This Quick Reference Guide contains detailed, step by step instructions for performing the organization (department, center, institute, SBR) review in the eIRB.

- For a general introduction to the eIRB, including how to navigate the different workspaces, please see the General Reference Guide.
- For information about reviewing studies in other roles, see the Reviewer User Guide.
- For information about how to create and submit new studies, see the Study Staff User Guide.

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Explanation of Changes

On March 1, the IRB will implement a change in the eIRB workflow for departmental review of new study submissions.

The new review workflow will contain the following:

- When the PI electronically signs, an “owning organization” for the study is determined based on the selections on page 01. of the study application.
  - If an SBR is selected, the SBR is the owning organization.
  - If no SBR is selected, the Study Organization is the owning organization.
- All regular study applications are routed to the administrators of the owning organization for pre-IRB review.
- Administrators can assign one or more of the organization’s reviewers to review the study, in parallel.
- Once all assigned reviews are complete, an administrator must issue a final motion (approve or disapprove) to move the study forward to the next reviewer.
How to Log In to eIRB

1. In your internet browser, go to the eIRB Home page: http://eIRB.mc.duke.edu.
2. Type your NetID, tab to the password field and type your NetID password, and click the Login button or press the Enter key.
   Your personal workspace displays.

How to View Your Task Lists

Your eIRB Task List is designed to show you work that is awaiting your action. Each eIRB role assigned to you has its own Task List.

1. Click the white My Home link at the right of the top blue banner.
   Your roles are listed under the My Roles heading in the column at the left. The Task List for the selected role displays in the main section of the window. The selected role is shown in the colored banner at the top, and in bold text under the My Roles heading. To return to your Task List from anywhere in the eIRB, click the My Home link again.
2. To view the Task List for a different role, click the role under the My Roles heading in the column at the left.
For Study Staff

During organization review, administrators, reviewers, and approvers can send you requests for changes. You will receive an email notification and the study will show in the Tasklist when you select the Study Personnel role.

How to Respond to Reviewer Requests

When changes are needed to the study application, responding to requests for changes is a two-step process. First, you make the changes to the application. Second, you must perform an activity to notify the reviewer that your changes are complete and ready for review.

1. To view your Tasklist, click the My Home link in the top blue banner. Study Personnel must be selected under My Roles in the column at the left.

2. Click the link to the study under the “Name” column to open the study.
The reviewer comments display in the History tab.

3. If changes to the study are needed, click the View/Edit activity in the column.
4. Go the appropriate study page and make the changes and/or attach revised documents directly on the page. Save the pages and exit the application. Changes to the study pages appear as entries in Change Log in the History folder. For more information about these steps, see the *General Reference Guide*. 
5. When your changes are complete, click the Send Comment to Reviewer activity in the column at the left.
6. To explain your response, enter comments and/or attach documents.

7. Click OK. Your comments display in the History tab. An email notification is sent to the Reviewers and the study is removed from your Tasklist. All assigned reviewers who have not yet completed their reviews will receive the email notification.

How to Respond to Administrator Requests

When you submit and electronically sign your study, the “owning organization” is determined and the study is routed to that organization’s administrators. If the owning organization is not correct, the administrator will send you a request for changes. You can edit the study pages as above, change the Study Organization or SBR as appropriate, and Submit Changes. If the owning organization changes, the study will be routed to the administrators of the new owning organization.

How to Respond to the Final Motion

To complete the organization review, an administrator must issue a final motion of approve or disapprove. In either case, an email notification is sent to the study staff.

- If the motion is approve, the study is moved forward to the next reviewer and you do not need to take any action.
- If the motion is disapprove, the study is returned to the Presubmission state. You can edit the study and submit it again, or you can withdraw the study.
For Reviewers

How to Complete Your Review

1. To view your Tasklist, click the My Home link in the top blue banner.

2. Click the link to the study under the “Name” column to open the study.
3. Click the Complete Review activity in the column at the left.
4. Select a Motion and enter comments and attach review documents as applicable.
5. Click OK.
Your review displays in the History folder.
How to Send Comments to the Study Team

1. Click the Send Comments to Study Team activity in the column at the left.
2. Type a comment and attach checklists or revised study documents as applicable.
3. Click OK.
The request displays in the History folder.

The study team can make the requested changes and use the Send Comment to Reviewer activity to enter a response and send email notification to you and any other assigned reviewers who have not yet completed their reviews.
For Approvers and Administrators

Organization administrators can create the pool of reviewers, return studies to the study team for changes, assign studies to reviewers, and issue the final motion for the organization. Each organization can decide which of these roles each administrator is responsible for performing.

How to Take Ownership

You must first take ownership of a study before any activities are available to you. Although owning a study puts it on your task list, anyone with the same rights and responsibilities you have can perform the same activities you can.

1. To view your Tasklist, click the My Home link in the top blue banner.
2. Organization must be selected under the My Roles heading at the left.
3. Click the link to the study under the “Name” column to open the study.
4. When the study is opened, it will look like this:

5. Click the Take Ownership activity in the column at the left.
6. Click OK

The study is added to your Tasklist.
How to Assign Reviewers

You can assign and re-assign as many reviewers as you like, as often as you like. As reviewers are assigned, they are added to a Reviews Pending list. As reviews are added, reviewers are automatically removed from the pending list. When all assigned reviews are added, the study moves forward to the Review Complete state.

1. Click the Assign Reviewers activity in the column at the left and you will see the following:
2. Click the Add button to display the list of potential reviewers.

3. Click one or more check boxes to assign reviewers.
4. Click OK to add the reviewer to the list and enter comments if applicable. Click OK to assign the selected reviewers.
An email notification is sent to each selected reviewer and the study is added to the selected Reviewer’s Tasklist.
5. To re-assign reviewers (for example, if someone is away on vacation and you want to choose an alternate reviewer), click the Re-assign Reviewers activity in the column at the left and you will see the following.

To add reviewers, follow steps 2-4 above.
To remove reviewers:

- Click the check box in front of the reviewer.

![Reviewer removal interface](image-url)
- Click the Remove button in the header to remove the reviewer from the list.

```
<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joseph</td>
<td>Farmer</td>
<td>Surgery-Otolaryngology</td>
</tr>
</tbody>
</table>
```

Enter any comments you have for the reviewer(s):
• Then, click OK.
If you use this activity to remove all pending reviewers, the study will move forward to the Review Complete state and will be added to the Administrator Tasklist.
How to Forward to the Approver

When all the assigned reviews have been added, you can forward the study to an approver listed on your organization so he or she can issue the final motion.

1. Click the Forward to Approver or Administrator activity in the column at the left and you will see the following.

2. Click the radio button to select the individual.
3. Click OK.

An email notification is sent to the selected person and the study is added to the person’s Tasklist. Any approver can issue the final motion, but each SBR must choose who has this permission.
How to Issue the Final Motion

You can approve or disapprove the study for your organization. If you approve the study, it will move forward to the next organization for review. If you disapprove the study, an email notification will be sent to the PI and the study will be returned to the Presubmission state. In the Presubmission state, the study team can make changes and submit and electronically sign the study again, or withdraw the study.

Use this activity to issue the final motion for studies belonging to your organization or SBR. If a study has been routed to your organization or SBR in error, see the Request Changes activity below.

1. Click the Issue Final Motion activity in the column at the left.
2. Click the arrow in the drop down and select the motion.
3. Enter comments if applicable, and click OK.

An email notification is sent to the study staff.
• If the motion is Approve, the study is moved forward to the next reviewer.

• If the motion is Disapprove, the study is returned to the Presubmission state. The study staff can then edit the study and submit it again, or can withdraw the study.
How to Request Changes of the Study Team

You can return the study to the study team for changes.

*If a study has been routed to your organization or SBR in error, use this activity. Ask the study team to select the correct the organization or SBR selection and submit the change. The changed study will route to the newly selected organization or SBR.*

To be able to return a study to the study team for changes, you must first follow the steps in the *How to Take Ownership* section above and you will see the following.

1. Click the Request Changes activity in the column at the left.
2. Enter comments to the study team and/or attach documents.
3. Click OK.
Your request shows in the History.

An email notification is sent to the study team. The study is added to the study team Tasklist, and removed from your Tasklist.
How to Maintain Personnel for Your Organization

For administrators of organizations that are not SBRs, continue to email eIRB@mc.duke.edu to request changes to assigning Approver (Chair/Director), Administrator and Reviewer (IRB Committee Member) roles for your organization. We are piloting the following function in the SBRs. When we have feedback and are able to make any revisions, we will make this available to additional organizations.

You can maintain all people who have roles in the eIRB for your organization.

1. To view your Tasklist, click the My Home link in the top blue banner.

Your organizations are listed under the gray Administration banner at the top of the column at the left.

2. Click the organization name link. In the example above, “TEST DUKE (SBR)”.

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• To assign people to each role, click the Add button in the header of the section, select the people and click OK.
• To remove people from each role, click the check box in front of the person and click the Remove button.

3. Click **Apply** to save the changes.

4. Click the **x** in the top right corner to close the Organization window and return to your Tasklist.
Getting Help

Technical Support

eIRB Home

eIRB Email
Email eIRB@mc.duke.edu to contact IRB IT staff for help using the eIRB.

DHTS Help Desk
Call the DHTS Help Desk at 684-2243 for help with network connectivity, NetID and NetID password.

Research Support

IRB Office
See http://IRB.mc.duke.edu for guidance and information from the IRB Office.

CRSO Office
See http://crso.som.duke.edu for guidance and information from the CRSO.

CRSO Email
Email CRSO.Help@notes.duke.edu if you have any questions about SBR assignment.