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, the 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 University/Johns Hopkins Health System faculty, staff and students 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 38 staff members with diverse expertise. Thirty-five 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

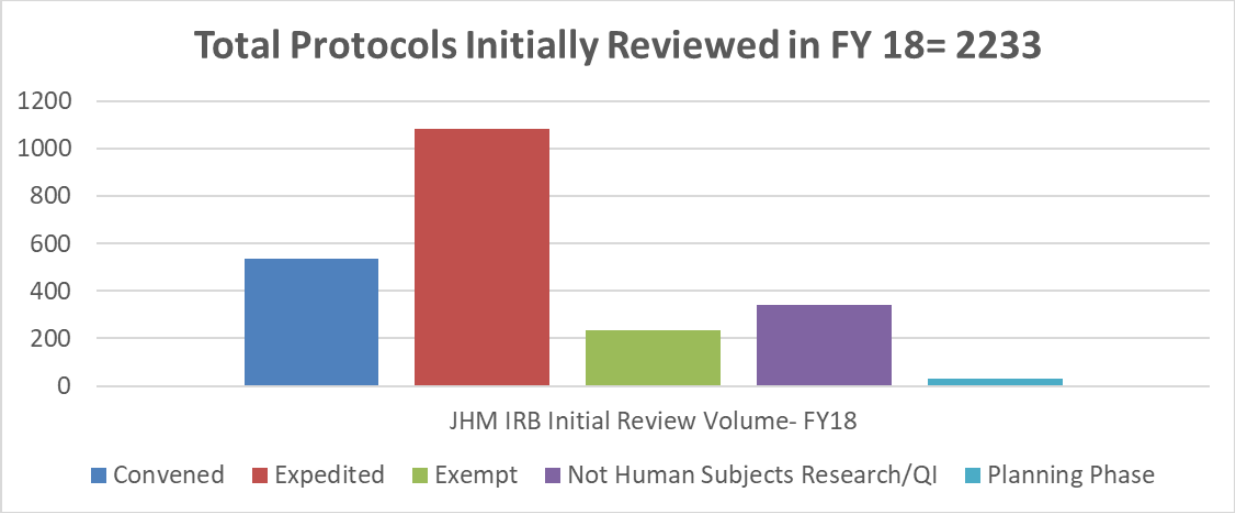
Barbara Scherer, Director of Operations

Philip Rocca, Director of Compliance

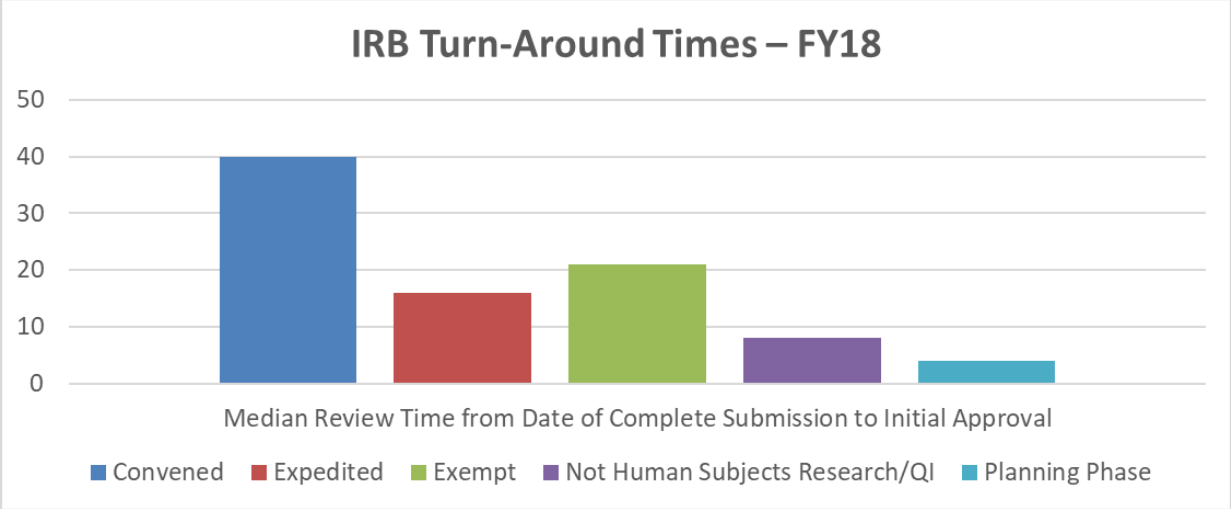
A complete staff listing may be accessed here.

PERFORMANCE IN THE PAST YEAR

In the past year, the JHM IRB completed an initial review of a total of 2233 submissions.



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



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 approximately 85% 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. Survey respondents identified two key areas for improvement; a) enhancement of the intersection of IRB review with other required ancillary reviews to reduce overall review time and b) further streamlining the eIRB application to improve user experience.

In the most recent IRB member evaluation, IRB members reported high satisfaction with the IRB review process. Members indicated that IRB deliberations are free of inappropriate influence from institutional leaders or others and the IRB uses an effective decision-making process.

The JHM IRB has recently undergone two successful evaluations by external oversight entities. In 2016, the JHM IRB received full re-accreditation by its accrediting body, the Association for the Accreditation of Human Research Protections Programs (AAHRPP). In May 2017, the JHM IRB

underwent a routine audit by the Food and Drug Administration and the audit yielded no findings.

CHANGES IN THE PAST YEAR

The staffing of the OHSR has remained consistent in the past year. The office is currently seeking a new research subject specialist to replace Matthew Riesner who left the OHSR in July 2018.

There have been several changes in the leadership of the JHM IRBs. In July 2018 Doug Smith assumed the role of Chair and Craig Hendrix assumed the role of Co-Chair for IRB 2. Lisa Lubomski became Co-Chair of IRB X in July. Additionally, several new IRB members joined the IRB Committees this past year. A full listing of IRB membership can be found here.

In the past year, 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 requirement for sIRB review for multi-site research, the JHM IRB is committed to providing sIRB services to researchers across Johns Hopkins University who require these services.

Since April 2017, the JHM IRB has begun serving as the single IRB for 11 major multi-site studies with a range of 4 to 45 relying sites. The JHM IRB has also agreed to provide oversight for at least one non-JHU researcher or research site for an additional 40 studies. In this same time period, the JHM IRB agreed to rely on an external IRB for 52 studies.

Since April 2017, the JHM IRB has provided 52 letters of support related to sIRB review for grant applications. The JHM IRB agreed to serve as the sIRB for 31 multi-site projects and agreed to rely on an external IRB for 21 projects, if these projects are successfully funded.

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. The JHM IRB is also undertaking a major revision of the eIRB system to enable direct communication between the JHM IRB and relying site study teams.

As part of its work with the Trial Innovation Network, the JHM IRB is actively collecting metrics on sIRB review and evaluating user experiences. The JHM IRB welcomes feedback to best inform these new processes as they are developed.

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

NEW DEVELOPMENTS FOR THE UPCOMING YEAR

The upcoming year will bring major new changes in human subjects protections.

On January 21, 2019 a final revision to the Common Rule (the key federal regulation governing human subjects research) will go into effect. The new rule includes changes to the categories of

research that may qualify as low risk [eligible for an exempt determination], creates flexibility in the requirements for continuing review and introduces new consent form requirements.

In response to these new requirements, the OHSR plans to release a new consent form template in Fall 2018, will revise the eIRB application to accommodate the new rule and will release new guidance documents to assist researchers in incorporating the new requirements in their IRB applications.

The IRB, in conjunction with the Data Trust Council, is working to streamline the review of projects requiring IRB/Data Trust approval. This effort includes a) revisions to the eIRB application to better identify projects requiring Data Trust Council review at the time of IRB application and b) guidelines for researchers working with Johns Hopkins Health System data that will direct researchers to best practices for data management and simplify the review process for these projects.

To prepare the research community for the changing regulatory environment, the OHSR will be offering a number of new training sessions [both in person and online].

Visit the IRB's training page frequently for information on course offerings in Good Clinical Practices, the new Common Rule, and sIRB review.

INCORPORATION OF SERVICES INTO GRANT APPLICATION

As of January 25, 2018, JHU researchers preparing grant applications for multi-site research projects must incorporate a plan within their grant application to meet NIH's new sIRB review requirements. 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.