We would like to welcome you to the inaugural issue of our Annual Report. The Human Research Protection Office and the Institutional Review Boards are pleased to share with you our accomplishments as well as provide a look forward to the upcoming year.

The past year has seen exciting changes in many areas including our workflow times, education and consultation activities and significant awards and recognition for our programs. We are especially gratified to be highlighting two Washington University researchers with whom we have worked over the past year.

We are looking forward to continuing to serve the Washington University research community in the upcoming year. We began the year with the rollout of our new website that will feature easier navigation and more user-friendly information including a new Investigator’s Guide. We hope you will take the time to look around the site and let us know what you think! We will also be continuing to build infrastructure to support the use of central IRBs that are becoming the “norm” for NIH-funded multi-center trials, as well as developing our capacity to serve as a central IRB for our researchers conducting multi-site studies. An important event this year is the re-accreditation process for the Human Research Protection Program (HRPP) at Washington University. This process occurs every five years and affirms the institution’s commitment to the protection of human subjects and support for the ethical conduct of research.

We hope that you enjoy this first report and that it reflects the incredible research conducted over the past year by our faculty, staff and students as well as our colleagues at Barnes Jewish Hospital and St. Louis Children’s Hospital. We look forward to continuing to serve the research community in the next year.
What Happens When You Revamp Your IRB Structure?

At Washington University you experience improved review times, more engaged IRB members, and a flexible service model in support of human subjects research. In 2013 we transitioned 10 separate IRB committees, each of which met monthly, into one IRB that meets 6 times per week. We have continued to see improved review times over the past year. By increasing the number of meetings held each month, we have increased the capacity of how many protocols can be reviewed. This means that once an application is screened it can normally be placed on a full-board agenda within a week to ten days.

This new model has also improved the experience of our IRB members. While increasing the number of meetings, we have actually been able to decrease the time commitment of each individual IRB member. Each member is still only asked to attend one meeting a month, the same as in the previous model, but what used to be two-hour long meetings or longer are now typically only one hour. The agendas under the previous model often included between 15 and 20 studies to review while our current model reduces the number to seven or eight items. In addition, members now self-schedule themselves to one meeting each month, but they can choose between any of the 24-30 meetings held each month. This allows members more flexibility in scheduling and the ability to work around other work or personal commitments. Amazingly, this successful change has not required an increase in the overall number of IRB members, which has remained at around 180 members. Key to this accomplishment was reducing the required number of members attending a meeting from 15-18 down to 4-7. This smaller number allows each member to be more engaged in the discussion.
What role do you think the IRB plays in the WU research community?

“I am a proud member of the IRB committee. I have found the breadth of research that is taking place at Washington University both stimulating and encouraging as a physician. The IRB plays an integral role in ensuring ethical research practices are maintained.”

Thomas Keefe Davis, MD
IRB Member

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

“I am a ten-year plus member of the WUSM IRB and joined as a non-scientific member because of my commitment to cancer research, because both my parents died from cancer, as well as to represent BJC, BJH, and SLCH on the IRB.”

Bruce Lane, JD
IRB Member
IRB Chairs

Important to the success of the IRB has been the commitment of our incredibly dedicated Chairs. Each Chair runs a meeting either every week or every other week, reviews minutes, consults with researchers and HRPO staff as needed, and attends a monthly meeting with HRPO senior staff. Led by Dr. Jonathan Green, the Executive IRB Chair they include (left to right):

Amanda Cashen, MD
Derek Byers, MD, PhD
Douglas Char, MD
Mitchell Sommers, PhD
Jonathan Green, MD
Julie Margenthaler, MD, FACS
Joel Picus, MD
Ed Casabar, PharmD, BCPS

Increasing demands led to the recruitment of an additional IRB Chair in 2014, Fredrick Huang, MD. Dr. Huang is Associate Professor of Pediatrics and Clinical Director of the Division of Hematology/Oncology, Department of Pediatrics (pictured below).

IRB Community Members

In addition to the increased involvement of IRB meeting Chairs, the commitment of our IRB community members has also been crucial to the successful ethical review of research involving human subjects at Washington University in St. Louis. Community members bring an important perspective to the review process, bringing a fresh eye to the consent process and thinking through participant vulnerabilities present in research.

In 2014, over 30 community members committed their time and expertise to fill this important role in our IRB meetings.
Educating the IRB—A Visit from FDA

The Food and Drug Administration recently updated guidance on Investigational Device Exemptions (IDEs) for studies that involve *in vitro* diagnostic devices. As this new guidance has an impact on research conducted at WU, we invited representatives from the FDA to come talk with IRB members, HRPO staff, and the WU research community about these changes.

**E. David Litwack** (PhD, Personalized Medicine Staff, Office of In Vitro Diagnostics and Radiological Health, US FDA) provided two lectures on “Investigational Device Exemption” and “Using Sequencing (and other assays) in Clinical Trials: FDA Rules and Regulations.” After each session a Q&A session was held with Dr. Litwack and his colleagues from the FDA for an informative conversation about this new development in regulatory policy. Joining Dr. Litwack for Q&A sessions were (*pictured below, right*):

**Donna Roscoe** (PhD, Senior Scientific Reviewer, Office of In Vitro Diagnostic Evaluation, Center for Devices and Radiological Health, US FDA)

**Yun-Fu Hu** (PhD, Associate Director, Division of Immunology and Hematology Devices, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, US FDA)

**Živana Težak** (PhD, Associate Director, Science and Technology, Personalized Medicine, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, US FDA)
Mayor Slay Proclaims: “Washington University Institutional Review Board Day”

St. Louis Fire Chief, Dennis Jenkerson, and his wife, Michelle Jenkerson, Washington University IRB Member and Compliance Coordinator in the Center for Advanced Research Sciences, presented the Washington University IRB with this Proclamation on behalf of the City of St. Louis and Mayor Francis Slay. The official Proclamation now hangs in the IRB conference room. The text of the Proclamation is an excellent summary of the history of the WU IRB and its service to the St. Louis Community.

**Thank you Chief Jenkerson and Michelle Jenkerson!**
The **Human Research Protection Office (HRPO)** is a group of professional staff dedicated to:

- The protection of human subjects
- Administration and support of the Institutional Review Boards
- Supporting researchers and the conduct of ethical research compliant with local, state, and federal requirements
- Educating the research community
2014 Numbers At a Glance

Total Forms Received 15,244

Expedited
12,076
HRPO Expedited Review Staff = 6
# Forms/Reviewer = 2,013

Full Board
2,136
# Meetings 2014 = 304
# Items/Week = 41

Other 1,032

983 --------------- New --------------- 527
2,352 --------------- Continuing Review --------------- 181
1,461 --------------- Modification/Continuing Review --------------- 750
7,280 --------------- Modification --------------- 678
727 --------------- REF --------------- 0
305 --------------- Other --------------- 0

The IRB reviewed New Projects in...

10 Days
For Expedited New Projects (Submit to Approval—Median)

42 Days
For Full Board New Projects (Submit to Approval—Median)
myIRB is an efficient, effective, and scalable Data Management System

In an average month, the myIRB system supports

2,304 unique users

who access the system

19,636 times/month

and who view

607,979 different pages/month
WU currently has enrolled a total of

29,192,547

research subjects (including retrospective use of data or specimens) in a total of

5,532

open studies

WU participants are enrolled at a variety of locations.

WU studies feature a wide range of enrollment figures.
HRPO staff are often praised for their ability to assist researchers throughout the IRB review process. This involves a high level of knowledge and professionalism. When acknowledgements are received, they are often shared with HPRO staff via email or posted on the “HRPO Hoorays!” bulletin board in the IRB Conference Room. Here are just a few of the compliments received in 2014:

“Wow...that mod was approved in 2 hours 39 minutes...start to finish! I am impressed!”

“I called [HRPO] yesterday right after I left your office and [the staff member] was very nice and agreed to meet with me this morning at 9 so that she could approve it before my meeting. She went through each point one by one with me, and she was super helpful and patient (putting in a good word because she was seriously great).”

“I just wanted to share a great experience that we had today...[HRPO staff] carefully explained the reasoning behind all of the questions that she had regarding the new HRPO submission and showed patience with questions. Many times it is daunting to see and interpret reviewer questions. [HRPO staff] made this process much easier.”

“I want to send a note of thanks for the help you gave me this morning, the sponsor was very anxious for news of the HRPO approval for one of the studies I was working on. I was connected with you because the HRPO review person is off work today and as usual, you answered the phone with a very, very pleasant "always willing to help" attitude! You took care of the approval within minutes and, if you heard shouting, that was the PI, study coordinator and the sponsor all cheering!!! Thank you again for your help!”
The WU IRB serves as the IRB of Record

180 Institutions

195 non-WU study team members or community partners

A Step Ahead Foundation * Barnes-Jewish Extended Care * Barnes-Jewish Hospital * Barnes-Jewish Hospital North * Barnes-Jewish West County Hospital * BJC Behavioral Health * Breakfast Club * California State Dominguez * District for the Deaf * Revenue west * Life * Emory University * Esse Health * Family Care Health Centers- Carondelet and Forest Park Southeast * Fathers Support Center * Fresenius Medical Care North America, Clinical Studies Department * Gateway Greening * Grace Hill Neighborhood Services * Jewish Community Center * Johns Hopkins * Kansas City University of Medicine and Biosciences * Laureate Institute for Brain Research * Lutheran Senior Services * Maryville University * Meharry Medical College * Memphis Health Center * Mercy Medical Group * Metropolitan St. Louis Psychiatric Center * Missouri Baptist * Moog Center for Deaf Education * Myrtle Hilliard Davis Comprehensive Health Centers, Inc * Institute * National Central Institutional Review Board * National Marrow Donor Program * Houses * Nurses for Newborns * Paraquad * PCM Trials - Act for Health, Inc * Premier Dental Partners * Progress West * Psychological Associates * Quinnipiac University * Rehabilitation Inst. St. Louis * Ride on St. Louis * San Jose State University * Shriner's Hospital for Crippled Children * Southern Illinois University - Edwardsville * Southern Illinois University-School of Medicine-Board of Trustees-Springfield * St. Joseph Inst. For Deaf * St. Louis Area Agency on Aging * St. Louis Connect Care * St. Louis Regional Medical Center * St. Louis University * St. Lukes Hospital * Sudden Infant Death Syndrome Resources * The Betty Kerr People's Health Center * The Learning Tree * Therapeutic Horsemanship * Therapeutic Horsemanship * Total Renal Research, Inc. * Tots Thru Teens Pedi-Truman University * 2-1-1 Missouri Hos-Cleveland * University of Iowa * University of Missouri-Columbia * University of Missouri-Kansas City (UMKC) * University of Missouri-St Louis-The Curators of the UMSL * University of Missouri-St. Louis * University of North Carolina at Chapel Hill * University of Pennsylvania * University of Rochester * University of Southern Florida * University of Washington * Vanderbilt University * Wellesley College * Winghaven Pediatrics * non-WU Study Team Members Not Listed
9 WAYS WE’RE PROVIDING EDUCATION

1. Study Initiation Program

2. SWAT! (Staff With Answers Today!)
   On Call and Office Hours service for the WU research community.

3. Conferences, Series, and Workshops
   Presentations and workshops for the WU community and beyond.

4. Publishing and Media
   Original publication, podcast, and video production.

5. HRPO Digital Commons
   Open access publication of HRPP-oriented tools, research, guidance, and media.

6. myIRB Training
   Hands-on myIRB system training workshops.

7. HRPO On Demand
   Educational events tailored to departmental, investigator, and student needs.

8. Human Subjects Education
   Flexible CITI training options for WU faculty, staff, and community partners.

9. Community Outreach
   Guidance on local community-engaged research. Participation in local and national research ethics conversation.
In 2013, HRPO began the Study Initiation Program in partnership with the Human Research Quality Assurance Program of the Office of the Vice Chancellor for Research.

The program is designed to create collaborative working relationships with researchers that provides for open communication and support of the ethical conduct of human subjects research.

A typical visit provides protocol-specific, hands-on education to Principle Investigators and their staff for newly approved studies with guidance on best practices for issues like consent, study documentation, and regulatory compliance.

In 2014, the program was expanded to provide initiation visits for multisite research and open studies transitioning to a new Principle Investigator.

The SIP offered the following visits in 2014:

- **Study Initiation Visit** – For investigators new to WU, conducting human subjects research in new fields or disciplines, or those with unique or complex study designs.
- **Multisite Study Initiation Visit** – For investigators conducting their first multisite study or simply wanting advice about implementing an approved multisite study.
- **Transition Study Initiation Visit** – For investigators taking oversight as principle investigator for a study that has already been approved and implemented at WU.
- **IND or IDE Study Initiation Visit** – For investigators who hold an IND or IDE at WU.

K. Bennet Bain (PharmD, BCPS) shared her experience of the program:

“As a new practitioner with limited experience in conducting clinical research - the process of developing, designing and implementing a prospective clinical trial seemed very daunting. The SIP presenters have provided invaluable guidance in this respect - their knowledge and insight has helped to streamline the process, improve efficiency and ensure compliance with policies, guidelines, etc... I am very appreciative of having had the opportunity for their involvement and would strongly endorse/encourage utilization of their services to my colleagues.”
The HRPO SWAT! (Staff With Answers Today!) program continued to be a central feature of HRPO education for the WU community in 2014. The SWAT! program features an On Call service by phone or chat in myIRB. HRPO staff are available on call from 8-4 every business day. The Office Hours service makes staff members available in person for three hour shifts in designated locations on both the Danforth and Medical School campus.

The On Call service reached

- 3,300 Individual Contacts
- 70 Departments or Areas

SWAT! Office Hours were available approximately

- 4 days a week

The Office Hours service reached

- 279 Individual Contacts
- 40 Departments or Areas

- 3 hours per shift
- 620 total hours in 2014
HRPO Works With Faculty and Research Staff

“We could not have identified a HIPAA compliant way to search for contact information from study participants without direct input from HRPO consultants. We absolutely could not have solved this conundrum left to our own devices. I am now designing pilot, double-masked randomized sham controlled trials to test the safety and efficacy of an electro acupuncture device for the management of pain... Here again, HRPO consultation was sorely needed. and thankfully, available.”

Mae Gordon (PhD – Director, Vision Research Coordinating Center)

“The HRPO team invited the Kathryn M. Buder Center to present to their staff on: Getting through the IRB Process with Indigenous Research Methods and Community-Based participatory Research in American Indian and Alaska Native Communities. We were invited for a follow discussion via a Podcast and are collaborating on a guidebook for both AI/AN and non-native researchers to work with IRB about honoring and building relationships with tribal communities through the dissemination phases of research projects.”

Molly Tovar (PhD – Director, Kathryn M. Buder Center for American Indian Studies)
Each year the Human Research Protection Office sponsors or co-sponsors educational events to keep the Washington University research community abreast of current regulations, mandates, guidance and trends in human subjects research.

In 2014, HRPO participated in

<table>
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<tr>
<th>54 Presentations</th>
<th>229 Small Group Sessions</th>
<th>30 myIRB Training Sessions</th>
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<tr>
<td>2,139 Attendees</td>
<td>398 Attendees</td>
<td>88 Attendees</td>
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These programs reached:

| 89 WU Areas and Departments | 16 Hospitals and Universities | 4 Federal and State Agencies | 6 Nonprofit or Commercial Entities |
HRPO Digital Commons @ Becker is an open access library that houses materials relevant to the development, conduct, and review of human subjects research studies. The project is an ongoing collaboration between HRPO and Becker Medical Library.

HRPO Digital Commons is a way for WU HRPO to share best practices, educational presentations, and related materials with national and international audiences.

Materials are attributable, searchable and copyrighted so that authors feel comfortable contributing. Access is unrestricted so that individuals anywhere in the world at any time could view and use the information provided.

Since going live in 2012, HRPO Digital Commons has been accessed by 15,816 visitors from 53 different countries.
In 2014, the HRPO Digital Commons, in collaboration with Becker Medical Library, received two national awards.

The Association of American Medical Colleges granted the program the *2014 Building Bridges and Spanning Boundaries Award: Innovations in Research and Research Education*. This award was formally presented at an AAMC meeting and included a $2500 cash prize.

The Health Improvement Institute also awarded the HRPO Digital Commons program with an Award for Excellence.

HRPO Digital Commons has

113 published items

with

15,662 pageviews

and

6,406 downloads
10 most popular downloads of 2014 were:

- “The Challenges of Conducting Research in Developing Countries”
- “Washington University in St. Louis: Research Toolkit for Medical Student Researchers”
- “Ethics and Issues Related to the Use of Technology in Research”
- “Washington University in St. Louis: IRB Meeting Guide”
- “Human Research Protection Office: New Member Training—Guidance for the Non-Scientist”
- “What Makes Research Ethical?: Metabolic Complications of Obesity”

“More Than Meets The IRB” is a series of podcasts on research participants and the people who study them. This series remained popular in 2014, with three additional installments, involving participants from WU and FDA.

These conversations included:

- Social Media Research Ethics with Thomas Rodebaugh (PhD)
- American Indian and Alaska Native Research Ethics with Molly Tovar (PhD) and Pete Coser (MHR)
Key topics of conversation for the IRB Consortium in 2014 included:

- **IRB Review and Submission Process**
- **Managing Incidental Findings**
- **Current Events in Research Ethics**