Welcome

We are pleased to release the Human Research Protection Office (HRPO) and Washington University (WU) Institutional Review Board (IRB) Years in Review report. This report highlights the accomplishments of HRPO and the WU IRB and provides insight into the IRB review process and our daily functions. You will find commentaries from IRB members and researchers, along with some fun highlights of HRPO staff.

The last few years have brought unique challenges and opportunities. We successfully navigated the COVID-19 pandemic and its impact on human subject research. We have put tremendous effort into initiatives and educational improvements that align with our mission to protect research participants. During my time as Executive Director, I have had the pleasure of working with both Dr. Amanda Cashen as the former Executive Chair and now Dr. Derek Byers as the current Executive Chair. As HRPO and the WU IRB work together, our goal is to advance the ethical conduct of human subject research while fostering collaborative efforts with the research community.

Jeanne Velders, JD, CIP
Executive Director, HRPO
I became the Executive Chair of the Washington University IRB in August 2023. I have been a member of the IRB since 2010 and a committee chair since 2013. My clinical and research background is in pulmonary and critical care medicine. Throughout my time on the IRB, it has been a privilege to work with the prior Executive Chair, Dr. Amanda Cashen, and the Executive Director, Jeanne Velders. I greatly appreciate their leadership, especially during the COVID-19 pandemic, and congratulate them and their teams for doing such a great job!

Comparing the HRPO and IRB procedures of 2019 to today highlights the changes that Amanda and Jeanne have guided. Day-to-day operations have moved from in-person to now mostly online. This has improved the work-life balance for our HRPO staff and IRB members and allowed more flexibility for assignments. The application and review processes has improved, committee meetings have been streamlined, and resources have been developed that are more user-friendly and effective.

We have witnessed remarkable growth of new drugs, devices, tools, and technologies that impact all facets of human subjects’ research. Over the next four years of my tenure, we will be tasked with safely implementing artificial intelligence and related technologies in human research, applying tools of decentralized trial design to serve a larger and more diverse population, and assuring safe practices for data sharing. However, our most important priority remains to protect the rights and welfare of research participants in studies led by Washington University investigators.

We have an amazing group of talented researchers across the Danforth and Medical School campuses, and a skilled and knowledgeable workforce in the HRPO and IRB. By working together, I believe we can achieve our goals. I am proud to serve this institution and look forward to the important work ahead.

Derek E. Byers, MD, PhD
It was my honor and pleasure to serve as the Executive Chair of the IRB from the fall of 2018 until the summer of 2023. As an IRB member and Full Board meeting chair for ten years before that, I came into the position with an appreciation for the efficiency and expertise of the IRB full board committees. As Executive Chair, I witnessed the “behind the scenes” activities that promote human subjects research across the University. The HRPO leadership and staff are knowledgeable, experienced, and simply extraordinary.

The Covid pandemic undoubtedly had the greatest impact on my tenure as Executive Chair, as it presented significant challenges for the IRB and the conduct of human subjects research. The HRPO office quickly pivoted to remote work, and our IRB meetings moved to Zoom. The IRB worked harder than ever to help study teams modify their research for the protection of participants and to review the influx of Covid-related research. We also developed standards and procedures for electronic consent so that research could be conducted remotely. I am forever grateful to our IRB members for their flexibility and dedication amidst these challenges.

In addition to the initiatives motivated by the pandemic, the IRB and HRPO tackled other impactful projects during my tenure, including standards for return of research results, guidance for the conduct of international research, and improvements in consent language.

I thoroughly enjoyed my time chairing the IRB, and I know Dr. Derek Byers will provide excellent leadership in the years ahead. I want to take this opportunity to thank Jeanne Velders for her outstanding collaboration and support while I served as Executive Chair.

Amanda Cashen, MD
Executive Chair, WU IRB
2018-2023
The mission of the WU IRB is to protect the rights and welfare of individuals recruited for, or participating in, human subject research. The WU IRB includes members from various backgrounds and expertise, such as physicians, scientists, researchers, nurses, pharmacists, lawyers, clergy, and other individuals from the St. Louis community.

The commitment of our IRB non-scientist and community members is crucial to the success of the ethical review of research involving human subjects. These individuals provide an important perspective and play an integral role as IRB members by representing the research participant and community perspective, most notably with the consent process and advocating for vulnerable populations.

Our IRB members serve as volunteers. We are thankful for their dedication.
What role do you think the IRB plays in the WU research community?

The IRB is critical for ensuring that all of the amazing studies at Washington University are conducted in an ethical manner. As a clinician scientist, I have learned so much from being a WU IRB member, which has made me a better investigator.

Cynthia Ortinau, MD, MSCI

How long have you been an IRB Member and why did you join?

I have been on the IRB for just over ten years and joined as a non-Wash U scientist. As a psychologist I was familiar with the IRB and was curious how it actually worked. I have learned so much and am continually fascinated and impressed with the research being conducted at Washington University.

Nancy Williger, PhD
Institutional Review Board Chairs

George Van Hare, Professor of Pediatrics-Cardiology, and Joel Picus, Professor of Medicine-Oncology, stepped down as IRB Chairs in 2023. It was a privilege to have them serve as IRB chairs. A search is currently underway to appoint a new IRB chair in 2024.

2024 IRB Chairs

Group photo pictured left to right
Ed Casabar, PharmD, BCPS
Derek Byers, MD, PhD
Douglas Char, MD
Amanda Cashen, MD
Joel Picus, MD
Jeff Atkinson, MD

Individual photos pictured top to bottom
Fredrick Huang, MD
Mitchell Sommers, PhD

Important to the success of the IRB is the commitment of our incredibly dedicated chairs. The IRB has a rigorous schedule holding 4-5 meetings per week. Each chair runs a meeting either weekly or every other week, reviews minutes, consults with researchers and HRPO staff, and attends a monthly meeting with all chairs and HRPO leadership. The IRB chairs have served under the leadership of Dr. Amanda Cashen until the summer of 2023 and now under the current Executive Chair, Dr. Derek Byers.

Mitchell Sommers, Professor of Psychological & Brain Sciences, serves as the chair for Behavioral Minimal Risk Research bringing valuable expertise and support for the review of social and behavioral sciences research.

George Van Hare, Professor of Pediatrics-Cardiology, and Joel Picus, Professor of Medicine-Oncology, stepped down as IRB Chairs in 2023. It was a privilege to have them serve as IRB chairs. A search is currently underway to appoint a new IRB chair in 2024.
Philip A. Ludbrook, MD, MRCP (UK), FRACP, Professor Emeritus of Medicine and Psychiatry, served as the Executive Chair of the Washington University IRB from 1987 to 2010. As a pioneer in the field of human research protections, he laid the foundation of ethical review and established standards that make Washington University a leader in the field of human research protections and ethics.

In 2012, the Philip A. Ludbrook Award was established in honor of his service and commitment to human subject protections. The award is given annually to a member of the IRB for outstanding service and dedication to the protection of human subjects involved in research.

Most recently, the IRB was honored to issue the Philip A. Ludbrook Award to Dr. Douglas Char and Dr. Joel Picus. We are grateful for their years of service.

2022’s recipient, Douglas Char, MD, Professor of Emergency Medicine, has served on the IRB since 2001, becoming a chair in 2013.

2023’s recipient, Joel Picus, MD, Professor of Medicine, Department of Oncology, has served on the IRB since 2011, becoming a chair in 2013.
WU IRB & HRPO Appreciation Dinner

Each year the Human Research Protection Office and WU Institutional Review Board gather to acknowledge and celebrate the dedication of the IRB members and HRPO staff for protecting the rights and welfare of research participants.

This year’s celebration was held at the Forest Park Visitor Center Trolley Room. IRB members, HRPO staff and their spouses or partners were given an opportunity to enjoy each other’s company while also recognizing the achievements of both individual members and the group.
Dr. Derek Byers, Executive Chair, delivered an inspirational speech and reported on submission and review volumes, turnaround times and committee statistics. The event also provided the opportunity to say goodbye to retiring committee members and to welcome new members.

Pictured left to right: Allison Givens, Douglas and Debbie Char

Joel Picus (left) accepting P.A. Ludbrook Award from Derek Byers (right)

Pictured left to right: Brian and Sherry McKinnon, David DiFranco and Julie Moyer

Pictured left to right: Mitchell Saulisbury-Robertson and Roberto Ramirez, Larry and Carla Pinkston, Jackie Cleary and Adam Hughes.
The COVID-19 pandemic presented unique challenges for the WU IRB. There was an influx of new IRB submissions and many currently approved studies required modifications to account for the limitations on in-person contact. The new IRB submissions covered many aspects of the pandemic, spanning both the School of Medicine and Danforth campuses. Studies were reviewed in a prioritized fashion. Human subject research was not solely focused on clinical trials of investigating new treatments or diagnostic devices. Many of the research projects conducted at Washington University examined the impact of COVID-19 from a public health and social-behavioral perspective, including the impact on healthcare workers.

COVID-19 New Projects - 2020/2021
COVID-19 Impact on IRB/HRPO

IRB Meetings

Prior to the COVID-19 pandemic, IRB meetings were held in person with occasional allowances for IRB members to call in by phone. Due to restrictions on in-person contact, IRB meetings transitioned to a virtual format. IRB meetings remain virtual, with the exception of one in-person meeting per week.

HRPO Remote Work

As with many other departments at Washington University, HRPO functions quickly pivoted to a remote work environment. For HRPO, the transition to remote work is permanent. However, HRPO maintains a presence on campus for in-person activities, such as meeting with researchers and providing educational presentations to the research community.

e-Consent

Driven by the needs of the researchers, the use of e-consent became an important component of the IRB review process. While there was some use of e-consent prior to COVID-19, this mode of consent quickly expanded as the pandemic progressed. The WU IRB and institutional leadership created guidance for researchers on the use of e-consent and worked closely with Chris Sorenson, PhD, Senior Support Scientist, at Bernard Becker Medical Library as e-consent options were developed through RedCap. IRB/HRPO are participating in a working group developing e-consent options for studies requiring Part 11 compliance under the FDA regulations. The expansion of the use of e-consent had a positive impact on our research participants by offering options outside of the traditional written or verbal consent process.
My research interests have centered around the pathogenesis of infectious disease, with a particular emphasis on treatment and understanding the pathogenesis and immunologic response to viral infections, especially HIV and emerging viral infections such as COVID-19. Since 2006, I have conducted clinical trials at the Washington University Infectious Disease Clinical Research Unit (ID CRU), where I currently serve as the medical director of the research unit, the clinical site for the Washington University Center for Vaccines and Immunity to Microbial Pathogens, the AIDS Clinical Trials Group, COVID Vaccine and Prevention Network, and Vaccine and Therapeutic Network. I’ve also been a clinician scientist member of the Washington University IRB since 2015. We have utilized the expertise of the ID CRU to conduct groundbreaking clinical research in HIV, hepatitis and vaccines and responded aggressively to the COVID-19 pandemic, conducting both translational research to understand immune responses after infection or vaccination as well as treatment, prevention and vaccination trials in participants infected with or at risk of infection with SARS-CoV-2. The Washington University IRB was incredibly responsive, flexible and rapid at helping us review and stand up clinical protocols in the first year of the pandemic, allowing us to start up treatment and vaccine trials in record time without sacrificing appropriate oversight.
During the COVID-19 pandemic, our team was funded by NCI and CDC to be part of three national networks of community-engaged research to address racial disparities in COVID-19’s health and economic impacts. The pandemic altered how we conducted community engaged human subjects research, and no changes were more dramatic than the speed and frequency with which projects shifted. One day we are focused on distancing, then masking, then testing, then vaccines, then pediatric vaccines, with outbreaks and surges and new variants of the virus, all against a social and political backdrop of immense conflict. Community events and vaccine clinics at which we would operate would pop up with almost no advance notice, and we needed to be there and engage with community members. The IRB was really terrific in its timely responses to MANY requests to review new research activities or modified one, often responding in the same day, and a few times, overnight. Our team won the Confluence Award for community-engaged research in St. Louis during COVID, and we couldn’t have done it with the great work of the IRB.
Countries with highest number of research studies: Uganda, Ghana and India

While integral to the safe and ethical conduct of human subject research, the IRB review process for international research is complex. A researcher must navigate ethical standards, legal requirements and the cultural norms of a country/participant population. HRPO and IRB leadership collaborate with WU faculty that conduct international research to improve the quality, transparency and efficiency of the IRB review process. The Faculty Fellow for International Research and our staff that serve as HRPO partners are the stepping stones that guide researchers through the IRB review process from pre-IRB submission to final approval.
Faculty Fellow for International Research

Cindy Brantmeier, PhD, is a Professor of Applied Linguistics with a primary appointment in Global Studies at Washington University in St. Louis. Since 2019, Professor Brantmeier is the Faculty Fellow for International Research with Human Subjects in the Office of the Vice Chancellor for Research. She has extensive experience conducting international research on human subjects. In her role as faculty fellow, Professor Brantmeier provides guidance for faculty and students conducting research with human subjects in global contexts.

WU Committee for International Research with Human Subjects

In early 2021, the WU Committee for International Research with Human Subjects was established to support the conduct of international research with human subjects. This committee is comprised of faculty across disciplines and research methods, as well as IRB and institutional representatives. It is charged with improving the IRB review process and human subject protections for international research. The committee evaluated current practices and made recommendations that ultimately led to the development of guidance that has improved efficiency of the IRB review process while maintaining the necessary human subject protections. This guidance was released in April 2022.

The committee is co-chaired by Cindy Brantmeier and Jeanne Velders. It remains active and reconvenes as needed.
Brown School Professor and Associate Dean of Global Strategy and Programs, Lindsay Stark's global research focuses on the intersection of conflict, violence, and health outcomes, with a special emphasis on the well-being of women and children in crisis situations. Her work has contributed significantly to understanding the impact of armed conflict, displacement, and other humanitarian emergencies on mental health, gender-based violence, and overall human development. By conducting rigorous research, Dr. Stark aims to inform policies and interventions that can better support the needs of those affected by crises.

One notable aspect of Dr. Stark's research is its interdisciplinary nature, often incorporating a mix of qualitative and quantitative methodologies, and collaborating with colleagues across the Brown School, Medical School, and Arts & Sciences. Her studies delve into the complexities of humanitarian settings, shedding light on the unique challenges faced by communities in crisis and offering insights into effective strategies for intervention and support.
Dr. Stark served as a dedicated member of the Washington University Danforth IRB Advisory Board from September 2020 to August 2022. Additionally, she contributes her expertise as an invited member of the Washington University International Research with Human Subjects Committee focusing on international IRB submissions. Dr. Stark has emphasized the significance of the IRB's commitment to expanding global expertise and adapting to the ever-changing dynamics of global research. In her own words, "I have been pleased to see the IRB take seriously how it can grow its global expertise and increase its flexibility to adapt to the ever-changing and very dynamic realities of global research." This statement highlights her appreciation for the IRB's efforts in staying attuned to the evolving landscape of research practices on a global scale.

*Images courtesy of Lindsay Stark*
In response to the single IRB mandate set by the 2018 revised Department of Health and Human Service (DHHS) human subject research regulations, HRPO developed a robust single IRB program. The goal of the single IRB model is to enhance and streamline the IRB review process in multi-site research by requiring that one IRB oversee all sites. Currently, the WU IRB serves as the single IRB for over 100 studies, including over 30 sites for the highly innovative Kidney Precision Medicine Project (KPMP). The KPMP aims to provide understanding and treatment for kidney disease and injury by working with patient representatives on study design and implementation.

Looking to the future, HRPO is planning for the possibility of the single IRB mandate being extending to certain FDA studies.

Carissa Minder, Associate Director at HRPO, acts as a SMART IRB ambassador. SMART IRB is not an IRB but rather a platform that encompasses a common IRB reliance agreement and a suite of web-based resources to facilitate single IRB arrangements. Carissa assists sites around the country with use of the SMART IRB Master Reliance Agreement and implementation of single IRB studies. The work she does allows WU to stay at the forefront of single IRB policy, best practices and assist the research community at large with harmonizing single IRB implementation.
Human Research Protection Office (HRPO)

HRPO Staff—2023 WU IRB & HRPO Appreciation Dinner
The Human Research Protection Office is a group of professionals dedicated to the protection of research participants. We provide support for the WU IRB and the research community in many ways.

- Of our 32 staff members, 16 are Certified IRB Professionals.
- There are six expedited reviewers that conduct IRB review on the majority of all research submitted to the IRB.
- Educating the research community is a key component of our office.
- We conduct internal quality assurance activities on the IRB review of research.
- We maintain and continue to develop the electronic IRB submission system.
- Many staff members are nationwide leaders in the realm of human subject protections.
HRPO Staff Picnic
Forest Park Grand Basin

Pictured (L-R) Jacqueline Epps-Wilbanks, Niki Bridges

Pictured (L-R)
Top—Mitchell Saulisbury-Robertson, Tracy Minx
Bottom—Jeanne Velders, Erin Higgs
School of Medicine and Danforth IRB/HRPO Advisory Boards

An IRB/HRPO Advisory Board has been established for each campus of the University. These advisory boards are faculty driven and meet on a regular basis to advise HRPO and the WU IRB on issues pertaining to the human subject research enterprise at Washington University. Their expertise and advice has assisted HRPO with the rollout of major policy changes, helped to determine proper communication paths and serves as a viewpoint from the researcher’s prospective.

Danforth IRB/HRPO Advisory Board
Mitchell Sommers, PhD, Co-Chair
Cindy Brantmeier, PhD, Co-Chair

School of Medicine Advisory Board
F. Sessions Cole, MD, Chair
Stacey House, MD, PhD, Co-Chair

School of Medicine HRPO Liaison Group

The School of Medicine HRPO Liaison Group is an assembly of research coordinators, specialists and managers from a wide collection of departments at the Washington University School of Medicine. This group meets bi-monthly to discuss issues pertinent to the conduct of human subject research. The liaisons are responsible for bringing forward questions, concerns or feedback from research teams in their respective departments on areas such as IRB policies, guidance and the overall IRB submission and review process. The liaisons will then provide updates and new information to the researchers in their department. This feedback loop serves as a valuable tool for improving HRPO/IRB functions and interactions with the research community.

We greatly appreciate our HRPO Liaison group’s and Advisory Board’s time and commitment to improving HRPO and IRB functions.
The Association for the Accreditation of Human Research Protection Program (AAHRPP) accredits high-quality human research protection programs to promote excellent, ethically sound research. To earn accreditation of a Human Research Protection Program (HRPP), organizations must provide evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement.

The Washington University HRPP is accredited by AAHRPP and was one of the first institutions to receive AAHRPP accreditation in the early 2000’s. Re-accreditation occurs every five years. Institutional leadership, including HRPO and the IRB, are working on our re-accreditation application due in 2024.

A Human Research Protection Program (HRPP) is a comprehensive program established by an institution to ensure the protection of the rights, welfare, and well-being of human subjects involved in research. This program involves the integration of policies, procedures, and oversight mechanisms to promote ethical conduct in research activities.

AAHRPP standards were recently revised to require an emergency preparedness and response plan designed to protect the rights and welfare of research participants. Learn more about AAHRPP at https://www.aahrpp.org/.
HRPO Educational Offerings

- IRB Consultations
- HRPO Help Services
- HRPO on Demand
- Study Initiation Program
- HRPO Conference Scholarship Program
In August of 2020, HRPO launched the IRB Consultation Program as the newest offering of the HRPO Help Services menu. The program was born out of a desire to deliver an individualized educational experience that provides real time recommendations on existing or in-development projects. As a function of the IRB Consultation Program, the individual requesting the consult is paired with a HRPO staff member with the appropriate content area expertise. This is the key to the program’s success. Consults are scheduled as a priority meeting and at the convenience of the requestor. The IRB consultation program has:

- Reduced both the time and number of HRPO staff contacts needed to resolve an issue or answer a question
- Enabled researchers and their staff to establish a point of contact with the IRB for future questions and follow-up issues

Since program initiation over 400 consultations have been completed with requests coming from the Medical School, Danforth campus, and other affiliated partners. The program has been well received by the research community.

2023 Consultation Program Impact

185 consultations totaling 290 participants scheduled within 4 calendar days

“I very much appreciate this service and the willingness of the HRPO staff to help from scheduling to consultation. My questions were answered and the experience was pleasant!”

“The response to my request was virtually instantaneous and the outcome was very impactful to me and my research.”

“Very important and approachable service.”

“I think the IRB consultation is a must since there can be nuances that are difficult to explain in a written email or just interfacing with the website. So thanks for all the help – I appreciate it.”
SWAT! On-Call Service

The Staff with Answers Today! (SWAT!) On-Call Service continues to be the centerpiece of HRPO Help Service offerings. A dedicated HRPO staff member is on-call Monday-Friday from 8am-4pm to meet the needs of our research community.

Office Hours

In April 2020, HRPO suspended in-person office hours due to the University’s work from home mandate. Almost immediately, HRPO staff were able to pivot to virtual office hours via Zoom. Post-pandemic, remote work is here to stay and virtual office hours is a permanent component of HRPO Help Services. This allows HRPO staff to service a geographically diverse research community. Virtual office hours is available every Wednesday from 9:30am-1pm.

2023 SWAT! On-Call and Office Hours Activity

- 3,000 Inquiries
- 80% Resolved Immediately
- 291 WU Departments / Other Entities Represented
As an existing educational program, HRPO On Demand is designed to provide educational presentations tailored to departmental, investigator, and student needs. These in-person or virtual sessions are available upon request which brings a personalized approach to education.

Over the last year, HRPO On Demand was reinvented by launching a video library as an additional learning option. Still in its early stages, HRPO now offers pre-recorded educational presentations covering a variety of topics. Researchers and their staff must prioritize a multitude of duties and responsibilities that may make attending set educational sessions difficult. The HRPO On Demand video library allows researchers to seek education on topics of need or interest when their busy schedule allows. HRPO staff have created content to address those questions most frequently encountered through our HRPO Help Services such as:

- Getting started with the IRB and HRPO
- Investigator responsibilities
- Secondary use research
- Single IRB review

HRPO staff are working to expand these offerings and to obtain feedback from users on proposals for new content.
The Study Initiation Program, established in 2013, continues to be a staple educational offering. The program is a joint effort of the Human Research Protection Office (HRPO) and Human Research Quality Assurance Office (HRQA). The primary goal is to provide protocol-specific education to research teams to support the conduct of research in compliance with federal regulations, state law, institutional policies, and best practices. The program survived the pandemic’s work from home mandate by moving to a virtual format. This transition increased the program’s outreach by providing flexibility that allows for greater ease of scheduling and improved attendance.

### Study Initiation Program Activity
March 2020 - January 2023

- **142** Visits
- **418** Attendees
- **46** WU Departments / Divisions Represented
Each year, HRPO sponsors a research coordinator’s attendance at the Public Responsibility in Medicine and Research (PRIM&R) conference. The individual may be self-nominated or nominated by another member of the research community and must meet a variety of eligibility criteria including being actively involved in the conduct of human subject research for over a year and being a role model in the ethical conduct of that research. A committee comprised of members of the HRPO Liaison Group select the awardee. The selected individual attends the PRIM&R conference with other members of HRPO and provides a summary report to the HRPO Liaison Group on their experiences once they return.

The PRIM&R organization was founded in 1974 and advances the highest ethical standards in the conduct of biomedical, behavioral, and social science research. Their annual conference allows members from all areas of the research community to gather to discuss current hot topics in the research industry as well as to engage in networking opportunities.

**Recent Awardees**

2021 – Natasan McCray, Senior Clinical Research Coordinator, Surgery – Public Health Sciences
2022 – Zac Robben, Clinical Research Coordinator II, Orthopedic Surgery
2023 – Patricia Salyer, Clinical Research Supervisor, Psychiatry
In 2023, the IRB reviewed New Projects in...

Submit to Approval

For Expedited New Projects (Median Calendar Days)
8 Days

IRB Review
Submit to Approval

For Full Board New Projects (Median Calendar Days)
14 Days 40 Days
Active Studies

9,000+
Total Active Studies

- Full Board: 38%
- Expedited: 42%
- Exempt: 20%

Active Studies by School

- School of Medicine: 86%
- Danforth: 14%

Active Studies by Project Type

- Biomedical: 78%
- Behavioral/Social Science: 22%

Includes History/Anthropology