

# Office of Human Subjects Research and Institutional Review Board (IRB)



JOHNS HOPKINS  
MEDICINE

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## Financial Relationships

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## Commercial Support

This educational activity has not received any form of commercial support.

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This presentation will not discuss the off-label or investigational use of a drug, biological product, or medical device name.

# Overview

JHM IRBs are responsible for protecting the rights and welfare of the human subjects of research conducted by faculty and staff at the Institutions.

To fulfill the agreement underlying the assurances, and to satisfy institutional policy, all faculty and staff at the Institutions must submit for JHM IRB review on any human subject research project, regardless of funding source (or lack thereof) and/or location at which the research will be conducted.

# IRBs at Johns Hopkins

- First established in 1971
- Three separate IRBs
  - 1. School of Medicine
  - 2. School of Public Health
  - 3. Homewood
- Where to submit would be the PI's primary affiliation.

# SOM IRBs meeting composition and frequency

- 8 IRBs (1,2,3,5,6,X, EC and JHM ACH)
- Each IRB meets weekly except JHM ACH IRB and EC
- IRBs meet for 2 hours; review 20 plus applications/week including:
  - New Applications
  - Change in Research
  - Continuing Review
  - Protocol Events
- Agendas are finalized 7 to 10 days prior to the meeting

# Logging into eIRB

[https://www.hopkinsmedicine.org/institutional\\_review\\_board/](https://www.hopkinsmedicine.org/institutional_review_board/)

JOHNS HOPKINS MEDICINE MENU COVID-19 SEARCH

☰ Institutional Review Board

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## The Johns Hopkins Medicine IRBs

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### Quick Links

Contact Us > **Log in to eIRB >**

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# Investigator Home Page



- Left Navigation Bar
  - Account Management (Non- JHED Users Only)
  - My IRB Studies
  - Create New Application

- Welcome Message
  - Link to Archive eIRB website
  - User alerts
  - Important research community eIRB updates and announcements

- Account Management
- Admin Tools
- Biospecimens Transfer Workspace
- Compliance Team Workspace
- Department Review Workspace
- eIRB Training
- IRB Review Workspace
- IRB 1 Workspace
- IRB 2 Workspace
- IRB 3 Workspace
- IRB 5 Workspace
- IRB 6 Workspace
- IRB All Workspace
- IRB EC Workspace
- IRB EXT Workspace
- IRB X Workspace
- JHM ACH IRB Workspace
- My IRB Studies
- Sibley Workspace
- Suburban Workspace
- Create New Application
- Create...

## Welcome to eIRB2

Updates to the Human Subjects Research Compliance Training Registration Process: Starting January 10<sup>th</sup>, 2022, improvements will be implemented to the registration process for Human Subjects Research (HSR) Compliance Training. Investigators and Study Team Members will be able to enroll in required training courses (initial training, ICH GCP and recertification) by selecting one "bundle" in myLearning. Once enrolled in myLearning, you will be directed to the CITI site where courses will be added to your plan by selecting the "bundle" you wish to complete. Please review this guide on how to get started. For additional questions, please contact the IRB Help Desk at [jhmeirb@jhmi.edu](mailto:jhmeirb@jhmi.edu).

**NOTICE: eIRB101 Training** is available virtually every 3<sup>rd</sup> Friday of the month from 10 am - 12 pm. Please use the following link to register: <http://lms14.learnshare.com/l.aspx?CID=89&A=2&T=358053> **Email** [jhmeirb@jhmi.edu](mailto:jhmeirb@jhmi.edu) **to cancel registration.**

*eIRB1 is accessible to study teams and IRB members and staff in a read-only format for the foreseeable future. For studies that were approved in the original eIRB system, you may view the application, its associated FSAs and approval letters, and approved stamped documents at the following link: <https://archive.e-irb.jhmi.edu>*

**Questions? We have answers!**  
Click here to contact the JHM IRB

Action Required	Researcher Prep	In Process	Approved	All My IRB Studies
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### New Application

Filter by ? ID

No data to display.

◀ page 1 no results ▶  / page



# Investigator Tabs

## Action Required (*default tab*)

- Studies that have been returned for PI response

## Researcher Prep

- Studies that have never been submitted

## In Process

- Studies awaiting Pre-IRB or IRB review

## Approved

- Studies that have been approved

## All My IRB Studies

- All approved, disapproved, expired, terminated, or withdrawn studies with which you are associated.

Navigation tabs: Action Required | **Researcher Prep** | In Process | Approved | All My IRB Studies

### New Application

Filter <sup>?</sup> ID   + Add Filter ✕ Clear All

ID	Name	Current State	State Change Date	PI Last Name
NA_00072994	IRB Staff Application	Researcher Prep	1/25/2014 12:18 PM	Singleton

1 items | page 1 of 1 | 10 / page

### Change In Research

Filter <sup>?</sup> ID   + Add Filter ✕ Clear All

ID	Name	Study Title	Current State	State Change Date	PI Last Name
CIR00056270	Change In Research: CIR00056270 For: IRB000000007	Test application for 2019 Release #3.	Researcher Prep	2/6/2020 1:23 PM	Scherer

1 items | page 1 of 1 | 10 / page

### Continuing Review/Progress Report

Filter <sup>?</sup> ID   + Add Filter ✕ Clear All

No data to display.



# Application Workspace

## Current Status

- Displays the current status of the application. See [‘New Application Workflow’](#) to understand what the different states of the application are.

## Study Vital Statistics

- Displays the study title, IRB number, PI, IRB committee, review type, date submitted and review date.

## Notices

- Flags and alerts will appear in the Notices box on the left hand side.

The screenshot shows the 'Application Workspace' interface. A red circle highlights the 'Current Status' tab, which is currently set to 'Researcher Prep'. A red arrow labeled 'Current Status' points to this tab. Below the tabs are links for 'Project Editor', 'View/Edit', 'Print Friendly', and 'View Differences'. Under 'Current Activities', there are icons and links for 'Request Study Team Participation' and 'Submit IND Safety'. A red box highlights the main content area containing the following information:

- Title: IRB Staff Application
- Number: NA\_00072994
- Principal Investigator: Megan Singleton
- IRB Committee:
- Review Type: Expedited
- Date Submitted:
- Review Date:
- Common Rule Version: The Revised Common Rule 2019

At the bottom of this box is the text 'IRB Review Form'. To the right, a 'Notices and Flags' section is highlighted with a red oval and a red arrow labeled 'Notices and Flags'. It contains a 'Notices' box with a red oval around it, listing: 'Application Waiting To Be Submitted'. A red arrow labeled 'Study Vital Statistics' points to the main content area.

# Application Workspace

## IRB Review List

- Displays the review date, review type, outcome, and letter sent (*only if the application has undergone IRB review*).

### IRB Review Items:

Review Date	Review Type	Outcome	Letter Sent	Response	Agenda Topic
4/19/2023	Expedited	Approved	<a href="#">View Letter</a>		New Application
4/4/2023	Convened	Approved with Administrative Changes	<a href="#">View Letter</a>	<a href="#">View Response</a>	New Application

<input type="checkbox"/> Male Children	<input type="checkbox"/> Female Children	<input type="checkbox"/> Prisoners
<input type="checkbox"/> Written Consent	<input type="checkbox"/> Oral Consent	<input checked="" type="checkbox"/> Consent Waiver
<input type="checkbox"/> Written Assent	<input type="checkbox"/> Oral Assent	PRA - PRA Not Required
<input type="checkbox"/> COI	<input type="checkbox"/> Drugs	<input type="checkbox"/> Devices / <input type="checkbox"/> Investigational Devices
<input type="checkbox"/> Imaging/Radiation	<input type="checkbox"/> Pregnant Women	<input type="checkbox"/> Neonates
<input type="checkbox"/> Non English Speakers	<input type="checkbox"/> Monetary Support	<input type="checkbox"/> Material Support

# Application Workspace

## Workspace Tabs

### History Log

- Reflects completed activities.

### Reviews

- Lists all the ancillary reviews and will show which ones are triggered.

### Reviewer Notes

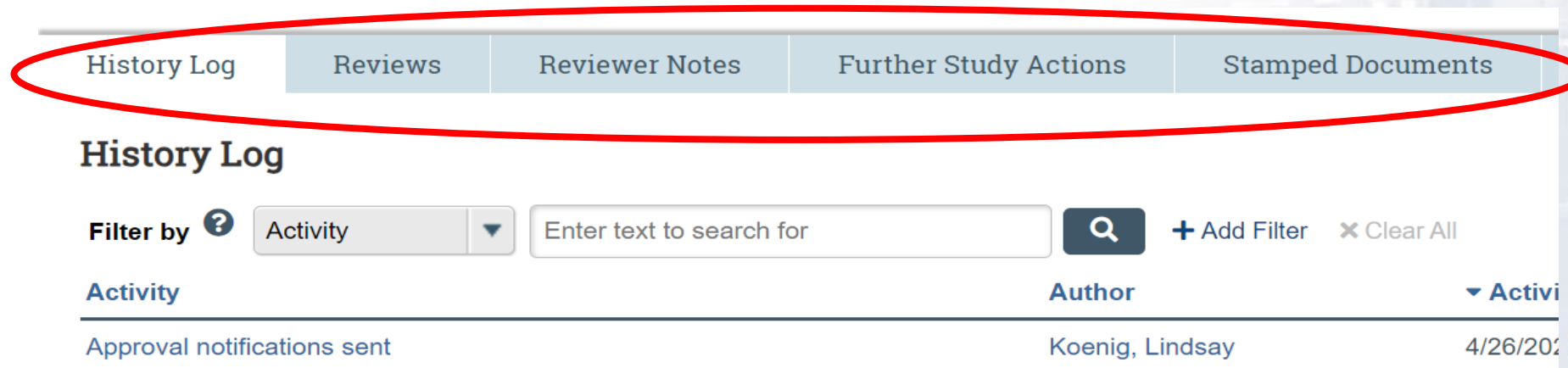
- Displays a collective list of IRB issues.

### Further Study Actions

- Displays after an application has secured initial IRB approval. Where your CIRs, CRs, etc. are located.

### Stamped Documents

- Can access all your stamped documents from this tab after application has been approved.



Activity	Author	Activity
Approval notifications sent	Koenig, Lindsay	4/26/202

# Application Workspace

## Project Editor

- The **View/Edit** function is how you access the application
- The **Print Friendly** function is similar to the *View* function which allows you to access the application and view in a continuous scroll.
- **View Differences** function will show any changes made to the application since the last submission.

## Current Activities

- Displays a list of activities that may be completed.



The screenshot shows the Johns Hopkins eIRB2 Application Workspace interface. At the top, there is a header with the Johns Hopkins School of Medicine logo and the text "eIRB2". Below the header is a navigation bar with "Dashboard" and "All IRB Studies" options. The main content area is divided into two columns. The left column contains a sidebar with a "Current Status" section showing "Researcher Prep" and a "Project Editor" section with links for "View/Edit", "Print Friendly", and "View Differences". Below this is a "Current Activities" section with three items: "Request Study Team Participation", "Submit IND Safety Reports", and "Agree to Participate". The right column displays the "Application Workspace" details for an "IRB Staff Application" with the number "NA\_00072994" and Principal Investigator "Megan Singleton". Other details include "IRB Committee:", "Review Type: Expedited", "Date Submitted:", "Review Date:", and "Common Rule Version: The Revised Common Rule". At the bottom right of the workspace area is a link for "IRB Review Form".

# Navigation Panel

- Navigation Panel appears on left side of application.
- The Navigation Panel shows eIRB application sections on the left side and is available on all actions (new, change in research, continuing review, etc.).
- Each available application section will appear on the left navigation panel allowing you to jump to a specific section in the application.

The screenshot displays the Johns Hopkins eIRB2 application interface. At the top, the Johns Hopkins School of Medicine logo and 'eIRB2' are visible. Below the header, there are 'Validate' and 'Compare' buttons. The main content area is titled 'Editing: NA\_00072994'. On the left side, a navigation panel is highlighted with a red border, listing various sections: 1 - General Information (highlighted in orange), 2 - Study Team Compliance Training, 6 - Protocol Information, 7 - Clinical Trials Information, 8 - Conflict of Interest, 9 - Support Information, 10 - Study Location, 11 - Sample Size, and 12 - Participant Information. The main content area shows the '1 - General Information' section with the following fields:

- 1. \* **Principal Investigator:**  
Click **Select** to choose PI:  
Megan Singleton [Select] [X]
- 2. \* **Will the PI obtain consent for this study ?**  
 Yes  No [Clear](#)
- 3. \* **Is the PI a JHHS RN?**  
 Yes  No [Clear](#)
- 4. \* **Indicate the PI's primary affiliation:**  
(Select 'Other (Affiliation Not Listed)' if the PI's primary affiliation is not listed):  
Other - Affiliation Not Listed [Select] [X]
- 5. \* **Title of Study:**

# The IRB Reviews

- **Convened:** more than minimal risk and/or research involving vulnerable populations; full board review
- **Expedited:** must present no more than minimal risk as defined by DHHS/FDA regulations; 1 reviewer
- **Exempt:** Includes some research done in educational settings, observations of public behavior, surveys, most chart reviews, use of publicly available data, or taste and food quality evaluation. This category does not apply to FDA regulated research
- **Not Human Subjects Research (NHSR)/ Quality Improvement (QI):** Research does not involve identifiable human subjects/their data (NHSR). Data collection and analysis activities in the health services area that are not intended for general scientific knowledge, but rather are used as a management tool to improve the provision of services to a specific health care population (QI/QA)



# Outcomes

## Approved/Acknowledged

Application is approved/acknowledged and research may begin.

## Approved/Acknowledged with Administrative Changes

The application requires administrative changes and re-review before final approval documents can be issued.

## Tabled

The application does not meet the criteria for approval at the time of review. A letter will be issued to the PI with review issues to resolve.

## Disapproved

Application is disapproved. A new application must be submitted to pursue this study

# Who can be PI:

The following may serve as PIs of HSR studies reviewed by the JHM IRBs:

- Faculty members of The Johns Hopkins University who are compensated from the institution (including Part Time Faculty)\*;
- Properly credentialed clinicians, employed by a JHM entity
- The following groups of people may serve as PI if they meet the educational, experience and any additional requirements agreed upon by their departments and the OHSR, and provide a letter of support from an appropriate department representative
  - Designated senior staff members of the Johns Hopkins Applied Physics Lab;
  - Registered nurses or Nurse Practitioners in the Johns Hopkins Health System (JHHS);
  - Non-faculty pharmacists in the Department of Pharmacy at the Johns Hopkins Hospital;
  - Non-faculty physical and occupational therapists in the Department of Physical Medicine and Rehabilitation;
  - Senior staff members designated by departmental authorities

# JHM IRB Request a Consult Service

Need help navigating the IRB review process?

Use the QR code or visit the IRB website

<https://www.hopkinsmedicine.org/institutional-review-board/about/contact> to

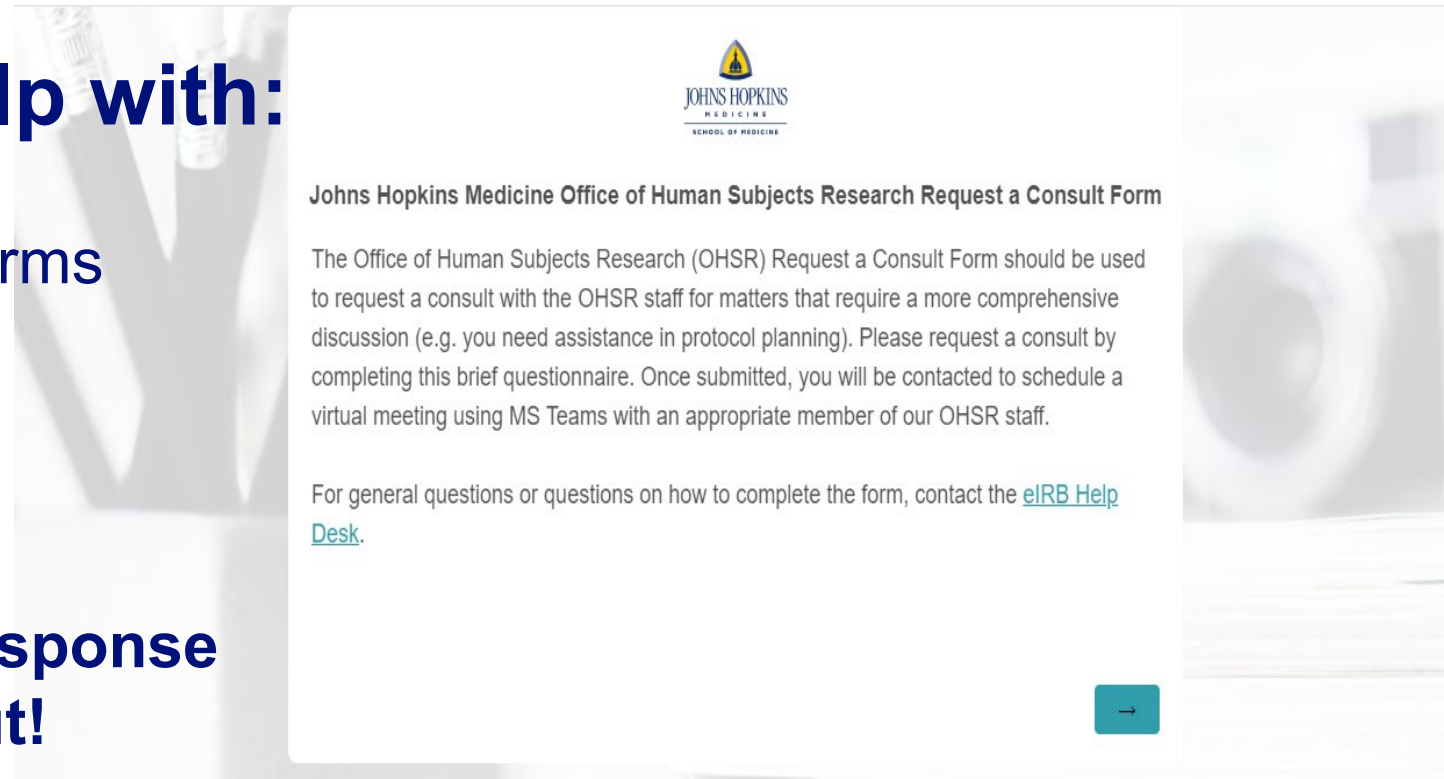
request a consult and be matched with IRB staff who will address your needs.



## Sample topics we can help with:

- Protocol planning
- Determining IRB review type & forms
- IRB regulations and policies
- Recruitment & consent
- Responding to IRB review

**Consult requests will receive a response within 24 hours – please reach out!**



# Additional Training

Join us for JHM IRB's monthly Office Hours! April's session is on the 30th at 1pm and will discuss exempt and expedited research. Our Exempt/Expedited Team will provide a brief category overview, explanation of the Exempt/Expedited OHSR pathways and common misconceptions when submitting for this type of research. [Register Here](#) or search "IRB Office Hours" in [MyLearning](#).

[eIRB 101: An Intro to SOM IRB and Submitting an Application](#) -Researchers will gain a better understanding of how to prepare and submit an IRB application, how to respond to IRB issues, how long the review process takes, and how to submit further study actions. Such as continuing reviews and changes in research.

[IRB Basics course](#) -teaches the history of Institutional Review Boards (IRBs) and provides researchers with the basics for conducting human subjects research at JHM., the meaning of IRB review types and the JHM IRB review process.

# Questions

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Find staff phone numbers, emails  
and Teams Chat links at  
[https://www.hopkinsmedicine.org/institutional\\_review\\_board/about/contact.html](https://www.hopkinsmedicine.org/institutional_review_board/about/contact.html)