



# VCU HRPP Newsletter

## HRPP Toolkit Training for the Community

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. These trainings are virtual (registration is required) and offered live to facilitate Q&A and cover topics pertinent to the research community. Please see the complete schedule of training sessions below. Additional information about HRPP Toolkit Training for the Community is available on the HRPP blog at <https://blogs.vcu.edu/humanresearch/>, in the HRPP Transformation Project tab.

<b>Date</b>	<b>Time</b>	<b>Topic</b>	<b>Registration Link</b>
N/A	12:00pm-1:00pm	<b>Foundational Toolkit Documents &amp; Protocol Templates</b>	<a href="https://us02web.zoom.us/meeting/register/tZYsd-ugrjwrHt0510PDX501SZuhlsT7kmjK">https://us02web.zoom.us/meeting/register/tZYsd-ugrjwrHt0510PDX501SZuhlsT7kmjK</a>
N/A	12:00pm-1:00pm	<b>Minimal Risk Research Considerations</b>	<a href="https://us02web.zoom.us/meeting/register/tZ0rduCpqTopG9U29eji6x7KJuvh9GnUNDPn">https://us02web.zoom.us/meeting/register/tZ0rduCpqTopG9U29eji6x7KJuvh9GnUNDPn</a>
N/A	12:00pm-1:00pm	<b>Clinical Drug and Device Trial Considerations</b>	<a href="https://us02web.zoom.us/meeting/register/tZUrd-6rpjojEtw03wiwHcBdMpUSbF86lBYT">https://us02web.zoom.us/meeting/register/tZUrd-6rpjojEtw03wiwHcBdMpUSbF86lBYT</a>
N/A	12:00pm-1:00pm	<b>Informed Consent</b>	<a href="https://us02web.zoom.us/meeting/register/tZAkdOGgrTktGdXxK7QBrLzTMXMAdeV04-">https://us02web.zoom.us/meeting/register/tZAkdOGgrTktGdXxK7QBrLzTMXMAdeV04-</a>
Friday, June 16, 2023	12:00pm-1:00pm	<b>Vulnerable Populations</b>	<a href="https://us02web.zoom.us/meeting/register/tZwrfuqupj0tHdwGAe8PFsdi4ZdfTI-znQMU">https://us02web.zoom.us/meeting/register/tZwrfuqupj0tHdwGAe8PFsdi4ZdfTI-znQMU</a>
Friday, June 30, 2023	12:00pm-1:00pm	<b>Single IRB and Multi-Site Research</b>	<a href="https://us02web.zoom.us/meeting/register/tZwkc-iuqjkoGtMEM1l6YAUyCAgaFePDza4L">https://us02web.zoom.us/meeting/register/tZwkc-iuqjkoGtMEM1l6YAUyCAgaFePDza4L</a>
Friday, July 7, 2023	12:00pm-1:00pm	<b>Reportable New Information</b>	<a href="https://us02web.zoom.us/meeting/register/tZApcuGpqjwiG9R6HeX1Pw0DppwwOkGLEku_">https://us02web.zoom.us/meeting/register/tZApcuGpqjwiG9R6HeX1Pw0DppwwOkGLEku_</a>
Friday, July 21, 2023	12:00pm-1:00pm	<b>Open Forum/Emerging Topics</b>	<a href="https://us02web.zoom.us/meeting/register/tZUvdeysqTkpHNfbF0laxELCSI9vQK-x7mxV">https://us02web.zoom.us/meeting/register/tZUvdeysqTkpHNfbF0laxELCSI9vQK-x7mxV</a>

**Recordings of past sessions are available at:**

<https://blogs.vcu.edu/humanresearch/?cat=186>

**Registration links for upcoming sessions are available at:**

<https://blogs.vcu.edu/humanresearch/?p=2646>

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

# Protocol Templates

As of June 1, 2023, respective protocol templates are required for all human subject research submissions. New IRB submissions that do not contain a formal protocol as of June 1, 2023 will be returned to the researcher to include a protocol. Protocols are available for biomedical studies and clinical trials, submissions not involving an investigational agent and for submissions that have a sponsor protocol.

Contact Tom Bechert of the Huron Team at [bechertt@vcu.edu](mailto:bechertt@vcu.edu) or the HRPP Office at [orsp@vcu.edu](mailto:orsp@vcu.edu) for any questions or assistance with the new protocol templates.

**Protocol templates are available at:**

<https://research.vcu.edu/forms/>

**For more information visit:**

<https://blogs.vcu.edu/humanresearch/?p=2781>

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## Reminder to Researchers Separating From VCU

Principal Investigators (PIs) leaving VCU who no longer meet the PI eligibility requirements may not continue to serve as Principal Investigators on research conducted under VCU IRB approval. Guidance for separating PIs and instructions for amending or closing an IRB study can be found at:

<https://blogs.vcu.edu/humanresearch/?p=2798>.

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## Education Opportunities

### Office for Human Research Protections (OHRP) Common Rule Basics Webinar Series

*Registration is required to attend and receive a certificate of attendance.*

#### Unlocking the Mysteries of the §46.111 Criteria for IRB Approval of Research

**Date:** July 11, 2023, 12:00 PM EDT

**Description:** This presentation will explain the criteria for IRB approval of research and include case studies and interactive quizzes to demonstrate the way the criteria can be applied.

**Registration:**

[https://www.zoomgov.com/webinar/register/WN\\_9RbRyAwjQY2N\\_kRxFPbT-w](https://www.zoomgov.com/webinar/register/WN_9RbRyAwjQY2N_kRxFPbT-w)

#### The Who, What, Why, and Where of IRB Meetings and Membership

**Date:** July 18, 2023, 12:00 PM EDT

**Description:** This presentation will provide an overview of the requirements for IRB meetings and membership, including quorum, minutes, records, and more.

**Registration:**

[https://www.zoomgov.com/webinar/register/WN\\_PXvtUeq2QU2fq5qBV8eq\\_Q](https://www.zoomgov.com/webinar/register/WN_PXvtUeq2QU2fq5qBV8eq_Q)

## **How Do I Review Thee? Let Me Count the Ways: The Types and Manners of IRB Review**

**Date:** July 25, 2023, 12:00 PM EDT

**Description:** In this presentation, attendees will learn about the different types and manners of IRB review, including full board, limited review, expedited review, and for various lifecycle actions like, initial review, review of amendments, and continuing review applications.

**Registration:**

[https://www.zoomgov.com/webinar/register/WN\\_izsACPN5REOZXeOGOTRnYA](https://www.zoomgov.com/webinar/register/WN_izsACPN5REOZXeOGOTRnYA)

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## **Making a Difference in Human Subjects Research: Empowering Participants, Engaging Communities, and Protecting Data**

**Location:** Ann Arbor, Michigan

**Date:** September 26th-27th

**Description:** OHRP is partnering with the University of Michigan for our next Research Community Forum (RCF) which will include case discussions, reviewing research under the Common Rule, and writing participant-centered informed consent documents. Other sessions will cover topics such as health inequities in research and how emerging AI technologies could impact future research with human participants.

**Registration:** <https://research-compliance.umich.edu/human-subjects/ohrp-research-community-forum>

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## **OHRP's 6<sup>th</sup> Annual Exploratory Workshop, Old Trips, New Destinations: Exploring the Ethical and Practical Considerations of Psychedelics Research**

**Description:** Experts will deliberate on the ethical, practical, and legal questions pertaining to psychedelics research, including unique risk considerations, issues pertaining to informed consent, study design and integrity, inclusion of vulnerable groups, as well as the importance of preserving public trust. This is a timely and important discussion that responds to tremendous interest in this topic from diverse stakeholders, including patients, researchers, funders, regulators, and policymakers at both the state and federal levels.

**Live-streamed September 14, 2023 from 9:45 a.m. to 4:15 p.m. EDT**

Visit <https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/2023-workshop/index.html> for more information.

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# Congratulations and Farewells

Farewell to Dr. Steve Kates, who has stepped down as IRB Chair. Thank you for your invaluable contributions to the HRPP/IRB. A flag was flown in his honor over the National Capital in Washington, DC, in May 2023 to recognize his tenure as IRB Chair for the Clinical Trial Subcommittee.

Congratulations to Dr. Moeller, appointed Deputy Institutional Official (DIO). As the DIO, he will provide the support necessary to comply with all requirements for research involving human subjects. Please welcome Dr. Moeller to his new role within the HRPP.



Congratulations to our Director, Dr. Sanjur "Sandy" Brooks! Dr. Brooks has been featured in Richmond Style Weekly's "Top 40 Under 40" for her accomplishments in the field of ethics and her work with the VCU Human Research Protection Program (HRPP).

Read the full article at:

<https://www.styleweekly.com/richmond/sanjur-sandy-brooks-39/Content?oid=20086489>

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**If you would like your research featured in one of our upcoming newsletters, please submit a request here <https://forms.gle/eQaqH5hcTCW496947>**

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