JOHNS HOPKINS
INSTITUTE for CLINICAL & TRANSLATIONAL RESEARCH

OFFICE OF HUMAN SUBJECTS RESEARCH & THE JOHNS HOPKINS MEDICINE INSTITUTIONAL REVIEW BOARDS

ROLE OF OFFICE

The primary purpose of the Office of Human Subjects Research (OHSR) is to support the activities of the Johns Hopkins Medicine Institutional Review Boards. Johns Hopkins Medicine (JHM) IRBs operate under the direction of Daniel Ford, MD, MPH, vice dean for Clinical Investigation. There are seven JHM IRB Committees. Each IRB Committee is comprised of faculty from various disciplines and a non-scientific member from the community.

The IRB Committees, with support from OHSR staff, provide review and oversight of all research conducted by Johns Hopkins Schools of Medicine and Nursing faculty, Johns Hopkins Health System employees and trainees that involves human participants. Six of the seven IRBs meet weekly and one IRB meets monthly.

Megan Kasimatis Singleton, JD, MBE, CIP oversees the Office of Human Subjects Research. The office has a total of 43 staff members with diverse expertise. Forty staff members are located in Baltimore and three staff members are located at Johns Hopkins All Children's Hospital. Staff members' responsibilities include administrative and compliance review of all applications, scheduling applications for IRB review, consent form review and revision, coordinating required ancillary committee reviews and monitoring research activities for compliance with applicable requirements.

OHSR Leadership:

Megan Kasimatis Singleton, Assistant Dean for Human Research Protections & Director of the Human Research Protection Program

Barbara Scherer, Director of Operations

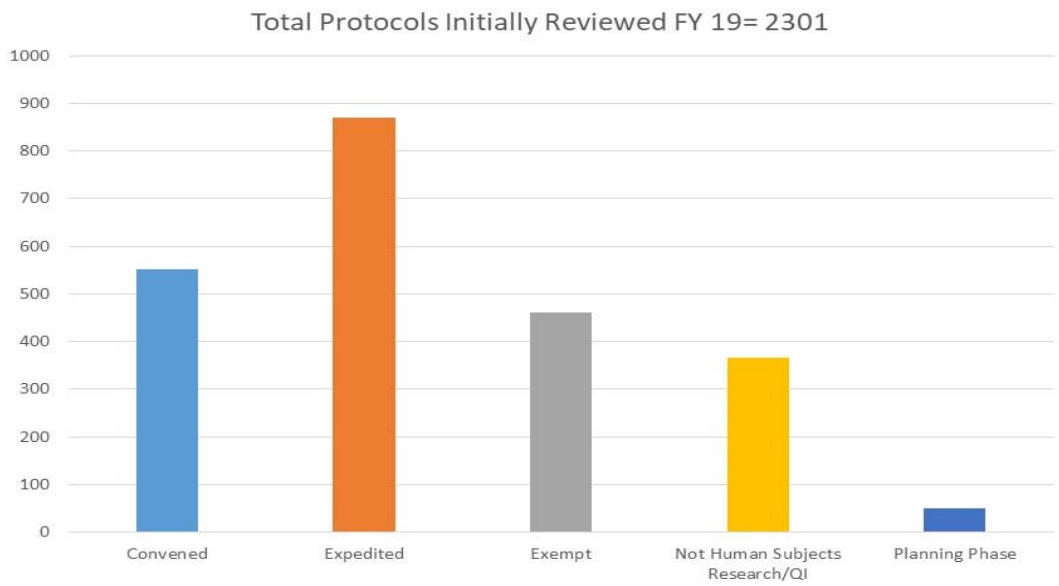
Philip Rocca, Director of Compliance

Fred Luthardt, Director of the Compliance Monitoring Program

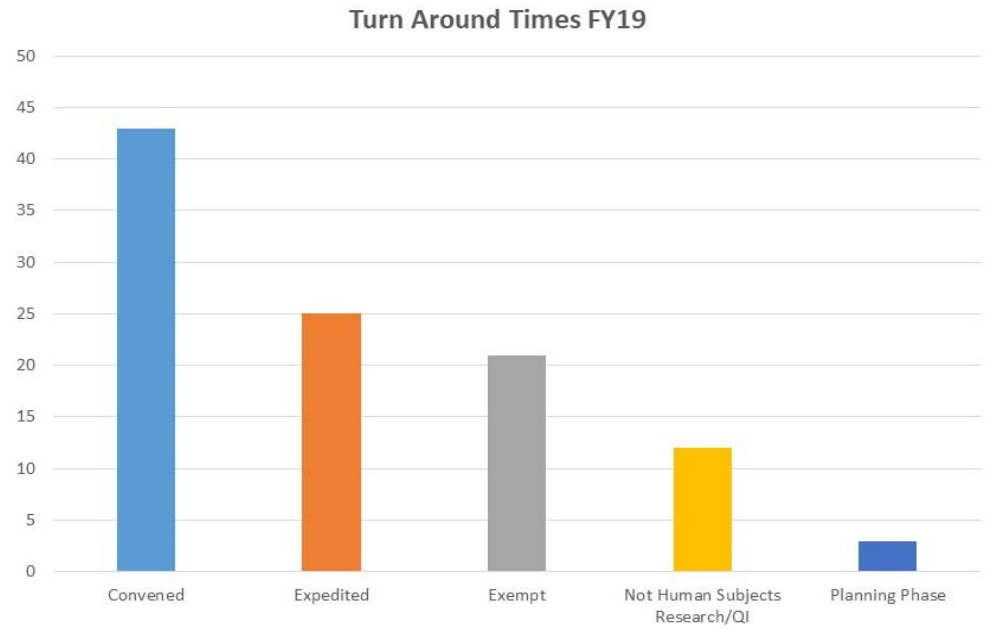
A complete staff listing may be accessed here.

PERFORMANCE IN THE PAST YEAR

In the past year, the JHM IRB completed an initial review of a total of 2301 submissions.



The average turn-around times for IRB review are listed below:



Median Number of Days from Complete Submission to Initial Approval

The research community reports high level of satisfaction with their interactions with the OHSR and IRB review process. The most recent clinical research management survey results indicate that the majority of PIs are satisfied or extremely satisfied with verbal/email communication of IRB staff, the quality of the IRB review and the efficiency of the IRB review.

In the most recent IRB member evaluation, IRB members reported high satisfaction with the IRB review process. Members indicated that the IRB uses an effective decision-making process and IRB members can openly discuss areas of concern.

In April 2019, the JH-ACH IRB Program, a component of the Johns Hopkins Medicine Human Research Protection Program underwent a routine audit by the Food and Drug Administration and the audit yielded no findings.

CHANGES IN THE PAST YEAR

OHSR Staffing and IRB Member Changes:

Due to increased volume and changes in the regulatory landscape, the OHSR staff expanded in the past year with a new consent form specialist, Human Research Compliance Associate and two new compliance monitors joining the team. A new IRB Reliance Coordinator was also hired. Several team members left the OHSR to pursue new opportunities and staff within the office have assumed new roles.

A few notable changes include the following:
Ken Borst has assumed the role of IRB Operations Manager.

Suzanne Damare has assumed a new role as the Biospecimen Program Administrator. In this role she will be responsible for supporting the new Biospecimen Transfer Committee, described below.

There have been several changes in the leadership of the JHM IRBs. In February 2019, Maggie Moon assumed the role of Co-Chair for the JH-ACH IRB and in July 2019 Deb Armstrong assumed the role of Co-Chair for IRB 1. Additionally, several new IRB members joined the IRB Committees this past year. A full listing of IRB membership can be found here.

Single IRB (sIRB) Review:

As noted in last year's report, since 2018, the JHM IRB has taken on a new role as a single IRB (sIRB) for multi-site research. The JHM IRB serves as the central IRB [CIRB] for the Johns Hopkins/Tufts Trial Innovation Center providing sIRB services to investigators who are approved to receive services through the Trial Innovation Network. Additionally to help researchers adhere to the new NIH and Revised Common Rule requirements for sIRB review for multi-site research, the JHM IRB provides sIRB services to researchers across Johns Hopkins University (e.g., School of Public Health) who require these services.

The JHM IRB is currently supporting 23 major sIRB projects with a range of 2 to 50 relying sites. Six of these projects are supported by the Trial Innovation Network and two have principal investigators from the School of Public Health.

In the past fiscal year JHM IRB agreed to serve as the sIRB for 100 new studies, offering letters of support for 51 studies at the time of grant application.

In this same time period, the JHM IRB agreed to rely on an external IRB for a total of 81 studies.

Since initiating its role as a sIRB the JHM IRB has introduced several new innovations to support the sIRB process including a new consent model for sIRB studies, targeted trainings for relying sites and a new required online training for JHM researchers relying on external IRBs.

The JHM IRB has also made many electronic system enhancements to support the sIRB review process.
Through TIC support, the JHM IRB, in collaboration with IT@JH's Research Environment Systems [RES] team launched a new platform in November 2017 to enable sIRB submissions from external PIs for projects where JHU is not engaged in the research. To date, this system, called JH-sIRB has enabled the submission and review of three TIC projects. The JH-sIRB system is the primary IRB submission system for TIN studies for which Johns Hopkins is not participating in the research.

Likewise, the JHM OHSR has been working collaboratively with RES to make substantial improvements to JHM IRB's main submission system, eIRB2. This past year a new functionality was launched which enabled individual relying sites to be added to a parent protocol as separate "sites", each with a dedicated section of the study application where information about that site may be captured and reviewed by the JHM IRB. This enhancement greatly improved processing time for sIRB studies as sites can now be added simultaneously rather than via a change in research (CIR) to the parent protocol where only a limited number of sites could be added at one time.

In November 2018, a new functionality was created allowing individual participating sites (psites) to submit site specific modifications (pMods). This enhancement enabled local study teams to submit site-specific changes to the JHM IRB including site specific recruitment materials and local study team changes, such as a change in PI or identification of a new conflict of interest. In the coming year individual participating site protocol event reports will also be enabled through a psite protocol event report function.

Additionally, in May 2019, the eIRB system was upgraded to permit direct access to participating site records for relying site investigators and lead study contacts. With this feature relying sites may communicate directly with the JHM IRB. Participating sites may either access their site's record via federated authentication or through a specific account provisioned by the JHM IRB/RES team.

To help support researchers requiring sIRB services, the JHM IRB has developed a number of online resources including a dedicated email address for inquiries regarding sIRB review and a new section of the OHSR website. Resources and tools are now available to assist investigators with initial reliance requirements and ongoing sIRB requirements

For more information about sIRB review, visit the IRB's website or contact the IRB's Reliance Manager, Janelle Maddox-Regis.

The Revised Common Rule

On January 21, 2019 a new version of the Common Rule, the primary federal regulations governing human subjects protections went into effect. All federally funded human subjects research studies must comply with the Revised Common Rule. In addition, all research conducted in Maryland must follow the Revised Common Rule. Protocols initially approved by the JHM IRB prior to January 21, 2019 must continue to adhere to the original Common Rule requirements. The major changes incorporated in the Revised Common Rule include new required consent elements and a new required consent format, changes to the requirements for continuing review and an expansion of the types of research activities that may qualify for exemption.

To help researchers adjust to the Revised Common Rule the OHSR held several educational sessions about the revised rule. The eIRB system was revamped to incorporate the Revised Common Rule requirements for new applications and new forms, tools and templates, updated to adhere to the new rule requirements were posted on the IRB's website in a section dedicated to the Revised Common Rule. Research teams with questions about the requirements for the Revised Common Rule are encouraged to attend the IRB's open office hours.

Integration of IRB and Data Trust Review Processes

In response to feedback from last year's Investigator Satisfaction Survey, the OHSR worked closely with the Data Trust Council to integrate the Data Trust review process as a formal ancillary review within eIRB. Applications requiring Data Trust or IT Risk review now are identified as part of the initial IRB submission process. The IRB application was also updated to include a new "Risk Tiers Worksheet" which must be completed by study teams as part of every eIRB application and contains information outlining how study teams plan to manage, store and share their data. The OHSR welcomes feedback about mechanisms to improve this integration as we continue to partner with the Data Trust to improve the review processes for projects requiring review by both Committees.

NEW DEVELOPMENTS FOR THE UPCOMING YEAR

The upcoming year will continue to bring new changes in human subjects protections. The FDA has a federal mandate to harmonize their regulations with the Revised Common rule to the extent possible by the end of 2019. We anticipate additional regulatory changes from the FDA and expect new guidance to be released from the Office of Human Research Protections related to implementation of the Revised Common Rule. Research teams are encouraged to check the OHSR website for updates.

One key provision of the Revised Common Rule is the extension of the sIRB review requirement to all federally funded cooperative research [research involving more than one site]. As of January 2020, all federally funded cooperative research receiving initial approval by the JHM IRB must comply with the sIRB review requirements. This requirement extends the need for sIRB review beyond NIH-funded studies to studies funded by other federal agencies. As sIRB review requires planning and careful coordination with relying sites, investigators are encouraged to

contact the OHSR now to prepare for upcoming multi-site research projects subject to these new requirements. The OHSR will offer several training sessions this fall to help investigators prepare for the expanded sIRB review requirements. Additional information about upcoming training can be found here.

Biospecimen Transfer Committee

In February 2019, a new policy was released related to biospecimen transfers. This policy requires that for external transfers of biospecimens for research, there be evidence of a research collaboration with JHU investigators. It also formally establishes a Biospecimen Transfer Committee charged with reviewing requests to transfer biospecimens to external entities. Researchers transferring specimens for research purposes are required to complete a Biospecimen Transfer Information Sheet in addition to any Material Transfer Agreement. Please see the OHSR forms page to access the necessary form. In the coming year the Biospecimen Transfer Committee review process will be formally integrated into eIRB as an ancillary review.

INCORPORATION OF SERVICES INTO GRANT APPLICATION

JHU researchers preparing grant applications for multi-site federally-funded research projects must incorporate a plan within their grant application to meet both the NIH and Revised Common Rule requirements for sIRB review. JHM investigators seeking to rely on an external IRB and those interested in requesting sIRB services from the JHM IRB must submit a formal request for a letter of support from the OHSR through the online 'Reliance Request' tool.

Investigators preparing grant applications for multi-site research are encouraged to reach out to the OHSR early in the grant preparation process. Early contact will enable the OHSR to provide all required information for the grant application including a) a letter of support for the JHM IRB to serve as the sIRB, b) grant text to describe the sIRB plan and c) a budget for sIRB fees. **A major change is that sIRB fees need to be included in the direct costs for the grant.**

BEST WAY TO WORK WITH PROGRAM

The OHSR offers a number of resources to help researchers navigate the IRB review process.

For general information about policies and guidelines and the IRB review process, visit the JHM IRB website.

For questions about the eIRB system contact the IRB help desk at 410-502-2092 or email jhmeirb@jhmi.edu.

For questions about training requirements or enrolling in online courses, contact the IRB Training Specialist at 410-502-3860 or email jhmeirb@jhmi.edu.

Walk-in Office Hours: IRB staff are available Tuesday 10:00 - 12:00 and Thursday 12:00 - 2:00 during walk-in office hours. Our office is located in Reed Hall Room B-130.