Research Professionals Network
Duke Research Professional Network

eIRB

Behind the scenes

February 24, 2015

ORI Office of Research Informatics
Nancy Walden
IT Analyst
2015

Integrated research home

MyResearchHome@Duke

Mobile component
Welcome to Thefacebook!

Thefacebook is an online directory that connects people through social networks at colleges.

We have recently opened up Thefacebook at the following schools:

Alabama A&M • Alabama Huntsville • Aquinas • Art Chicago
Bellarmine • Belmont Abbey • Bethel KS • Bethune Cookman
Brevard • Brookdale • Caldwell • Catawba • Cedar Crest • Central College
Clarke • COE College • Concord • Concordia MN • Concordia NY
CSU East Bay • CSU Mont. Bay • CUNY Lehman • Delaware State
Delaware Valley • Detroit Mercy • Dowling • Erskine • Evergreen
Fayetteville • FL Southern • Fort Hays • Francis Marion
Franklin • Franklin CH • Franklin Pierce • Full Sail • Georgian Court
Houston Baptist • Incarnate Word • Johnson CC • Juilliard
Juniata • LA Monroe • Lander • Lasell • Lawrence Tech • Lesley
Lincoln MO • Lincoln PA • Marietta • Maryland Art • Maryland Eastern
Marywood • McKendree • Mesa State • Mills College • Monroe
Mount Ida • Muskingum • N.E. Illinois • Nebraska Kearney
New College FL • NJ City • Oakwood • Oglethorpe • Ohio Dominican
My study looks like it is stuck.

How can I get it moving?
Answer: Execute an activity

If a study is anywhere in your workspace, it’s waiting for the study team to

open the study

do an activity from those in the column at the left
Study Personnel

This is your Study Personnel Workspace. This workspace shows the work you have to do as a study team member.

- The Tasklist contains items currently under review that are awaiting action by you or a member of your study team before they can proceed further.
- The Items in Presubmission tab contains projects which have been created but not yet submitted for review.
- The Studies link in the blue header at the top of the page will show all studies, in any state of review, in which you have a role.
- Clicking on My Home in the blue header at the top of the page will return you to this workspace.

Tasklist | Items in Presubmission | Studies Requiring Renewal or Closure

Items Requiring Action by the Study Team

This section displays items which are in review and awaiting action by the study team before they can proceed further.

No data to display.

Items Requiring Your Electronic Signature

This section displays items awaiting your signature. These items cannot proceed further until all PI signatures are obtained.

No data to display.
Study Personnel

This is your Study Personnel Workspace. This workspace shows the work you have to do as a study team member.

- The Tasklist contains items currently under review that are awaiting action by you or a member of your study team before they can proceed further.
- The Items in Presubmission tab contains projects which have been created but not yet submitted for review.
- The Studies link in the blue header at the top of the page will show all studies, in any state of review, in which you have a role.
- Clicking on My Home in the blue header at the top of the page will return you to this workspace.

Items in Presubmission

This section displays items in "Presubmission", meaning they have not yet been submitted for review. Once an item is ready for review, a member of the study team can begin the review process by opening the item and clicking on the "Submit" button.

Filter by: ID

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Date Created</th>
<th>Type</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pro00054123</td>
<td>Test Polio Vaccine Study</td>
<td>2/19/2015 12:00 AM</td>
<td>Application</td>
<td>Presubmission</td>
</tr>
</tbody>
</table>
End of Application Form

You have reached the end of the New Protocol Application form. Upon clicking the "Finish" button below, this application **will not** automatically be submitted for review. It will instead appear under the "Presubmission" tab on your workspace, allowing further edits to be made to the application later if it is not yet ready for submission.

If this application is complete and ready to be submitted for review, you must click the "Submit Study" activity button, located in the left column of this application's workspace, to begin the Duke HRPP review process.
OK, OK, OK….

How can I tell if it worked?
Answer: View the activity details

state changes

activities available change

activity link added to the History
Activity Details (Submitted Study)

Author: April Showers (RADIOLOGY SPORTS MEDICINE)
Logged For (Application): Test Polio Vaccine Study
Activity Date: 2/19/2015 1:00 PM EST

This activity allows study staff with edit rights on this protocol to submit it for review.

After this activity is executed, PIs and Co-PIs on the study will need to electronically sign this Protocol before it can proceed for further review. The system will automatically notify each PI of this requirement. If you are a PI on the protocol, you will be able to electronically sign the protocol immediately after this activity finishes processing.

*Check the confirmation box below and click the "OK" button to submit the protocol and begin the review process.
Activity Details (Submitted Study)

Author: April Showers (RADIOLOGY SPORTS MEDICINE)
Logged For (Application): Test Polio Vaccine Study
Activity Date: 2/19/2015 1:18 PM EST

Activity Form | Property Changes | Documents | Notifications
---|---|---|---
[Link: eIRB: A Protocol Requires your Electronic Signature] | [Link: eIRB: A Protocol Requires your Electronic Signature] | [Link: Anna Belle (Ambulatory Care Operations) email:aeb71@dm.duke.edu] | [Link: Elsa Queen (Biochemistry) email:e.baena@duke.edu]

Recipients: Anna Belle (Ambulatory Care Operations) email:aeb71@dm.duke.edu
Elsa Queen (Biochemistry) email:e.baena@duke.edu
Workflow rules

For new study applications, the PI and all Co-PI’s must electronically sign, in any order.

For amendments, continuing review, and safety events, only the PI must sign.

If a PI returns a study to Presubmission, he has to do 2 activities: Submit and Electronically Sign.
I see my activity worked.

What other reviews does my study need?
Answer: View the HRPP Reviews Required

set when the PI signs
# Study: Test Polio Vaccine Study

## Protocol Information

- **Protocol ID:** Pro000054123
- **Full Study Title:** Test Polio Vaccine Study
- **Owning Organization:** Radiology (SBR)
- **Principal Investigator:** Elsa Queen
- **Study Coordinator:** April Showers
- **Sponsor, Funding Source(s), Drug & Device Source(s):** National Institutes of Health

## HRPP Reviews Required

<table>
<thead>
<tr>
<th>Organization</th>
<th>HRPP Role</th>
<th>Review Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiology (SBR)</td>
<td>Review &amp; Oversight</td>
<td>Pending</td>
</tr>
<tr>
<td>Duke Office of Clinical Research</td>
<td>Review &amp; Oversight</td>
<td>Pending</td>
</tr>
<tr>
<td>Research Data Security Plan</td>
<td>Research Data Security</td>
<td>Pending</td>
</tr>
<tr>
<td>Institutional Review Board</td>
<td>Review &amp; Oversight</td>
<td>Pending</td>
</tr>
</tbody>
</table>

## Codes

- **Protocol Application Type:** Regular Application
- **IRB Review Type:**
- **IRB Primary Reviewer:**
- **IRB Review Date:**
- **IRB Action Notice:**
- **Current Expiration Date:**

## History

- **Investigator Signature and Assurance Received**
  - **Activity:** Investigator Signature and Assurance Received
  - **Author:** Queen, Elsa
  - **Date:** 2/19/2015

- **Submitted Study**
  - **Activity:** Submitted Study
  - **Author:** Queen, Elsa
  - **Date:** 2/19/2015
How can I tell which division/department/CRU/center/institute will review my study?
Answer:

Study routes to the SBR/CRU if one is selected

If no SBR/CRU is selected, study routes to the selected Study Organization

In some views reports, other terms are used:

Owning / Oversight Organization is one that issues organizational approval

Division or Department is a kind of Study Organization
<table>
<thead>
<tr>
<th>* Short Title:</th>
<th>Key words or phrases that can be used to quickly identify the study.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>* Full Title:</td>
<td>Full title of the study.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>* Oversight organization:</td>
<td>The organization that provides oversight of the research study. More information can be found on the Duke Office of Clinical Research (DOCR) website, <a href="http://docr.som.duke.edu">http://docr.som.duke.edu</a></td>
</tr>
<tr>
<td></td>
<td>Questions concerning oversight organization selection should be directed to <a href="mailto:docr.help@dm.duke.edu">docr.help@dm.duke.edu</a></td>
</tr>
<tr>
<td>Reporting attribute, if applicable:</td>
<td>The sub-organization/therapeutic area/cluster to which this study belongs. This selection is for analysis and reporting. It is not used for security or routing.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Study: Test Polio Vaccine Study

**Protocol ID:** Pro0054123  
**Full Study Title:** Test Polio Vaccine Study  
**Owning Organization:** Radiology (SBR)  
**Principal Investigator:** April Queen  
**Study Coordinator:**  
**Regulatory Coordinator:** April Queen  
**Sponsor, Funding Source(s), Drug & Device Source(s):**  
National Institutes of Health  
**Protocol Source:** PI initiated  

**HRPP Reviews Required:**

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<td>Pending</td>
</tr>
</tbody>
</table>

**Codes:**

- **Protocol Application Type:** Regular Application  
- **IRB Review Type:**  
- **IRB Primary Reviewer:**  
- **IRB Review Date:**  
- **IRB Action Notice:**  
- **Current Expiration Date:**

#### History

- **Filter by** Activity  
- **Activity**
  - Investigator Signature and Assurance Received
  - Submitted Study
- **Author** Queen, Elsa  
- **Activity Date** 2/18/2015 1:30 PM EST  
- **Activity Date** 2/19/2015 1:26 PM EST
# Activity Details (Investigator Signature and Assurance Received)

**Author:** Elsa Queen (Biochemistry)

**Logged For (Application):** Test Polio Vaccine Study

**Activity Date:** 2/19/2015 1:30 PM EST

<table>
<thead>
<tr>
<th>Activity Form</th>
<th>Property Changes</th>
<th>Documents</th>
<th>Notifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>eIRB: A Protocol Requires Specialty Committee Review</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>eIRB: New Protocol in Organization - Awaiting Screening</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Recipients:**
- Barbara Croft (Radiology - General) email: barbara.croft@duke.edu
- Barbara Kurth (Radiology - General) email: barbara.kurth@duke.edu
- Brenda Prince (Radiology - General) email: brenda.prince@duke.edu
- Steven Shipes (Radiology - General) email: steven.shipes@duke.edu
- Wendy Pate (Radiology - General) email: pate0044@mc.duke.edu
not all activities generate email notifications

list of recipients might be empty

few notifications are sent to IRB staff
I see my what reviews my study needs.

What order will it go in?
Answer: View the workflow diagram

User Guides section of eIRB Home
IRB Committee Review Workflow

1. **Create New Study Application**

2. **Presubmission**
   - Submit Study

3. **Awaiting Investigator Signatures**
   - Electronically Sign Protocol

4. **Awaiting IRB Screening**
   - Recommend Full Committee Review

5. **Recommended for Full Committee Review**
   - Finalize Meeting Assignments

6. **Scheduled for Full Committee Meeting**
   - Record Meeting Decision

As applicable:
- Department / Clinical Research Unit (CRU) Review
- Cancer Protocol Committee (CPC) Review
- Duke Clinical Research Unit (DCRU) Review
- Specialty Committee Review

As applicable:
- Modifications Review
- Duke Office of Clinical Research (DOCR) Review
- Office of Corporate Research Collaborations (OCRC) / Office of Research Administration (ORA) Review

**Approved**
Workflow rules

Specialty Committee reviews can be done in parallel. All must be complete before IRB review, with one exception: OCRC can complete with Risk Related Injury Language review with modification required.

ORA review is required when a commercial entity is involved.

DOCR review is required for all regular studies.

ORA and DOCR review can be completed after PI signature, and must be complete before a study can transition to Approved.
Our new data manager did her CITI training.

How can I find her on the person list?
Help text box

Add Key Personnel

To add a person to the list of key personnel of the study, select a name, select a role using the drop down menu, and then click the "OK" button in the lower right corner of this page. You must complete this process for each person you want to add to the study.

- **Key Person:**

  - Select...

  If you cannot find the person, go to the FAQ section of the eIRB Home page and click the link *I'm trying to add someone to my study, but I can't find their name.*

- **Role on study:**

  - If the exact role of the individual is not in the list, select the closest match.

- **Edit rights for study:**

  - Changing this to "Yes" will allow this individual to edit study forms and execute activities related to the study.

- **Receive emails for study:**

  - If this value is set to "Yes" this person will receive all study related correspondence that is sent from eIRB.

- **Required**
FAQ

Comments and suggestions are welcome. Please send feedback to eirb@mcd.duke.edu

**eIRB Personal Account Questions**

Why can’t I log into eIRB?
My personal information is wrong in eIRB. How do I change it?
I am not a Duke student, faculty or staff member. How can I access the Duke eIRB system?

**eIRB Basic Terminology**

What is a Project?
What is a Workspace?
What is an Activity?
What is a Form?
What is a State?
What is a Continuing Review?
What is a Safety Event?
What does it mean when my project is in the “Presetubmission” state?

**Navigating the eIRB System**
The protocol disappeared - why can I no longer see it?
How do I keep my sort and filter settings after I select a study?
How do I figure out the status of my project?
I got an email that I needed to do something, but when I log in nothing is there.
Why am I receiving an “X-1” error message?
My study says it is “Awaiting Final Approval by OCRC/ORA”. What does this mean?

**Performing Actions in the eIRB System**

How do I withdraw my Protocol/Continuing Review/Ammendment?
I’m trying to add someone to my study, but I can’t find their name on the list.

The most common reasons for this problem are:

1. The person’s Human Subjects Protection (HSP) training certification is not current in the eIRB.
2. You are adding the person as the PI or Co-PI and she does not have the PI role assigned in the eIRB.
3. You can add the person as Key Personnel in the Investigator role. You must be full time regular rank faculty in order to serve as PI or Co-PI, according to this Duke policy: http://rtb.duke.edu/arysys/go/downloads/Who_May.Serve.as.PI_in_the_Duke_HRPP_12-6-07_revision_6-12-2011.pdf. If you would like to request an exception to the policy, the contact person is the IRB Director, Jody Power.
4. The person does not have an eIRB account, either because she is a new employee or there was a problem loading her account information.
Verify that she completed the required CITI modules, as an affiliate of Duke Medicine, at least 2 business days prior, to allow time for the electronic transfer of her training record.
Verify that you are spelling the person’s name as it shows in www.duke.edu/online.
Login Help

Are you a new eIRB user?

If you are logging in to the eIRB for the first time, you must first meet Human Subjects Protection (HSP) training requirements. Two business days after you complete the HSP training, an eIRB account will automatically be created for you and you will be able to log in to the eIRB with your Net ID and password.

Duke Medicine

When you register for training on line, you must enter the following identifying information accurately:

- Enter your Duke Net ID as your Username
- Enter your First and Last Name as they appear in your Duke Human Resources record
- Enter your 7-digit Duke Unique ID
- Select Duke Medicine as the Participating Institution

See the Duke University School of Medicine Human Subjects Protection (HSP) training requirements and instructions here: http://medschool.duke.edu/research/hsp-certification.

Duke Campus

If you have completed the Duke University IRB training requirements and would like to submit a protocol to the Duke Medicine IRB, send email to eIRB Technical Support at eIRB@mc.duke.edu to request the manual creation of an eIRB account. Include documentation of completed training in the email.

For the policy regarding research that must be reviewed by the Duke Medicine IRB, see: http://irb.duhs.duke.edu/wysiwyg/downloads/Research_Subject_to_the_DUHS_HRPP_14__jac__.pdf.


Durham VA
<table>
<thead>
<tr>
<th>Last</th>
<th>First</th>
<th>M</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lentz</td>
<td>Aaron</td>
<td>C</td>
<td>Surgery-Urology</td>
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<tr>
<td>Poms</td>
<td>Abigail</td>
<td>D</td>
<td>Medicine - Pulmonary</td>
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<td>Perlman</td>
<td>Adam</td>
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<td>Adam</td>
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<td>Adam</td>
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<td>Cardones</td>
<td>Adela</td>
<td>R</td>
<td>Dermatology</td>
</tr>
<tr>
<td>Narayan</td>
<td>Aditee</td>
<td>P</td>
<td>Pediatrics-Child Abuse and Neglect Serv</td>
</tr>
<tr>
<td>Angold</td>
<td>Adrian</td>
<td>C</td>
<td>Child &amp; Adolescent Psychiatry</td>
</tr>
<tr>
<td>Hernandez</td>
<td>Adrian</td>
<td>F</td>
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<tr>
<td>Vidal</td>
<td>Adriana</td>
<td>C</td>
<td>OB/Gyn-Clinical &amp; Epidemiologic Research</td>
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<tr>
<td>Hariri</td>
<td>Ahmad</td>
<td>R</td>
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<td>Alan</td>
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<td>Smith</td>
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<td>Sun</td>
<td>Albert</td>
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<td>R</td>
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<td>Alex</td>
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<td>Limkakeng</td>
<td>Alexander</td>
<td>T</td>
<td>Surgery-ER Med</td>
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<tr>
<td>Kulinski</td>
<td>Alexander</td>
<td>M</td>
<td>Org Unit for Unassigned Positions</td>
</tr>
<tr>
<td>Badea</td>
<td>Alexandra</td>
<td></td>
<td>Radiology - General</td>
</tr>
</tbody>
</table>
Advanced search

![Advanced search interface](attachment:image.png)

### Select Person

**Filter by**
- Last
- First
- Organization

**Select Criteria**
- Last: Lentz, Poms, Perlman, Goode, Buchanan, Cardones, Narayan, Angold, Hernandez, Vidal, Hariri, Mahmood, Proia, Carlson, Smith, Sun, Kemper, Cho, Wilkins
- First: Aaron, Abigail, Adam, Adam, Adam, Adela, Aditee, Adrian, Adrian, Alan, Ala
- Organization: Surgery-Urology, Medicine - Pulmonary, General Internal Medicine, Physical Therapy, DCI-Basic Research, Dermatology, Pediatrics-Child Abuse and Neglect Servi, Child & Adolescent Psychiatry, Cardiology, OB/Gyn-Clinical & Epidemiologic Research, Psychology and Neuroscience, Medicine - Oncology, Pathology Clinical Services, Ophthalmology-General, Medicine - Gastroenterology, Cardiology, Pediatrics-Primary Care, General Internal Medicine
wildcard % search
I still can’t find her.

How can I get her added to the list?
Two business days after CITI training is complete, email eIRB@mc.duke.edu and ask to have her account added or updated manually.

Provide all identifying information: Duke unique ID, Net ID, last and first name as appears in payroll system (or guest account request).

PI and Co-PI selection lists only contain people with the PI role assigned, by job code when an account is created. Email eIRB@mc.duke.edu with identifying information and ask to have the PI role assigned.
CITI Training Workflow

**Citiprogram.org**
Person registers for account and completes Duke Medicine required modules

**Duke Person Directory (RDR)**
DOCR runs process to match Duke Net ID and Last Name to find person and update Certification Expiration Date

**eIRB**
ORI runs process to match Duke Unique ID to find person and update Certification Expiration Date or create new eIRB account
Ideas for new workflow

**Citiprogram.org**
Person registers for account and completes Duke Medicine required modules

**Duke Learning Management System (LMS)**
Rules determine training status (CITI, HSR)

**eIRB**
Person registers for account
eIRB checks LMS for person’s training status

Real time
The sponsor requires us to change the wording of the IRB letter.

Who do I call?

your IRB Specialist