



## \* 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 Training for the Research Community

**\*\*\*SAVE THE DATE\*\*\***

### **Upcoming training -**

#### **HRPP/IRB Research Community Training - Criteria for IRB approval and the role of post-approval monitoring**

Join us on **March 28, 2024, from 3:00 – 4:30 p.m. EST** for an online training about the criteria 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 the March 28 training here](#)

**\*\*\*SAVE THE DATE\*\*\***

**Fall 2024...**

Mark your calendars and save the date for an exciting event you won't want to miss!

The Human Research Protection Program (HRPP) is thrilled to announce the upcoming VCU HRPP Conference: "Ensuring Ethical Excellence in Human Studies Research Compliance"

Hosted by the Human Research Protection Program at Virginia Commonwealth University, this conference promises to be an invaluable opportunity for researchers, ethicists, compliance professionals, and all stakeholders involved in human studies research.

Date: **Thursday, October 24, 2024**

Time: **9:00 am est- 4:00 pm est**

Location: **Virtual Event via Zoom**

**\*Registration link will be released at a later time\***

Join us as we delve into critical topics surrounding ethical excellence in human studies research compliance. From best practices to emerging trends, our lineup of speakers and sessions will provide insight, inspiration, and practical guidance to enhance your work in this vital field.

Stay tuned for further details regarding speakers, agenda, and registration information. We look forward to your participation in this important event as we strive to uphold the highest standards of research ethics and compliance.

Together, let's ensure ethical excellence in human studies research. Save the date and be part of the conversation on October 24, 2024!

Additional details will be released over the coming weeks through the HRPP blog and newsletter.

## **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](#)

*\*Includes matrix outlining review pathway/fee applicability\**

## **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 Toolkit Spotlight Documents \*\*\***

**Introducing...**

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## **\*New Template Document\***

### **Introducing the HRP-503b Template for Not Human Subject Research (NHSR) Determination Requests!**

Whether you're conducting literature reviews, quality improvement activities, or educational research, the [HRP-503b Template for NHSR Determination Requests](#) is here to support you every step of the way.

Developed by the Human Research Protection Program (HRPP) at Virginia Commonwealth University, this template is set to revolutionize the way we handle research inquiries that fall outside the purview of human subject research.

What makes this template so special? It provides researchers with a clear and comprehensive framework for submitting NHSR determination requests, ensuring that all necessary information is included and facilitating efficient review and processing by our dedicated HRP team. By utilizing this standardized template, researchers can expedite the determination process and focus more time and energy on advancing their groundbreaking work.

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### **\*Vulnerable populations\***

The HRPP Toolkit contains checklists, worksheets and SOP's that address federal categories for federally recognized vulnerable populations, along with considerations for situational vulnerability. The FDA (21 CFR 56.111) recognizes "children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects." There are three categories of specific vulnerability that are specified under the Common Rule (DHHS; 45 CFR 46.111), including pregnant women (subpart b), prisoners (subpart c), children (4subpart d).

The following checklists are used to supplement the IRB's review when determining whether criteria for inclusion of federally regulated vulnerable populations:

[HRP-412 - CHECKLIST - Pregnant Women](#)

[HRP-413 - CHECKLIST - Non-viable neonates](#)

***Situational vulnerability*** is also a factor considered when performing human subjects research. When performing research with students/employees, military personnel, persons with low socioeconomic status, decisionally impaired adults, unhoused individuals, persons who experience intimate partner violence, and historically marginalized populations, particular care should be given to minimize burden to participants, and minimize potential for undue influence or coercion.

The following worksheets and checklists are used to supplement the IRBs review when including persons with certain situational vulnerability.

HRP-013 - SOP - Legally authorized representative (LAR), children, and guardians

HRP-417 - CHECKLIST - Cognitively impaired adults

HRP-317 - WORKSHEET - Short form of consent documentation

Refer to the [HRP-103 - Investigator manual](#) for detailed guidance about inclusion of vulnerable populations, consent requirements, and processes for use of legally authorized representatives (LAR). Studies approved by Single IRB review should refer to the [HRP-103p - Investigator manual - Single IRB review of multi-site research \(pSite\)](#)

Designated IRB reviewers and consultants for the IRB use these worksheets 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

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.

*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.*

**\*\*\*HRPP SPOTLIGHT\*\*\***

*Women's History*

*and*

*National Ethics Awareness*

*Month*

*Historical insight...*

[The Doctors Trial: The Medical Case of the Subsequent Nuremberg Proceedings - United States Holocaust Memorial Museum](#)

[The Belmont Report: Respect for Persons, Beneficence, and Justice](#)

[Nuremberg Code: Directives for Human Experimentation - HHS Office of Research Integrity](#)

[Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects](#)

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*VCU-driven population health education and research...*

VCU Institute for Women's Health

VCU Department of Gender, Sexuality and Women's Studies

18th Annual VCU Women's Health Research Day

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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...*

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.

<i>Respect for Persons</i>	<i>Beneficence</i>	<i>Justice</i>
<b>Why Human Subjects Research Protection Is Important - NIH National Library of Medicine</b>	<b>The Belmont Report at 40: Reckoning with Time - NIH National Library of Medicine</b>	<b>Burdens on Research Imposed by Institutional Review Boards: The State of the Evidence and Its Implications for Regulatory Reform - NIH National Library of Medicine</b>
<b>Equitably Sharing the Benefits and Burdens of Research: Covid-19 Raises the Stakes - The Hastings Center</b>	<b>The Protection of Non-Subjects from Research Harm - SACHRP</b>	<b>The Ethical Implications of Clinical Trials in Low- and Middle-Income Countries - American Bar Association</b>
<b>NIH Inclusion of Women and Minorities as Participants in Research Involving Human Subjects</b>	<b>Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research</b>	<b>How does Environmental Protection Agency (EPA) Protect Human Subjects?</b>
		<b>VCU Libraries Research</b>



Ethical Considerations  
for Including Women as  
Research Participants

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

Guides  
VCU Libraries Research  
Guides: Gender,  
Sexuality and Women's  
Studies  
VCU Libraries Research  
Guide: Women's Health

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

[Reproductive rights in America - NPR.org](#)

[American Academy of Dental Sleep Medicine Special Update: AGGA  
Investigation](#)

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

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

September 16-18, 2024

[NIJ Annual Conference: Advancing justice through science](#)

## Federal and State Human Research Resources

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

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