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

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Disclosure Statement

Financial Relationships

All individuals involved in the planning and delivery of this activity have no relevant financial relationship(s) with ineligible companies.

Commercial Support

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

Off-Label or Investigational Use

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

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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.

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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.

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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

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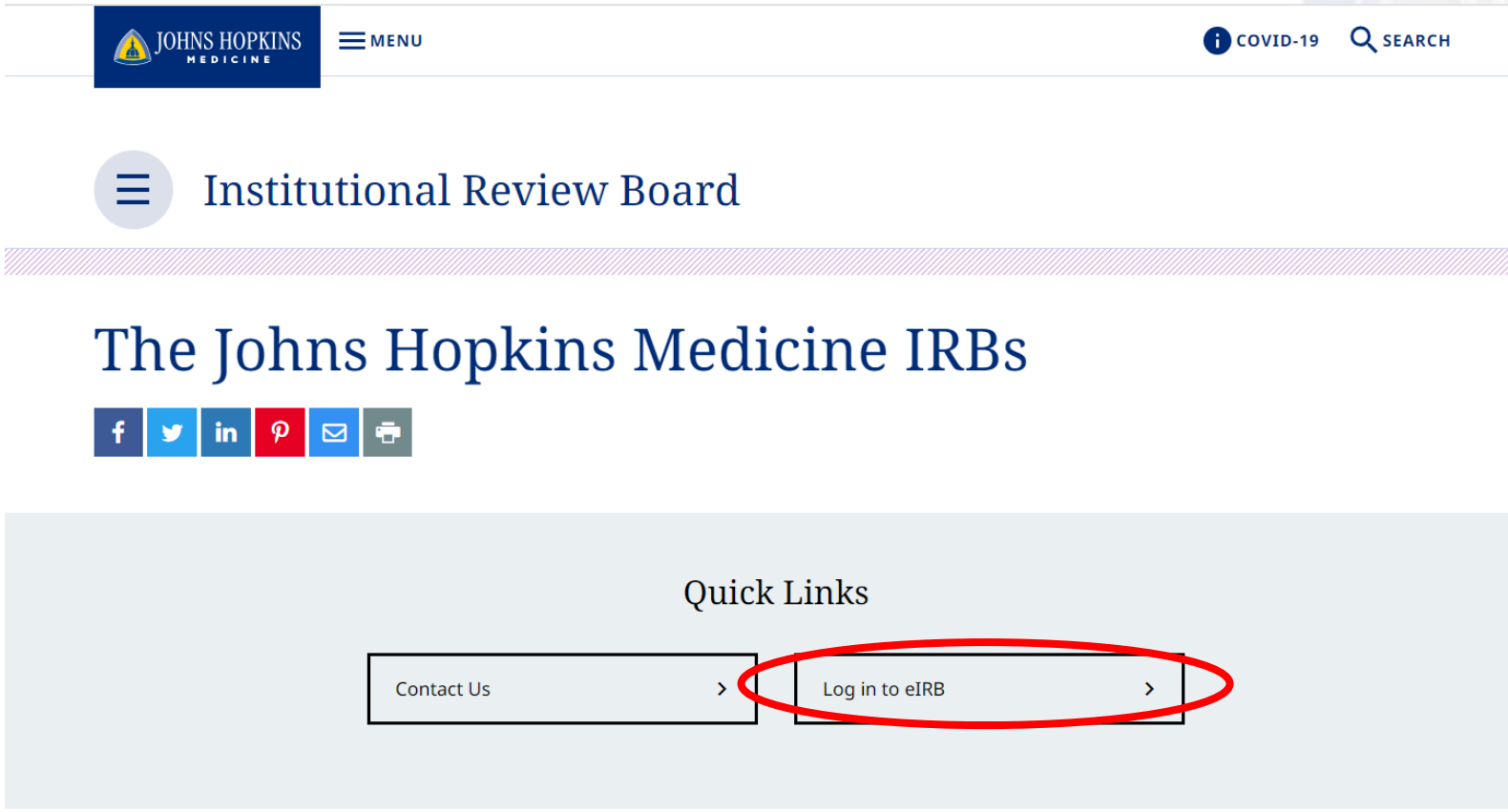
Logging into eIRB

https://www.hopkinsmedicine.org/institutional_review_board/



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Investigator Home Page

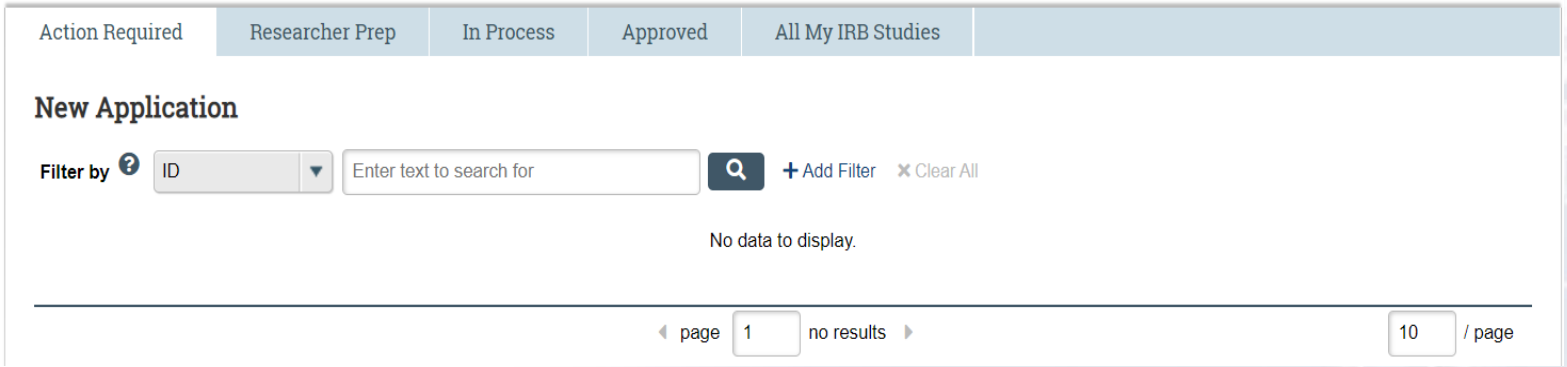
- Left Navigation Bar
  - Account Management (*Non- JHED Users Only)*
  - My IRB Studies
  - Create New Application

- Welcome Message

  -Link to Archive eIRB website

  - User alerts

  -Important research community eIRB updates and announcements



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Investigator Tabs

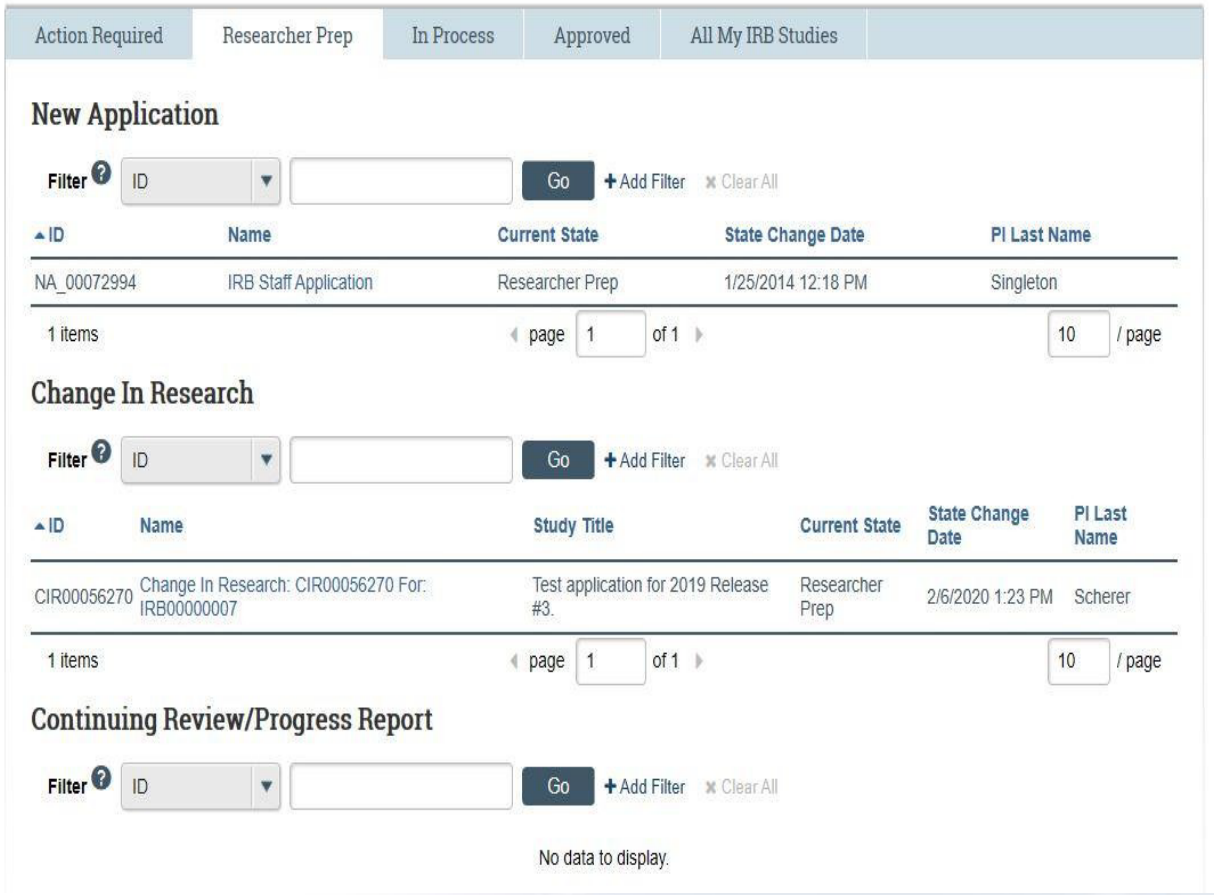
Action Required (*default tab*)
- Studies that have been returned for PI response

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.



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Application Workspace

Current Status

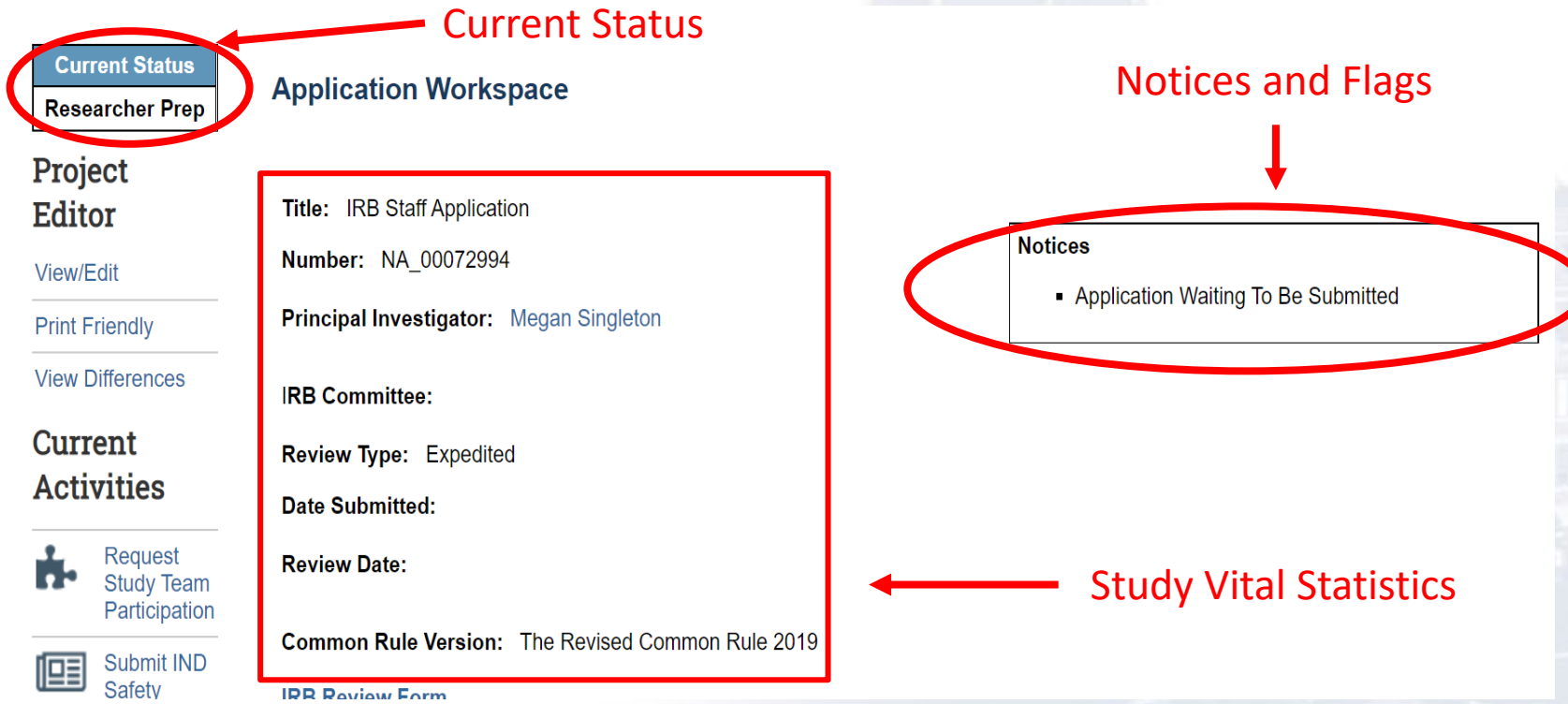
- Displays the current status of the application. See 'New Application Workflow' to understand what the different states of the application are.

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.



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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	View Letter		New Application
4/4/2023	Convened	Approved with Administrative Changes	View Letter	View Response	New Application

☐ Male Children	☐ Female Children	☐ Prisoners
☐ Written Consent	☐ Oral Consent	☑ Consent Waiver
☐ Written Assent	☐ Oral Assent	PRA - PRA Not Required
☐ COI	☐ Drugs	☐ Devices / ☐ Investigational Devices
☐ Imaging/Radiation	☐ Pregnant Women	☐ Neonates
☐ Non English Speakers	☐ Monetary Support	☐ Material Support

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Application Workspace

Workspace Tabs

History Log

- Reflects completed activities.

Reviews

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

Reviewer Notes

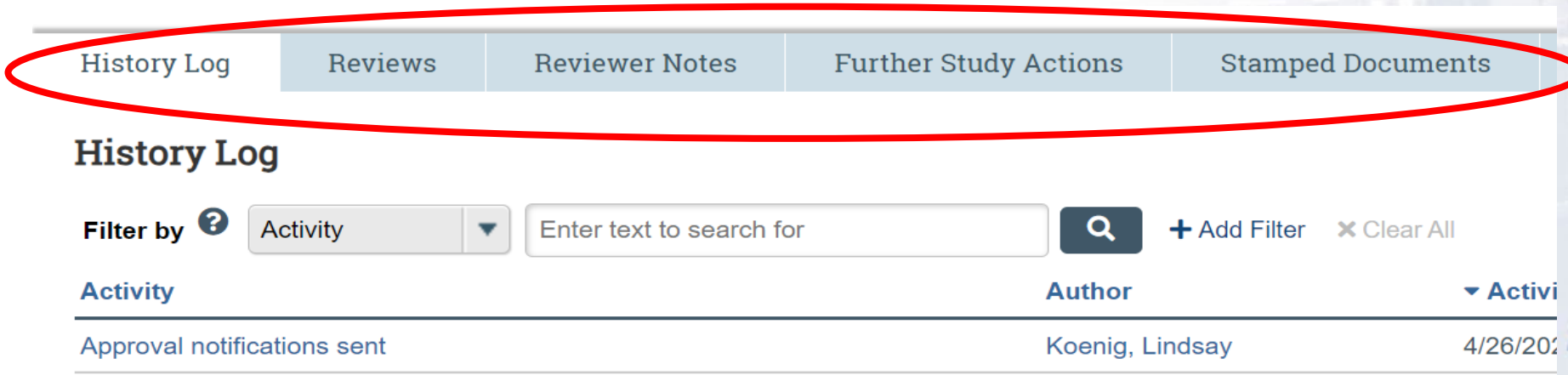
- Displays a collective list of IRB issues.

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.



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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.

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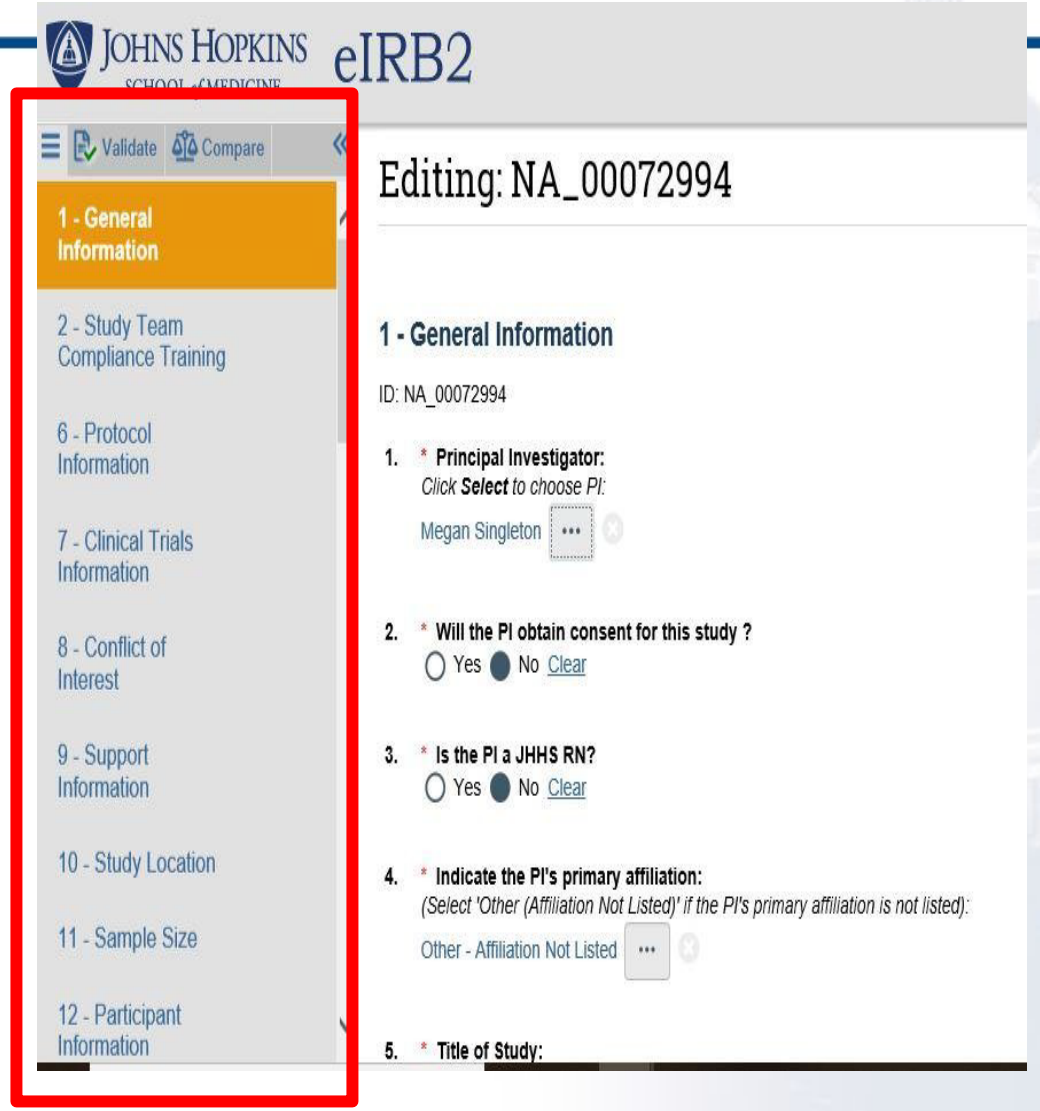
Navigation Panel

- 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.



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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

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JHM IRB Request a Consult Service

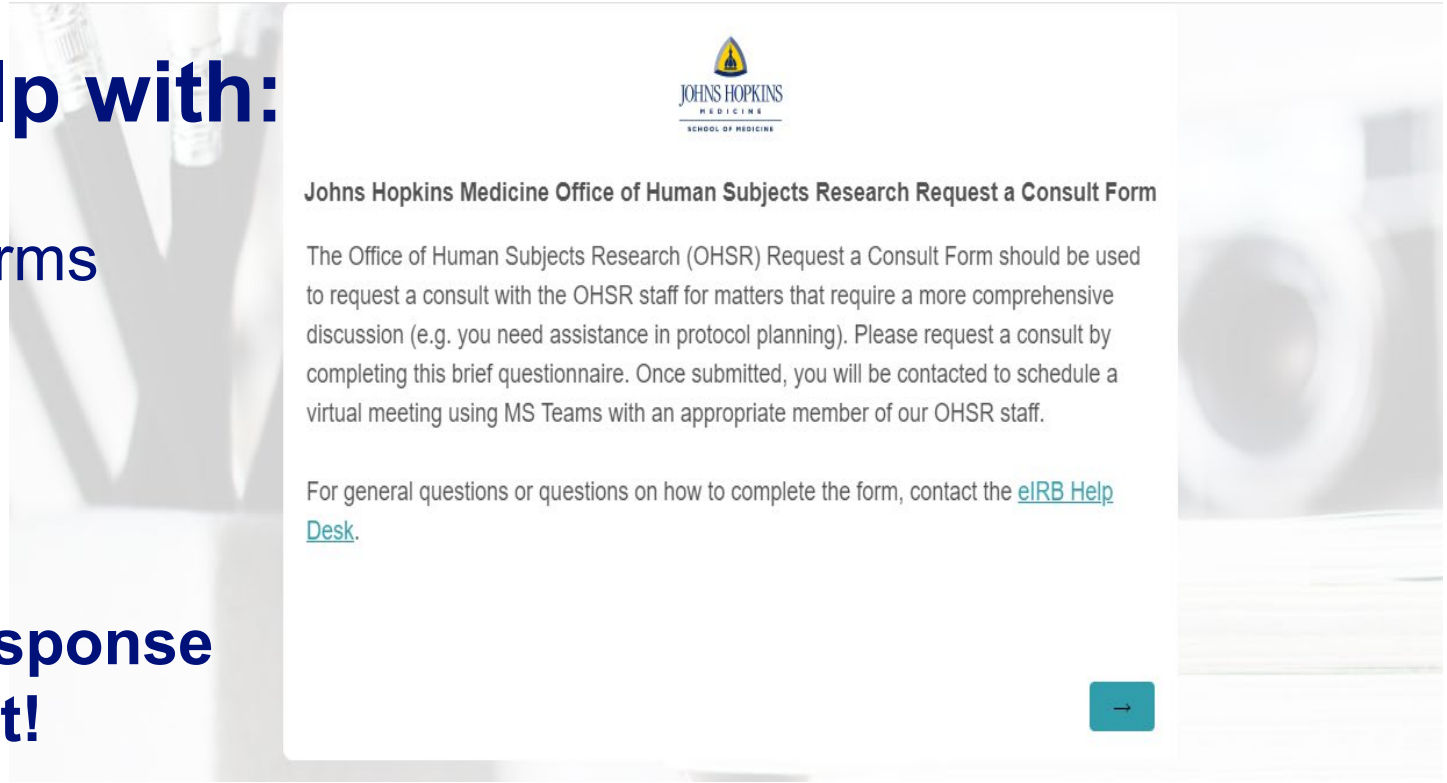
Need help navigating the IRB review process?

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.

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Questions

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jhmeirb@jhmi.edu

Find staff phone numbers, emails and Teams Chat links at https://www.hopkinsmedicine.org/institutional_review_board/about/contact.html

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