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.

HRPP Training for the Research Community

SAVE THE DATE

Upcoming training

HRPP/IRB Research Community Training - Conditions of IRB approval and the role of post-approval monitoring

Join us **Thursday, March 28, 2024, from 3:00 – 4:30 p.m. EST** for an online training about the **conditions for IRB approval and the role of the post-approval monitoring process in the conduct of human subjects research.** This training is designed for those within the VCU research community, including research faculty, team members, coordinators, and administrators who oversee human research protocols and those who apply regulations for human research protocols.

Register for this training here

Previous Event

January 31, 2024, HRPP/IRB Research Community Training

Latest Insights on NIH Data Sharing Policies Revealed in HRPP/IRB Research Community Training Update!

We're thrilled to announce that on January 31, 2024, the VCU HRPP joined forces with the esteemed National Institutes of Health's (NIH) Science Policy and Extramural Research divisions to deliver an electrifying online training session for our cherished community. Tailored specifically for research teams backed by NIH support, this training sparked immense enthusiasm and participation from our vibrant research community! What a tremendous turnout it was for this monumental event! The presentation included the 2023 NIH data sharing policy changes, implementation of the updated policy, and considerations for privacy.

There are particular considerations for Responsible Management and Sharing of American Indian/Alaska Native Participant Data that are outlined in the updated guidance. Of mention, the full NIH policy also includes guidance that goes beyond data and samples that meet the definition of human subjects research. Refer to the HRP-309 - WORKSHEET - Ancillary review matrix for all institutional review requirements related to data sharing and applicable agreements. If you have any questions about data sharing, privacy, or other NIH requirements for human subjects research, reach out to the HRPP office!

A direct link to the recording for this training is included below. All recordings for HRPP trainings can be found in the HRPP's Kaltura MediaSpace. The recording and slides are uploaded into the *HRPP's Kaltura MediaSpace* in the *Attachments* section within the media recording.

Recording Link:

HRPP Research Community Training - Updated NIH Data Sharing Policies 1.31.2024.mp4

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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.

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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

***HRPP Toolkit Spotlight Documents ***

Introducing...

HRP-320 - WORKSHEET - Scientific or scholarly review

and

HRP-314 - WORKSHEET - Criteria for approval

The **HRP-320 - WORKSHEET - Scientific or scholarly review** is used to supplement the IRB's review when determining whether a study is scientifically sound and the research is justified. Designated IRB reviewers and consultants for the IRB may use this worksheet 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**

Massey Comprehensive Cancer Center Clinical Trials Office

The Protocol Navigator Consultant (PNC) projectprovides 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 <u>VCU's School of the Arts, School of Education, College of Humanities and Sciences, the Wilder School, and the School of Social Work</u>. **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.*

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 HRPPblog post.

HRPP SPOTLIGHT

Black History Month

Exceptional contributions and historical insight...

38 African American scientists and engineers who made important

contributions to science, technology, engineering, and math (STEM) - sciencebuddies.org

Here's the story behind Black History Month — and why it's celebrated in February - NPR

Black History Month: A Commemorative Observances Legal Research Guide - Library of Congress

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VCU-driven population health education and research...

VCU School of Medicine holds events February 22 and 27 to commemorate Black History Month

VCU Center on Health Disparities identifies and combats health disparities through impact

VCU Department of Health Behavior and Policy - Health Disparities and Health Equity human research

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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...

The History of Research and Clinical Trials and Its Impact on the African-American Community	**Racial Disparities Persist in Human Subjects Research - Harvard.edu**	**Addressing Problematic Issues in Research - Columbia.edu**
"This Isn't Your Data, Friend": Black Twitter as a Case Study on Research Ethics for Public Data - Sage.pub	**Henrietta Lacks and America's dark history of research involving African Americans - NIH National Library of Medicine**	**40 Years of Human Experimentation in America: The Tuskegee Study**
A Systematic Review of Barriers and Facilitators to Minority Research Participation Among African Americans, Latinos, Asian Americans, and Pacific Islanders - NIH National Library of Medicine	**Secret World War II Chemical Experiments Tested Troops By Race - NPR.org**	**More than Tuskegee: Understanding Mistrust about Research Participation - NIH National Library of Medicine**
NIH Guidelines for the Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research	**NIH ALL OF US Diversity and Inclusion**	**NSF Diversity, Equity, and Inclusion in Engineering**

The Belmont Report: Respect for Persons, Beneficence, and Justice **The Belmont Report at 40: Reckoning with Time - NIH National Library of Medicine**	**DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH: Toolkit for IRB's and HRPP's - by the Multi-Regional Clinical Trials office of Brigham and Women's Hospital and Harvard**	**VCU Libraries Research Guides** **VCU Libraries Research Guides: Diversity, Gender, Race and Ethnicity** **VCU Libraries Research Guide: Racism and Health**

Some federal investigations involving human research ethics that are currently on the radar...

Research at the heart of a federal case against the abortion pill has been retracted - NPR.org

Evaluation of Safety Concerns with Certain Dental Devices Used on Adults – FDA Safety Communication

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

February 20, 2024

2024 NIJ Forensic Science R&D Symposium

February 20, 2024

Humanitarian and Human Rights Resource Center Virtual Library 2024

April 10-11, 2024

OHRP Research Community Forum (RCF) with the University of Miami

April 14-17, 2024

[WCG MAGI Clinical Research Conference](#)

May 21-23, 2024

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

August 9, 2024

[NIJ Discovery, Disclosure and Ethical Considerations](#)

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