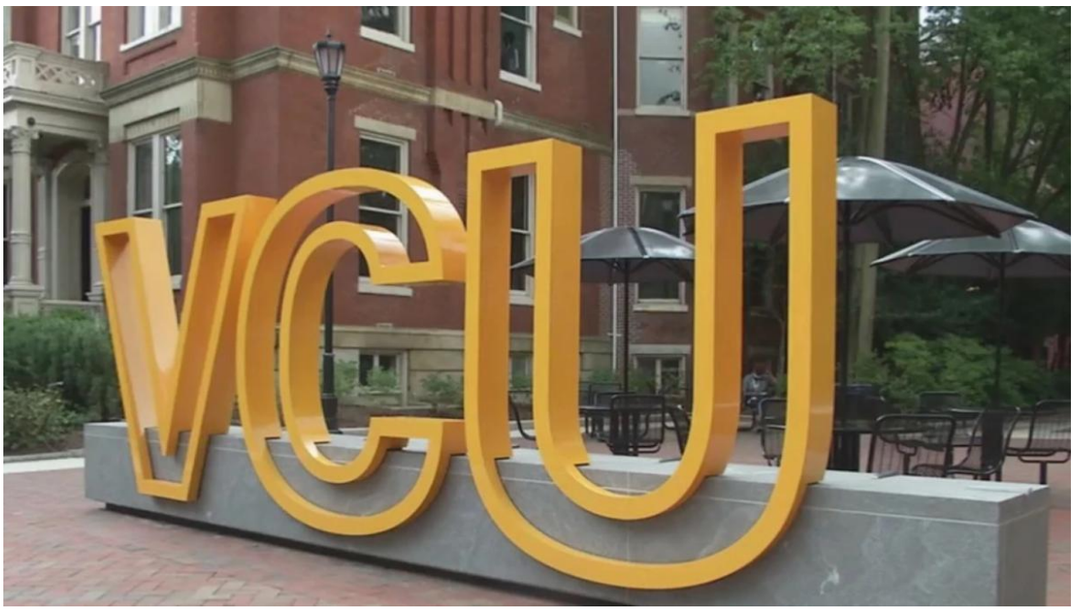
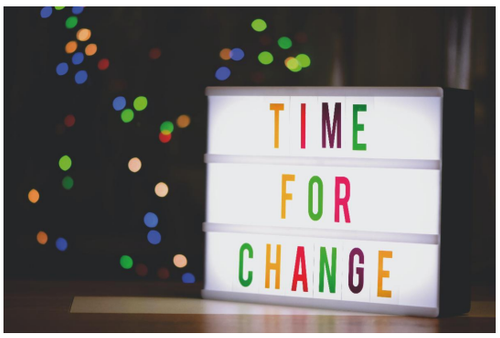
Volume 006 | April 2023



VCU HRPP Newsletter

The HRPP Transformation Project



The VCU Human Research Protection Program (HRPP) is pleased to announce the initiation of the **HRPP Transformation Project** to improve human research compliance with federal, state and institutional requirements, enhance review process efficiency, and minimize administrative burden for the VCU human research community. VCU is partnering with HRPP consultants from Huron to facilitate transformation efforts.

Read more *from Dr. Rao and learn more about what we're planning from this kick-off video.*

Research Community Feedback Survey

Please take a moment to share your opinion by completing theResearch Community Feedback Survey (less than a few minutes to complete).

Please submit your responses by Friday, May 19, 2023.

Complete the survey

Training for the Community

Join us live or watch the recording for upcoming training for the community.

The first session will be Friday, April 21, 2023 from 12pm-1pm via Zoom.

- Session schedule and registration links are available **here**
- Topics include review of new research submission tools and templates, review process updates, guidance for inclusion of vulnerable populations in research and more
- Sessions will be virtual (Zoom), recorded, and offered live to facilitate Q&A
- Recordings will be made available on the VCU HRPP Blog in the **HRPP Transformation Project section**

Register for training sessions

New Tools to Assist with IRB Submissions

As part of the HRPP Transformation Project, the VCU HRPP Office is rolling-out protocol templates that are designed to:

- Minimize administrative burden by reducing the number of smartform fields investigators need to complete in RAMS-IRB.
- Obtain all relevant information the IRB needs to complete their review.
- Providing prompts and instruction that will enable investigators to develop IRB protocols that are compliant with all federal regulations, state laws, and local policies governing human research.

We will announce when the protocol templates are posted so investigators can begin reviewing and preparing submissions using the templates. We also plan to conduct training on how to use the templates in tandem with RAMS-IRB to make the IRB submission process more efficient.

Note: protocol templates are not required for use at this time but will be required as part of the IRB submission process starting in mid-May.

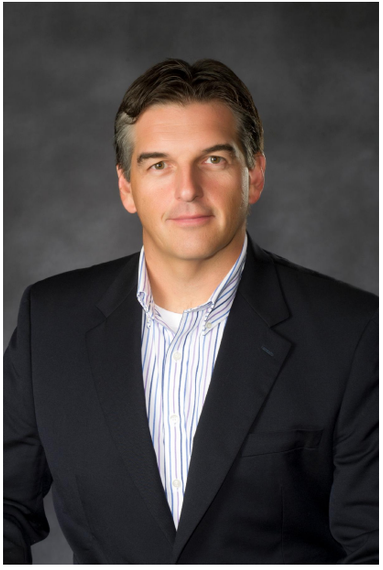
Advarra Partnership

Due to the growth of VCU's Human Research Protection Program (HRPP), we have formed a partnership with the Advarra IRB to continue to support our mission of protecting human subjects. To streamline the IRB review process and increase capacity of the HRPP, Advarra IRB will assist review of externally funded studies.

For more information and details regarding this new partnership with the Advarra IRB, please refer to the **April 6, 2023, HRPP blog post** with the explanatory matrix.

We appreciate your continued patience as we remediate, restructure, and reorganize the HRPP.

From the IRB Chair



Why is this an ideal time for transformation?

I have been a member of the VCU IRB since 2005. In that time, I have participated in and contributed to numerous initiatives that have sought to improve the quality and efficiency of the Human Research Protection Program (HRPP). Whether it was the transition from paper to electronic submissions, or the restructuring from four IRB panels that met monthly to one IRB panel that met weekly, or the decision to have all exempt and expedited studies reviewed “in-house” by IRB staff, the HRPP has continually sought ways to grow and improve to better support the research community while ensuring that the rights and welfare of individuals participating in research at VCU are protected. I think this is an ideal time for the HRPP to engage in a critical review of current processes and a subsequent strategic transformation to better meet the needs of a research community that continues to increase both the volume and complexity of human research activities at VCU.

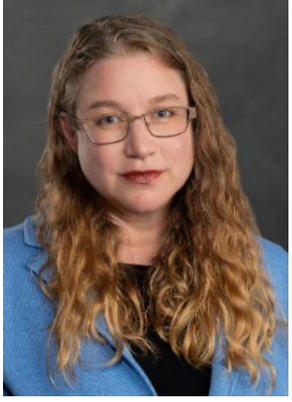
How will these changes benefit research and the research community at VCU?

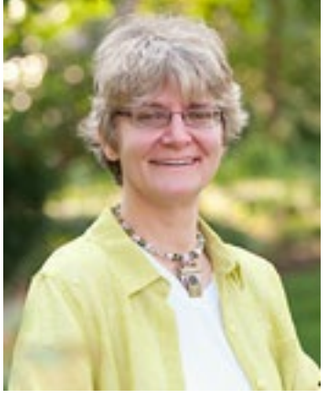
My initial impression is that this transformation process will benefit everyone within the VCU research community. From investigators and study teams to HRPP staff and IRB panel members, the new partnerships with Advarra and Huron Consulting will have an immediate impact on the capacity and efficiency of IRB reviews as well as long-term improvements in research infrastructure. The new protocol-based submission templates and new e-submission system will bring greater clarity to the information needed for IRB review, reduce investigator and administrative burden, and enhance transparency during the review process. HRPP staff and IRB panel members have already begun training on the new “Toolkit” that will provide a streamlined system to facilitate greater efficiency, consistency, and compliance during the review process.

What are your key takeaways from the HRPP transformation project?

It is critical for VCU to continue to improve research infrastructure and processes to support the research community. Just as previous quality improvement initiatives over the years have sought to better meet the identified needs of the research community at the time, this transformation process is being undertaken to address several immediate needs while developing an integrative and sustainable infrastructure that will benefit the research community and research participants at VCU for many years to come.

VCU Research Feature





Lisa H. Merck MD, MPH, MA, FACEP
VCU Department of Emergency Medicine

Marjolein de Wit, MD, MS
VCU Division of Pulmonary and Critical Care Medicine

Renin-Angiotensin System Modulation With Synthetic Angiotensin (1-7) and Angiotensin II Type 1 Receptor–Biased Ligand in Adults With COVID-19 Two Randomized Clinical Trials

JAMA. 2023;329(14):1170-1182. doi:10.1001/jama.2023.3546

This recent **JAMA publication** features the research of Dr. Lisa Merck and Dr. Marjolein de Wit, both serving in trial leadership for the published studies. The protocols represent two randomized clinical trials of adults hospitalized with acute COVID-19 and new-onset hypoxemia and were conducted at 35 sites in the US. The trials evaluated the efficacy and safety of RAS modulation using 2 investigational RAS agents, TXA-127 (synthetic angiotensin [1-7]) and TRV-027 (an angiotensin II type 1receptor–biased ligand), that are hypothesized to potentiate the action of angiotensin (1-7) and mitigate the action of the angiotensin II. Primary outcomes included oxygen-free days and mortality. This was an important study for many reasons - as VCU Health deployed and analyzed novel therapeutics during the peak of the pandemic, in the ICUs and on the hospital floors.

If you would like your research featured in one of our upcoming newsletters, please submit a request.

Submit a newsletter request

HRPP Student Worker Spotlight

Madelena Eifert, BS

Nice to meet you! My name is Madelena Eifert and I am a current first-year graduate student working towards a MPH. In my role as a student worker with the Human Research Protection Program (HRPP), I work directly with the Reliance Division, update guidance documents, take minutes for current IRB Panel meetings, and coordinate with faculty and staff to fulfill other positions as needed.

Contributing to projects and completing tasks for the IRB has provided me with invaluable insight into the regulations, policies, and discussions necessary to approve research studies. Often, my role as a HRPP student worker intersects with policy-based and ethical questions raised in my classes as a public health student, providing me a unique perspective in discussions.

Without a doubt, my experience with the HRPP has shaped how I approach research, increased my awareness of the various intricacies of the research process, and impacted my analysis of research in my field.

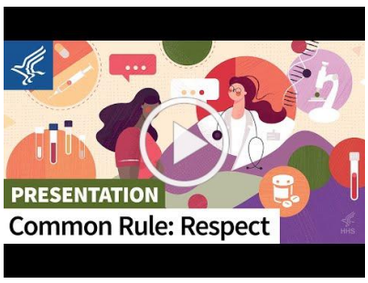
Research Resources

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

OHRP's recent webinar series on the Common Rule was a great success and attended by over 3,600 individuals! Click below to access the slides and recordings for the following presentations:

- Doing Research with Data and Biospecimens under the Common Rule Part 1 – What Researchers Should Know
- Doing Research with Data and Biospecimens under the Common Rule Part 2 – How Does that Work with Repositories and Future Use?
- Before Saying "I Do" to the Common Rule: Figuring out "Engagement"
- Respecting Persons – From Basic Requirements to Embracing Participant-Centered Informed Consent

Access OHRP Webinars on 45 CFR 46



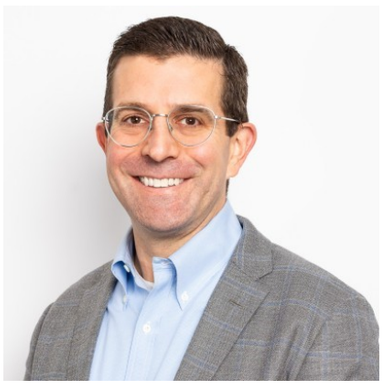
Respecting Persons – From Basic Requirements to Embracing Participant-Centered Informed Consent

This presentation reviewed ethical principles, discussed regulatory requirements for informed consent, and offered strategies to develop high-quality, participant-centered informed consent documents and discussions.

Hails and Farewells

The VCU HRPP Welcomes the Newest Additions to the Team

Huron Consultants



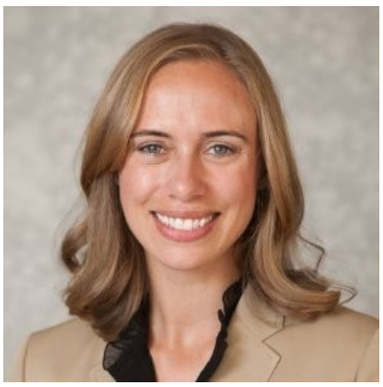
Tom Bechert

Tom has nineteen years of experience working with universities, hospital systems, academic medical centers, and cancer centers to maximize research program performance, improve the overall efficiency and effectiveness of research administration, and strengthen research compliance programs. Tom has an extensive background in IRB administration and human research protections, as well as clinical research operations and regulatory compliance. Tom's project experience has focused on Institutional Review Board administration, AAHRPP accreditation, clinical research infrastructure planning and development, and regulatory compliance evaluations.

Candi Loeb

Candi has over a decade of experience interpreting and applying federal regulations governing human subjects research. Candi also has experience assisting research institutions with compliance and operational improvements. Candi focuses on transforming Human Research Protection Programs (HRPP) with a focus on operational efficiency and

alignment with the Association for the Accreditation of Human Research Protections Program (AAHRPP) accreditation standards. Candi's project experience includes serving in interim HRPP leadership roles at major cancer centers, research institutions, and academic medical centers, assisting institutions achieve AAHRPP accreditation and re-accreditation, conducting research compliance assessments, and leading HRPP transformation efforts. Candi also leverages her expertise in federal human research regulations to guide the development of the Huron IRB solution and HRPP Toolkit.



Christina Moord

Christina has over 20 years of experience in higher education, health care and nonprofit sectors. Her work spans training and assessment in human and animal research regulations, responsible conduct of research, and research compliance. She has conducted fund development and grantsmanship efforts for academic and nonprofit institutions. Christina assists organizations in developing robust research programs through strategic planning, resource management, and organizational transformation. Since 2019, Christina's work with our clients has focused on human research program assessments, transformational change initiatives, toolkit implementation, GCP audit and compliance investigation, application of Huron toolkit methodology for designated reviews conducted as an IRB member, and use of Huron Research Suite software.

Brandy Stoffel

Brandy is a member of the IRB Services team. She concentrates on collaborative research and positive change management while developing compliance requirements. With extensive experience in single IRB regulations and operations, she specializes in assisting organizations implement and maintain IRB reliance processes. Additionally, Brandy has been instrumental in an engagement related to implementation of the Huron HRPP Toolkit.

The VCU HRPP Says Farewell to Those who Are Leaving VCU

Panel A exempt/expedited team

Courtney Roberts, M.A., CIP
IRB Analyst

Reliance team

Chantrice Rogers
IRB Reliance Coordinator

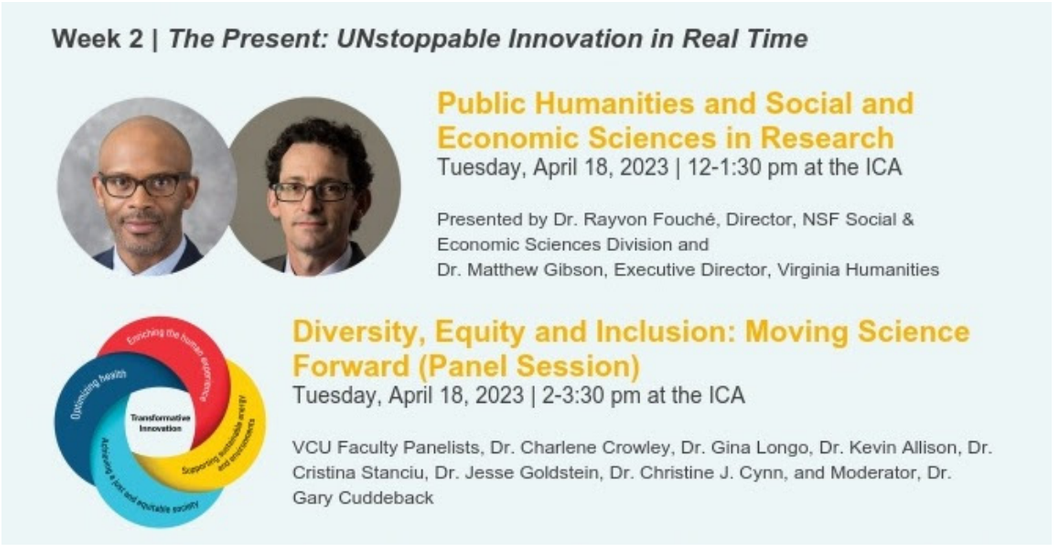
Save the Date

Upcoming Events

VCU Research Weeks 2023: UNstoppable Innovation

Research Weeks includes events highlighting student, trainee, and faculty research from units across VCU; panel sessions and symposia focused on VCU researchers' work in the four initiatives of the One VCU Research Strategic Priorities Plan; and a host of

distinguished guest lecturers. For more information, visit the VCU Research Weeks website or email researchweeks@vcu.edu.



VCU HRPP Annual Conference 2023

Mark your calendar for **Friday, September 29, 2023** and plan to join us for the VCU HRPP Annual Conference 2023. Stay tuned to the **HRPP Blog** for updates regarding this year's topic, featured speakers, and registration instructions.