway in preparation for the transition to a new online HRPP/IRB management system. As with our entire transformation project, the input and feedback from the VCU research community is of paramount importance. Through this process, we have identified opportunities to better optimize our systems integrations, starting with priorities identified by the VCU research community. As such, we will

be pausing the implementation of this new system for the next six months for review. For the remainder of the summer and moving into the new academic year, we will continue to involve the VCU research community in this evaluation process.

From an operational standpoint, all current human research protections processes are continuing as normal. Please continue to work with your HRPP administrators as you have been.

These efforts thus far have been complex and we would like to extend our gratitude to the entire VCU research community for your partnership. We would also like to acknowledge all staff for their continued dedication to reducing administrative burden and empowering our faculty researchers and administrators to continue to conduct safe and ethical research that reflects the quality, efficiency and compliance expected from a top tier research university.

As always, our goal is to provide services that help you do what you do best. We are confident that this re-evaluation will continue us in this direction.

Should you have any questions or concerns, please do not hesitate to contact the HRPP team.

Thank you,

The Human Research Protection Program team

(804) 828-0868
hrpp@vcu.edu
https://research.vcu.edu/human-research/hrppirb/

Key Components of the HRPP Transformation:

New Policies and Procedures

The VCU HRPP transformation has been powered by the Huron Consulting Toolkit. 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.

HRP-103 - Investigator manual

The introduction of an HRP-103 - Investigator manual 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.*

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 7- May 27, 2025

NIH Demystifying Medicine Series

January 14, 2025

FDA Webcast: OCE Conversations on Cancer, Cervical Cancer Treatment Innovation: A Collaborative Discussion

January 14, 2025

FDA Webinar: Final Guidance - Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions

January 28-29, 2025

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

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

Completed Human Research Training

PRIM&R Annual Conference 2024

November 17 - 20

PRIM&R celebrated it's 50th anniversary this year! The human subjects research (HSR) track of the annual conference focused on immersive technologies in research, emerging research areas, ethics driven standards, and regulatory oversight for conducting research with human subjects.

Recordings available to PRIM&R conference attendees

*****Notable takeaways for human research include:**

- Federal requirements and ethical considerations surrounding human research in space exploration.
- Insights into types of artificial intelligence (AI) and uses of AI in human research protocols.
- **Individual, values-driven, informed consent practices.**
- General considerations for review of FDA regulated products.
- Evolving research landscape and technologies involving gene therapies with humans.
- Privacy considerations when working with human subjects and their data.
- **Considerations for assessing risk when conducting social and behavioral research.**
- Research with tribal communities and maintaining respectful, collaborative relationships with a tribal sovereighnty.
- Collaborative and networking tools for strengthening the function and efficiency of HRPP's.

****PRIM&R conference attendees will be able to access the recorded sessions for 90 days post- conference.*

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 theHRPP 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 2025!

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

HRPP Transformation Project

IRB Reliance*

*IRB Reliance includes a matrix outlining review pathway/fee applicability.

Contact us with your questions

HRPP Toolkit

Spotlight Guidance

Introducing...

***Check out the fillable HRP protocol docs that were recently posted to the*HRPP Toolkit* and *HRPP Forms webpages!*

HRP-503 TEMPLATE PROTOCOL ***Revised 10/23/2024***

HRP-503a - TEMPLATE SBS PROTOCOL

HRP-508 - TEMPLATE Site supplement to sponsor protocol

HRP-503b - TEMPLATE NHSR ***Not human research determinations only***

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

Reminders...

- Researchers who plan to separate from VCU must close or amend studies prior to separation. Refer to the HRPP blogpost for IRB Requirements for Separating PIs.

- 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.

HRPP SPOTLIGHT

December is...

Universal Human Rights 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
The Universal Declaration of Human Rights Is Turning 75: Here's What You Need To Know	United Nations Education: What are human rights?	Universal Declaration of Human Rights History of the Declaration - United Nations
A Proclamation on Human Rights Day and Human Rights Week, 2024 - The White House	Human Rights Day - Library of Congress Research Guide	National Institutes of Correction (NIC) Celebrates Universal Human Rights Month
Virginia's Department of Education Training and Technical Assistance Center at VCU	December is National Universal Human Rights Month! - Parker Jewish Institute	Ways to Celebrate Universal Human Rights Month - End Slavery Now.org

Universal Human Rights Month includes...

World AIDS Day began in 1988 and is recognized on December 1

HIV and AIDS - World Health Organization (WHO)	World AIDS Day at NIH	VCU Health and Richmond AIDS Consortium Services and Research
HIV and AIDS Clinical Trials - National Institutes of Health (NIH)	VCU Libraries Health and Wellness Guides - HIV/AIDS	VCU Department of Health Policy - HIV and AIDS Research

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

******The HRPP website is currently under review. Each section of the website will be updated to include more robust resources for the research community. The resources found in this table are now available to the community on the final HRPP website under HRPP Policies and Guidance (Special Guidance - Regulations, Laws and Federal Guidance).***

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 Science and Research Special Topics
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)** 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)** VDSS IRB

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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