eIRB Help Desk FAQs

What the research community asks the most

What's the status of my IRB application?

- Researcher Prep – in the study team's queue. Has not been submitted to the IRB for review
- RSS Review Pre-IRB – in the IRB's queue for review and scheduling
- Waiting Outcome – has been scheduled for an IRB meeting
- RSS Review Post-IRB – has been reviewed at an IRB meeting and is being processed
- Lapsed – The Continuing Review has been received and is pending processing
- Expired – A Continuing Review was not submitted to the IRB before the study expiration date
- Acknowledged – An approval equivalent for Exempt, QI, and NHSR projects

Current Status

Researcher Prep

Project Editor

View/Edit

Print Friendly

View Differences

Current Activities

Request Study Team Participation

Submit IND Safety Reports

Agree to Participate

Log Comment

Contact Study Team

Alert PI

Remove Flag – Compliance Monitoring

Remove Flag – Conflict of Interest

Set Test Study

Application Workspace

Title:
IRB Staff Application

Number: NA_00072994

Principal Investigator: Megan Singleton

IRB Committee:

Review Type:
Expedited

Date Submitted:

Last Scheduled Review:

Version: The Revised Common Rule - Effective January 2019

***** APPLICATION WAITING TO BE SUBMITTED *****

ONLY when application is ready for submission
should the **PI** perform the *Submit* activity on the left

Click here to view IRB Review: RVIRB00021480

IRB Review Items:

Review Date	Review Type	Outcome	Letter Sent	Response	Agenda Topic
There are no items to display					

☑ Male Children	☑ Female Children	☑ Prisoners
☑ Written Consent	☑ Oral Consent	☐ Consent Waiver
☑ Written Assent	☑ Oral Assent	PRA - Open
☑ COI	☑ Drugs	☑ Devices / ☑ Investigational Devices
☑ Imaging/Radiation	☑ Pregnant Women	☑ Neonates
☑ Non English Speakers	☑ Monetary Support	☑ Material Support
☐ 404/51 Waived	☐ 404/51 One Parent	☐ 404/51 Both Parents
☐ 405/52 One Parent	☐ 405/52 Both Parents	☐ 406/53

History Log | Reviews | Reviewer Notes | IRB Staff

History Log

Filter Activity Go + Add Filter × Clear All

Current Status
Approved

Project Editor

View

Print Friendly

View Differences

Current Activities

- Log Comment
- Change Committee and Review Type
- Contact Study Team
- Return to RSS Review - Post IRB
- Suspend Study
- Place Enrollment on Hold
- Admin Changes
- Remove Flag – Compliance Monitoring
- Remove Flag – Conflict of Interest
- Priority Monitoring
- Set Test Study

Application Workspace

Title:
Caregiver Support in the Context of Multiple Chronic Conditions (Caregiver-Support)

Number: IRB00176025

Principal Investigator: Martha Abshire

Version: The Common Rule

IRB Committee:
IRB-5

Study Expiration Date:
7/15/2019

Review Type:
Expedited

Initial Approval Date:
7/16/2018

Date Submitted: 6/3/2018

Last Scheduled Review: 7/16/2018

Click here to view IRB Review: RVIRB00106164

IRB Review Items:

Review Date	Review Type	Outcome	Letter Sent	Response	Agenda Topic
7/16/2018	Expedited	Approved	View Letter		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

History Log | Reviews | Reviewer Notes | Further Study Actions | Stamped Documents | Legacy Documents | IRB Staff

History Log

Where can I find basic information?

- The IRB website www.hopkinsmedicine.org/institutional_review_board

On the website you will find links to training information, a contact page for the IRB staff, FAQs, a link to log in to eIRB, information about the Revised Common Rule, IRB application forms, and Guidelines & Policies

What training is required?

- Basic Human Subjects Research, Conflict of Interest and Commitment, and Health Privacy Issues for Researchers (formerly HIPAA for Research) are core requirements. BHSR and HPIR are administered on the CITI website. COIC is not.
- REWards is required for PIs when they submit their first application to the IRB. It must be completed within one calendar year of their initial submission date. PIs must complete two 90-minute workshops to satisfy the REWards requirement. The IRB does not manage REWards registration
- Human Subjects Recertification is required every 3 years. It is the only IRB required compliance training that is repeated.

Office of Human Subjects Research - Institutional Review Board

Human Subjects Research (HSR) Training

Required Training for New PI and New Study Team Members

There are two types of Compliance training required for New PIs and Study Team Members to perform human subjects research:

IRB Compliance Training – Principal Investigators (PIs) and study team members are required to complete IRB compliance training prior to submission of a human subjects research eIRB application. IRB Compliance Training includes: Human Subjects Research (HSR), Conflict of Interest (COI), and HIPAA for Research (HFR). For more information on IRB compliance training…

****In Addition to Compliance Training, first time Principal Investigators (PIs) are required to take REWards Training****

REWards – Required for PIs and Fellows. PIs must complete REWards training within 1 year from the date of their first eIRB submission of a human subjects research application. Fellows must complete REWards training by the end of their fellowship. For more information on REWards…

Recertification Training Requirements

Recertification – Required for all PIs and study team members engaged in human subjects research. PI's and study team members must complete recertification every three years. For more information on Recertification…

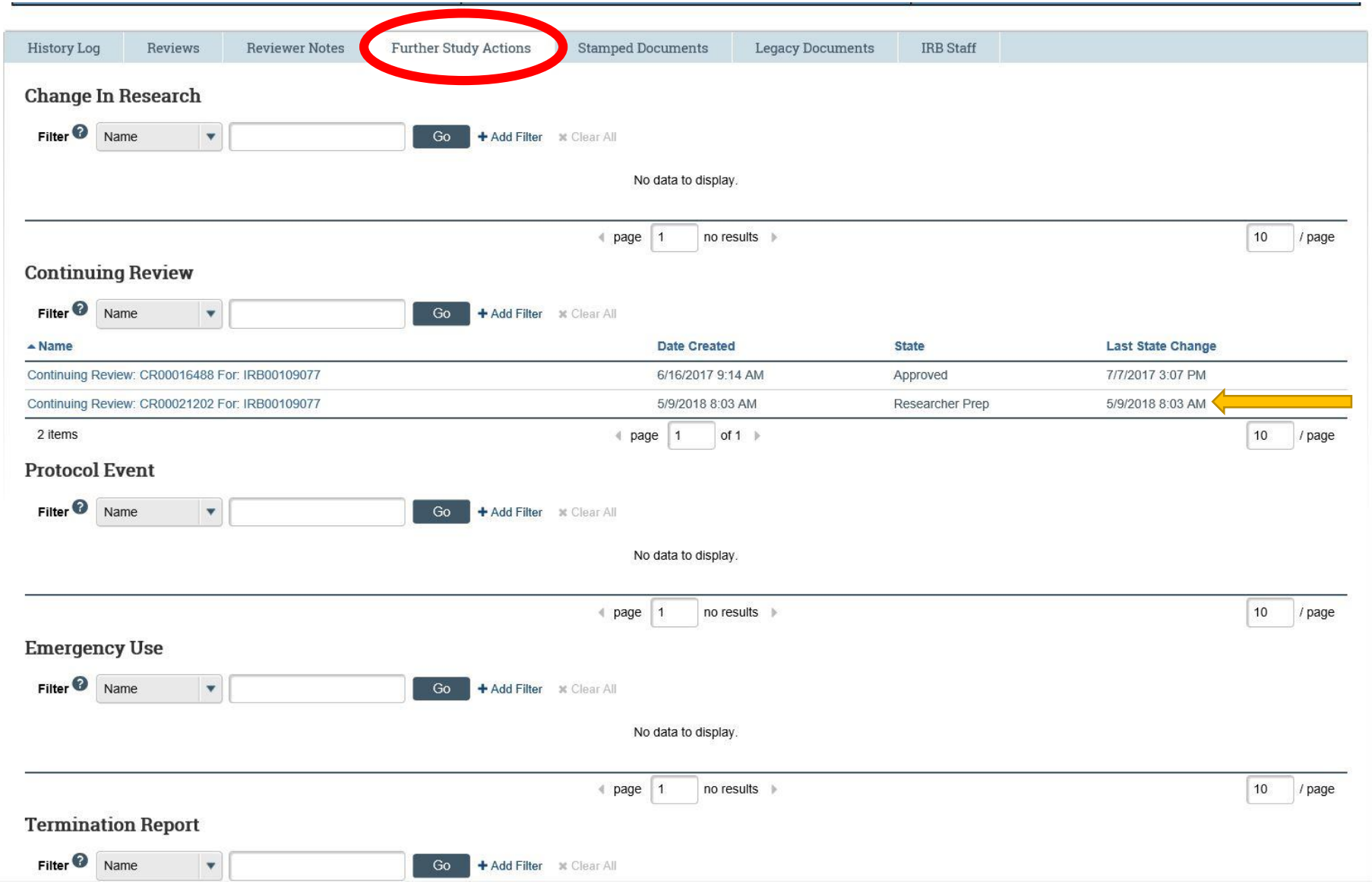
Good Clinical Practice (GCP) Training - NIH leadership released a new policy requiring GCP training as of January 1, 2017. For more information on GCP training…

Required Training for External IRB Studies

All new (NIH) grant applications and competitive renewals for multi-site research require a plan for use of a single IRB. The JHM IRB routinely serves as the single IRB, but there are also cases where Johns Hopkins will be asked to rely on an external IRB.

I can't create a Further Study Action…

If you get an error message that you cannot create a Further Study Action because one has already been created, click the Further Study Actions tab on your main application to find the pending action.



Adding study team members

Questions to answer when preparing to add study team members

1. Are they are Johns Hopkins affiliate?
2. Do they have a JHED ID?
3. Do they have an eIRB profile?
4. Have they completed compliance training?
5. If they are a student or a volunteer, have the completed the required forms?
6. Will they be obtaining physician or mid-level provider consent?

When the PI can’t submit…

- Is the PI listed as a study team member?
- Have you accessed the Hide/Show Errors feature to see what’s going on with the application?
- Is there a mismatch between the physician/mid-level provider consent and the agree to participate consent information?

What is the recertification process?

- There are currently two recertification courses
- If you are a PI of your own studies, you are required to take PI recertification
- If you are not a PI of your own studies, you are required to take Study Team Member recertification
- PI recertification requires an in-person activity
- You must finalize your recertification in myLearning after you complete all of your training
- Recertification certificates are produced in myLearning and cannot be obtained from the CITI website

Who do I contact with questions

- For questions about applications that have not been scheduled for an IRB meeting, please contact the IRB Pre-Team Analyst/Coordinator
- For questions about applications that have been scheduled for an IRB meeting, please contact the IRB Post-Team Analyst/Coordinator
- For questions about issues with the eIRB application, please contact the eIRB Help Desk
- For questions about regulatory or compliance issues, please contact a Regulatory Specialist
- For questions about billing, please contact the Budget Analyst

Contact Us

Contact

East Baltimore Campus (Central Office)
1620 McElderry St., Reed Hall - B130, Baltimore, MD 21205-1911
Monday-Friday 9:00am-5:00pm only
(Mail also can be dropped off anytime at the 1st floor Guard's desk and placed in the JHM-IRB mailbox.)

Bayview Medical Center Campus- JHAAC 1B39
Monday 9:00-12:00 & 3:00-5:00

For General IRB Questions:

Phone:410-955-3008
Faxes:410-955-4367 or 443-287-5353
E-Mail: jhmeirb@jhmi.edu

For eIRB Technical Assistance and Training Questions:

eIRB Help Desk
Phone: 410-502-2092
E-Mail: jhmeirb@jhmi.edu
For after hours or weekend technical support, email the eIRB Help Desk. We will contact you as soon as possible.

The JHU/WIRB Liaison Office
1620 McElderry Street, Reed Hall B-130, Baltimore, Maryland 21205-1911
JHU WIRB Liaison: TBD
Email address: jhmeirb@jhmi.edu

JHM IRB Research Subjects Specialists		
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IRB X		
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