

VCU HRPP Newsletter

Research Ethics: Past, Present and Future VCU HRPP's Inaugural Annual Conference



The VCU HRPP held its inaugural annual conference on September 29, 2022. The conference had over 150 registrants, including VCU faculty, staff and students, as well as members of the research community from other academic institutions in the area.

The keynote address was presented by Michael Dickinson, Ph.D., Assistant Professor in the VCU Department of History and author of the book "Almost Dead: Slavery and Social Rebirth in the Black Urban Atlantic, 1680-1807," published in May 2022 by The University of Georgia Press.

Other conference sessions included a panel led by Dr. Kevin Allison, Professor of Clinical Psychology in VCU's Department of Psychology, a presentation by Dr. Lisa Merck, Professor and Vice Chair of Research at the VCU Department of Emergency Medicine, and a panel discussion featuring the research of Dr. Robin Everhart, Associate Professor in Health Psychology in the VCU Department of Psychology.

View Dr. Dickinson's keynote address below and learn more about the other speakers and conference sessions.

Feedback from Conference Attendees

"...my take-away was [that] research ethics matter for scientific integrity, human rights and dignity, and collaboration between science and society. These principles make sure that participation in studies is voluntary, informed, and safe for research subjects."

"Great conversations, I liked the mix of presentations between history focused, research focused, and IRB focused."

"The selection of topics and presenters were wonderful and allowed for rich discussion."

Keynote Address: Dr. Michael Dickinson



Dr. Dickinson's keynote discussed his new book, "Almost Dead: Slavery and Social Rebirth in the Black Urban Atlantic, 1680-1807," and he read a powerful excerpt from it. He also discussed the interviews he conducted with descendents of Jeffrey Brace, the former West African slave and America Revolutionary War veteran who is the subject of his book.

The keynote address provided relevant historical context. This examination of the past provides an opportunity to reflect upon the importance of trust with research subjects and how those relationships can help facilitate the progression of science while building relationships with a marginalized community.

Dr. Dickinson's deeply moving and riveting book may be purchasedhere.

Perspectives on Research and Ethics with LGBTQIA+ Individuals and Communities

Kevin Allison, Ph.D., facilitated a panel discussion, "Perspectives on Research and Ethics with LGBTQIA+ Individuals and Communities."

Panelists included Eli Coston, Ph.D., Assistant Professor in the VCU Department of Gender, Sexuality and Women's Studies; Julian K. Glover, Ph.D., Assistant Professor in the VCU Department of Gender, Sexuality and Women's Studies; and Alex Wagaman, Ph.D., Associate Professor in the VCU School of Social Work.

A rich discussion ensued, as panelist shared their experiences with research studies that have informed their perspectives on conducting ethical research with LGBTQIA+ communities and participants. Panelists also discussed what they see as some of the most important issues and considerations in engaging LGBTQIA+ communities and participants in research from the lens of ethics.



Kevin Allison, Ph.D., Professor of Clinical Psychology in the VCU Department of Psychology



Panelist Eli Coston, Ph.D., Assistant Professor in the VCU Department of Gender, Sexuality and Women's Studies



Panelist Julian K. Glover, Ph.D., Assistant Professor in the VCU Department of Gender, Sexuality and Women's Studies



Panelist Alex Wagaman, Ph.D., Associate Professor in the VCU School of Social Work



Exception from Informed Consent (EFIC)

Lisa Merck, MD, Professor and Vice Chair of Research at the VCU Department of Emergency Medicine, spoke about Exception from Informed Consent (EFIC) research.

EFIC investigations are conducted with human subjects with a life-threatening medical condition that necessitates urgent intervention for which available treatments are unproven or unsatisfactory, and who cannot provide informed consent due to their condition (e.g., traumatic brain injury).

Dr. Merck's research focuses on neurological emergencies, critical care, resuscitation, cardiac arrest, and COVID pandemic response.

Assessing Risk in Social, Behavioral, and Education (SBE) Research

HRPP Director Sanjur Brooks, DPS, MS, facilitated a panel discussion of Dr. Robin Everhart's "RVA Breathes" protocol.

The panel presentation focused on the review of this protocol from three distinct perspectives: the Principal Investigator represented by Robin Everhart, Ph.D., the VCU IRB Chair represented by Ronald Evans, Ph.D., and the former VCU reviewer and IRB Analyst represented by Nyssa Towsley, MS, CIP.

The rich discussion provided a rare 360-degree perspective of assessing risk throughout the IRB submission and review process.



Sanjur Brooks, DPS, MS, VCU HRPP Director



Panelist Robin Everhart, Ph.D., Principal Investigator



Panelist Ronald Evans, Ph.D., FACSM, IRB Chair



Panelist Nyssa Towsley, MS, CIP, former VCU reviewer and IRB Analyst



Brittany Keegan, Ph.D., Director of Research and Outreach in the Wilder School's Center for Public Policy

Protocol Navigator Consultant (PNC) Pilot Program Overview

Brittany Keegan, Ph.D., Director of Research and Outreach in the Wilder School's Center for Public Policy, spoke about an exciting new pilot initiative that launched this fall.

The Protocol Navigator Consultant (PNC) project is a collaboration between the VCU HRPP and VCU's School of the Arts, School of Education, College of Humanities and Sciences, the Wilder School, and the School of Social Work.

Dr. Keegan serves as a Protocol Navigator Consultant for the Wilder School, in addition to faculty members from each of the collaborating schools. Protocol Navigator Consultants are available to assist researchers in navigating the research enterprise at VCU, including the IRB submission process.

Request a Consult with a PNC

VCU HRPP's Second Annual IRB Member Conference

In addition to the inaugural annual conference open to the research



VCU Office of the Vice President
for Research and Innovation

community, the VCU HRPP held its second annual IRB Member Conference on September 30, 2022.

This member-specific event included didactic sessions and small group discussion about topics relevant to IRB members.

Richard Findling, MD, Chair of VCU's Department of Psychiatry, presented the evolution of informed consent; Lauren Wallace, MS, VCU's FDA Program Manager, provided an overview of

Expanded Access and Emergency Use, as well as an overview of VEEVA's Site Vault and eTMF products. Jodi Kuhn, MPH, who serves as an unaffiliated scientist member on the IRB panel, offered unique considerations for evaluating risk; and Gerry Moeller, MD, Director of the CCTR reviewed the role of biomedical informatics in clinical research; and HRPP Director Sanjur Brooks, DPS, MS, provided HRPP updates.

VCUarts Qatar Week Celebration 2022

On September 20, 2022, P. Srirama Rao, Ph.D., Vice President for Research and Innovation, spoke at the Research Labs Exhibition reception at the Anderson Gallery.

As part of an exhibition exchange between the VCUarts Richmond and VCUarts Doha, Qatar campuses, the Research Labs exhibition featured groundbreaking projects from eleven teams of faculty, students, and alumni.

The exhibition explored cultural production, nanotechnology and textiles, sound design, art and law in the Gulf, product design, pedagogy, and emergent technology in creative practice. Visit the VCUarts website for more details about the event <u>here</u>.



Dr. P. Srirama Rao, Vice President for Research and Innovation, speaks at a VCUarts Qatar Week Celebration event at the Anderson Gallery. Lisa Ballance, M.A., CPW, CCP, Associate Vice President for Strategy and Regulatory Affairs in the Office of the Vice President for Research and Innovation, and Dr. Aaron Anderson, Associate Chair and Head of Undergraduate Studies for the VCU Theater Department.

Dr. Sanjur Brooks, HRPP Director, and Dr. Anderson. Dr. Anderson also serves as a Protocol Navigator Consultant.

Researcher Resources

Tools, Guidance and Training

Guidance Regarding Emergency Use and Expanded Access Protocols During a Public Health Emergency

During public health emergencies, it is common for new drugs, biologics, and therapies to be used under Emergency Use and Expanded Access protocols. As the number of cases of monkeypox continues to rise, the VCU HRPP would like to direct investigators to the available guidance on Emergency Use and Expanded Access protocols.



Read the Blog Post Here

Required for YOUR Research

Protocol Review and Oversight Committees (PROCs) You may be required to submit your research protocol to a Protocol Rovie and Oversight Committee (PROC). Currently, all research utilizing VCUID patients, facilities, and/or data is required to undergo PROC mires. The proposed PROC is accordaduated for and an approach reader largest to conduct and the submit was a subcurrent and what to do if there isn't a PROC for your research uses at the VOU OUTFIGN version.

<u>https://oretrac.rcu.edu/</u> if there is not a PROC for your area of research, email Mary Harmon at <u>mary.harmonByculealth.org</u> for guidance on next steps. A copy of this correspondence with Mary may be required to be submitted to the VI IRB to document the lack of PROC review.

Letters of Support

If your research involves K-12 settings, the school with which you are working may have certain you must follow in order to conduct research in the school. You may also require a letter of sup prior to initiating your research.

Cheering in your are suining exployments resources or personner norms that as incoments subside your own you so seek a letter of support from that unit to ensure you will be able to use the equipment, resources, or personnel needed.

'you are working with a community organization, again, a letter of support may be necessary in order to ensure ommunity organization is able and willing to support the research.

Where to Get Help With...

Biostatistics

The Wright Center offers biostatistics support to researc Learn more at this website: https://crt.vcu.edu/support/biostatictics/

Quick Start Guide for Human Subjects Research

The Human Research Quick Start Guide is a new REDCap-based tool to help investigators identify ancillary reviews and processes that go in tandem with IRB review.

It's as easy as clicking a few checkboxes!

Based on your selections, you'll receive a customized list of links, suggestions and contacts to get your research project off the ground and ready for IRB review. The list can also be saved as a PDF for later use.

Use the Quick Start Guide to make your project start up as smooth as possible!

Use the Human Research Quick Start Guide

New HRPP Consultation Addition

A new 30-minute consultation has been added for investigators and study team members with general questions about minimal risk projects. This consultation is for researchers with brief questions about the exempt/expedited review process, basic guidance on how to submit amendments, reports, status updates or continuing reviews, or how to use RAMS-IRB.

NOTE: This consultation is meant for basic questions and very general guidance about exempt/expedited projects only. If you have in-depth or specific questions about a study currently under review or already approved, please contact your assigned IRB Analyst directly.



Request a Consultation Now



RAMS-IRB Gif Guides and Videos

Did you know that the VCU HRPP offers video walkthroughs and narrative guides on how to navigate RAMS-IRB? Whether you're new to RAMS-IRB or have been using it for years, the RAMS-IRB Gif Guides and Video Walkthroughs can help you navigate RAMS-IRB with ease!

See the RAMS IRB Gif Guides

See the RAMS IRB Videos

Hails and Farewells

The VCU HRPP Welcomes the Newest Additions to the HRPP Team

Lea Olverson, MS

Lea Olverson, MS joins the HRPP as the Deputy Director and Change Management Subject Matter Expert. Ms. Olverson was previously a Research Oversight & Compliance Officer at Walter Reed National Military Medical Center, Department of Defense.

Her distinguished HRPP and compliance career spans over 15 years, and includes experience educating and training all levels of staff, including senior leadership, on federal, national, and international ethics, codes, laws and policies.

Ms. Olverson's expertise in the field of research oversight also includes working on a major innovative genetic research project as the Compliance Officer for the National Geographic Society. In that position, she extensively traveled to countries such as South Africa, Russia, Estonia, and China to assess the research sites.

Ms. Olverson holds a Master of Science degree in Applied Psychology from the University of Baltimore and several governmental commendations and honors for her contributions to the field of HRPP and compliance.



Vanessa Hernandez, MPH, CIP



Vanessa Hernandez, MPH, CIP recently joined the VCU HRPP Reliance team as an IRB Reliance Consultant. Prior to coming to VCU, Ms. Hernandez held positions in support of research and oversight and compliance at The Johns Hopkins University, University of Maryland, NIH (NCI) and the Department of Defense (various branches).

Her work in support of domestic and international research enterprises spans over 18 years and include progressive education, training and experience in drafting research policy, field support, project management and oversight and compliance.

Ms. Hernandez holds a Master of Public Health degree from

Benedictine University, and a Certified IRB Professional (CIP) certificate from PRIM&R.

The VCU HRPP Says Farewell to Those who Are Leaving VCU

A. Logan Clary, MS

A. Logan Clary, MS, served as IRB Reliance Analyst for the VCU HRPP. Mr. Clary was a valuable contributor to the Reliance team during his tenure.



Nyssa Towsley, MS, CIP

Nyssa Towsley, MS, CIP served as the Education and Outreach Manager for the VCU HRPP, and prior to that was an IRB Analyst. During their nearly seven years with our office, they helped shape and expand the HRPP's educational offerings, as well as strategize recruitment of diverse IRB members.

Elicia Preslan, MS, CIP

Elicia Preslan, MS, CIP served as the Quality Assurance and Quality Improvement Manager for the VCU HRPP and previously worked as an IRB Analyst and IRB Coordinator. Ms. Preslan designed and facilitated training for HRPP team members and refined the RAMS-IRB system during her 10-year tenure with the HRPP. All will be missed!



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