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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!**

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 Training for the Research Community

HRPP/IRB Research Community Training - Updated NIH Data Sharing Policies

Join us on **Wednesday, January 31, 2024, from 3:00 – 4:00 p.m. EST** for an online training about the **updated National Institutes of Health (NIH) data-sharing policies** and requirements that are relevant to human subjects research. **The VCU HRPP and University Libraries are collaborating with the NIH's Science Policy and Extramural Research divisions to provide this training for our community.** This training is designed for those within the VCU research community, including research faculty, team members, coordinators, and administrators with particular relevance to those conducting NIH-supported research.

Register for this training here:
https://us02web.zoom.us/meeting/register/tZYsfuuqpz4uHtRwVYwiEEK7vUx4weChQK6x

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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 Projec**t, 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

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

***HRPP Toolkit Spotlight Documents ***

HRP - 502 TEMPLATE CONSENT DOCUMENT

The HRP-502 - TEMPLATE CONSENT DOCUMENT has been updated to include applicable language related to authorization for use of protected health information (PHI) for research. Research teams have the option of using the standalone HIPAA authorization form, or incorporating all required elements of HIPAA authorization into a combined consent form.

An updated **Standalone HIPAA authorization template** has been provided to the HRPP office by VCU Health Compliance Services and has been posted to the **VCU HRPP/IRB Forms** web page.

To better facilitate review of studies that will obtain authorization (consent) from patients for use of their PHI in research, the HRPP has developed the HRP-330 - WORKSHEET - HIPAA authorization. The HRP-330 WORKSHEET - HIPAA is used by IRB reviewers to assure there is an appropriate mechanism for obtaining authorization and all required elements of HIPAA authorization have been addressed. The IRB protocol must be clear about the process that will be used to obtain prospective consent/HIPAA authorization.

The HRPP has also developed the **HRP-441 - CHECKLIST - HIPAA waiver of authorization** which is used by the privacy officer to document and approve waiver or alteration of HIPAA authorization. The IRB protocol must include sufficient justification for all conditions that apply to the waiver. IRB reviewers will compare the information in the IRB protocol against the criteria in the checklist for final approval of a protocol. If a waiver of authorization is being requested, the IRB protocol must be clear about the specific intent of the waiver as it relates to the nature of the research being conducted.

Refer to the **University's Audit and Compliance Privacy Press Release** for all resources related to general privacy expectations, along with privacy expectations for Student Educational Records, General Data Protection Regulation (GDPR), Sensitive and Personal Information - Healthcare and Research, and Web Privacy.

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 HRPP blog post.

HRPP SPOTLIGHT: Student Research at VCU

VCU offers many research opportunities for students who plan to conduct

research through their academic program. Students must reach out to their faculty mentors and department level resources to receive support for any projects that will take place.

There are specific requirements that apply to conduct of research with human subjects, and that is where the HRPP/IRB comes in. If you have any questions about whether your project requires IRB review or the IRB's review process, refer to the **HRPP Getting Started** page. As a reminder, at VCU, students are not allowed to serve as a principal investigator (PI) on human subjects protocols and the assigned faculty mentor is responsible for oversight of the human subject protocol and student work that is conducted under a protocol.

All research resources for students can be found **here**.

Be sure to check out some of the new developments in human subjects research that VCU students and faculty have contributed to!

Examples of Undergraduate Research at VCU

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

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Federal and State Human Research Resources

US Department of Health and Human Services (HHS)	National Institutes of Health (NIH)	Food and Drug Administration (FDA)
		FDA Meetings,

Human Research Protection Program Resources	Human Subjects	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