

VCU HRPP Newsletter

The HRPP Transformation Project



What is happening?

Human subjects research at Virginia Commonwealth University (VCU) continues to grow in complexity and volume. At the same time, there have been staffing changes and we do have gaps to fill. So, we are taking this opportunity to transform the VCU Human Research Protection Program (HRPP) to better meet both the current needs and prepare for the future needs of our research community.

What actions are being taken?

Throughout our Transformation Project, we will be focusing on reducing administrative burden, improving the quality and consistency of our educational and review processes, and improving overall efficiency with VCU research excellence. Our Transformation includes:

- 1. establishing a partnership with the Advarra IRB as a routine IRB review pathway to immediately increase IRB review capacity;
- streamlining policies and procedures for both the VCU HRPP and our local IRB through adaptation of a best practice model upon which many of our peers rely; and
- 3. implementing a streamlined and updated IRB submission system to reduce the administrative burden on both VCU investigators and IRB staff.

For additional information, don't hesitate to contact the HRPP Office via <u>orsp@vcu.edu</u>. Thank you, and we look forward to better serving you in the near future and beyond as VCU prepares to embark on growing an expansive research portfolio.

We ask for your patience as we remediate, restructure, and reorganize the HRPP.

The HRPP Transformation Project

Q&A with P. Srirama Rao, Ph.D., Vice President for Research and Innovation



Why is this an ideal time for transformation?

Several different circumstances brought us to the point of deciding to enact this HRPP transformation project. As leadership, we took the opportunity to evaluate current processes and procedures to align them to How will these changes benefit research and the research community at VCU?

The changes outlined in the HRPP transformation project were custom designed to greatly benefit the research enterprise based on an internal assessment within the OVPRI and comprehensive feedback What are your key takeaways from the HRPP transformation project?

That this project takes into consideration the diverse needs of our researchers across our three campuses. Meeting these needs and providing a high level of responsiveness empowers them to continue their impact locally, nationally, ensure compliance while best serving our research enterprise efficiently and effectively. Transformative innovation is a concept I encourage my leadership team to apply across the OVPRI and its respective divisions and units, and this is a prime example of that. It is important to regularly evaluate how we do things and how we can improve to best serve the research enterprise and also support and train our own staff.

from our stakeholders in and around VCU. We aligned our standards and processes with the model implemented by many of our R1 university and academic medical center peers to maximize efficiency and effectiveness. For example, the project includes methods to reduce the researcher application submission process by as much as 75%. and globally and brings us closer to our collective aim of improving the human condition.

IRB Appointlet Consultations Update

Due to staffing shortages, the Appointlet IRB Pre-Submission Consultation program has been paused.

For any questions that cannot be answered with the below resources, researchers can email **irbpanela@vcu.edu** for additional assistance. Please note, the IRB staff will have limited availability for meetings in order to focus on reviewing a backlog of submissions from recently separated staff, so the research community is kindly being asked to carefully review the information provided below before requesting additional IRB assistance when beginning a new study submission. The IRB staff look forward to resuming the Appointlet IRB Pre-Submission Consultation program as soon as they are able to do so, as this is a valuable service to the VCU research community.

Note: IRB staff will still be available to advise on questions about ongoing research projects already submitted and assigned to a reviewer/IRB Administrator. The above applies only to the Appointlet IRB Pre-Submission Consultation options previously offered.

For helpful contacts and resources on a variety of topics relating to how to get started in your research at VCU, please go to https://research.vcu.edu/human-research/hrppirb/getting-started/.

For a useful tool to plan for ancillary reviews and other VCU requirements that may impact your research, please use our Quick Start Guide at https://redcap.vcu.edu/surveys/? s=PTCX7XEENRH9C97H.

For a complete list of VCU IRB policies and procedures, please visit https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/.

HRPP Student Worker Spotlight

Amber Smith



Hello! I'm Amber Smith. I am a Junior, Adult Student, and a Psychology major with a double-minor in GSWS and Philosophy of Law. At the beginning of the fall semester I had the opportunity to join the HRPP as a Student Worker. In my role I was lucky to work closely with The Protocol Navigator Consultant (PNC) project. The 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. This program is designed to assist VCU researchers in navigating the human research approvals process at VCU. In my role I had the opportunity to meet and confer with the passionate educators from each school who are involved with the PNC project. So far the PNCs have helped many researchers in gaining approval for their studies. They have a clear passion for furthering their fields through research, and helping others to do the same; each PNC brings a unique viewpoint and strength to the project. I look forward to using the knowledge I gained in this role for future research I am excited about, and hope that the program can continue to support students like me. The program is currently finding further funding to help more researchers in the future.

Request a Consult with a PNC

PLEASE NOTE: In May 2023, administration of the PNC Program will be delegated to the participating schools.

Research Resources

Office for Human Research Protections (OHRP) Online Education

The Office for Human Research Protections (OHRP) offers online educational resources including Mini-Tutorials, Videos, and Hot Topics.

Access OHRP Online Education

How Do I Know if a Research Study is Human Subjects Research and What Does that Really Mean?

This presentation explains what makes a study "human subjects research" under the Common Rule, what responsibilities that entail, and what flexibilities may be available to simplify review for human research protections.

How Do I Know it a Research Study is Human St bjects Research and What Does the Really Mean?

NIH National Institutes of Health

Hails and Farewells

The VCU HRPP Welcomes the Newest Additions to the Team

Advarra Consultants



Cynthia Hahn

Cynthia Hahn, a Managing Expert with Advarra's center of excellence, is an executive biomedical research professional with over 20 years of experience in human subject research. Since 2017, Cynthia has been the president of Integrated Research Strategy, LLC. Some of her accomplishments as President of IRS is providing interim support and advisory services to a large university based human research protection program. As a Managing Expert at Advarra, Cynthia has developed a research administrative infrastructure, provided research compliance quidance, transformed the business and clinical operations of a mobile clinical care service provider during the COVID pandemic, etc. Her roles over the years have included IRB Director, Research Compliance Manager, Research Compliance Officer, Clinical Research and Regulatory Affairs Vice President, Chief of Staff, Managing Expert, and President.

Brigid Roy

Brigid Roy, CIP, a consultant with Advarra's center of excellence, is a subject matter expert with 20 years of wide-ranging experience in the Human Subjects Research Protection arena. She managed the HRP program at Children's Hospital Oakland (CHO) for many years and oversaw the integration of that department into the University of California San Francisco's program. Her roles over the years have included IRB Director, Research Compliance Officer, Research Privacy Manager, Research Auditor, and IRB Reliance Program Manager. Her experience with IRB reliance processes began in 2008 when CHO was selected to be part of the NCI CIRB pilot project. As a consultant, Brigid has worked with numerous institutions to establish, manage, and/or enhance their Human Subject Research Protection



Program (HRPP). Her skills encompass mentoring staff and supporting researchers, collaborating effectively in a fluid environment to prioritize tasks, and delivering essential services that meet regulatory requirements and the needs of a research institution.

Reliance Division



Krystal Parks

Krystal Parks is a current BSPH/MPH student at Kent State University. She is a healthcare professional with 15 years of work experience. She is dedicated to ensuring the quality of healthcare delivery for all. Before joining the team at VCU, she worked for University of California, Davis in an Assistant Clinical Research Coordinator role as well as in a Laboratory role with Kaiser Permanente where she has served on committees that focus on quality improvement initiatives as well as safety. In those positions she has gained valuable professional skills such as leadership, regulatory and compliance, data collection/analysis, and laboratory management. During her time off from her academics and work, she regularly volunteers within her community and is also an active member of the APHA.

Sa'Mara Brooks

Sa'Mara Brooks is a diversified professional with a 9-year career in Clinical Research. She recently joined the VCU HRPP Reliance Team as an IRB Reliance Analyst. Before coming to VCU, Ms. Brooks held positions in support of research, including project management, field support, and regulatory compliance.



Chantrice Rogers

Chantrice Rogers is a 2001 graduate of Savannah State University with a Bachelors of Science in Biology. Chantrice has a Master's Degree in Public Health from Mercer University ('05). Additionally, Chantrice also has completed a two (2)



year fellowship with the CDC. Chantrice's professional foundation includes work as a cell culture technician, a clinical research coordinator, and a project management associate. Clinical research is her passion and has been the focal point of her twentytwo (22) year career. Chantrice has worked phases I-IV of various research studies and has worked with various disease implications including MRSA. Cryptosporidium, and IBD. Chantrice has continued to be a lifelong learner and has extended her professional borders during her time at CRC and has developed her extensive background in research compliance and oversight.

The VCU HRPP Says Farewell to Those who Are Leaving VCU

Panel A exempt/expedited team

Christina Wright, M.A., CIP IRB Team Lead Elizabeth Schwartz, CCRP, CIP IRB Analyst Erik Williams, CIP IRB Analyst Jessica Lantz, CIP IRB Analyst Panel A full board team

Dawn J. Anderson, RD, CIP IRB Panel Administrator

Save the Date

Upcoming Events

VCU Research Weeks 2023: UNstoppable Innovation

Join us this spring as we celebrate our impact and showcase our UNstoppable pursuit of knowledge, creativity and scholarship. The Office of the Vice President for Research and Innovation, in collaboration with the Office of the Provost, invites you to attend our kick-off event on Tuesday, April 10, featuring internationally recognized pioneer of neurobiology, Dr. Terry Sejnowski. Dr. Sejnowski is at the forefront of research focused on artificial intelligence and learning, and will discuss his work to answer the question: AI can talk the talk, but can it walk the walk? On May 1, Dr. Bathsheba DeMuth, environmental historian, will conclude Research Weeks and the Humanities Research Center's series on environmental humanities with her talk "Do whales judge us?"

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 <u>VCU Research Weeks</u> website or email <u>researchweeks@vcu.edu</u>.



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 <u>HRPP Blog</u> for updates regarding this year's topic, featured speakers, and registration instructions.

Do you plan on attending this year's VCU HRPP Annual Conference on Friday, September 29, 2023??

Yes, count me in!

Maybe, I'll stay tuned for more details.

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