

**Working with a Review of a Submission**

This document describes the key areas for the role of Committee Member. This role allows users to review Studies as well as Amendments, Continuing Reviews, Reportable Events and Termination for studies that have been approved in the system.

1. Open your web browser and navigate to [http://eresearch.emory.edu/emory](http://eresearch.emory.edu/emory). Login with your username and password.

2. In your personal folder, Committee Member should show in the My User Roles section.

3. To begin a review, click on the item name in the middle of the workspace in the “My Assigned Reviews” tab.

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>📈 REV00000150</td>
<td>Review of: test reportable event</td>
<td>5/8/2</td>
</tr>
<tr>
<td>📈 REV00000141</td>
<td>Review of: Amendment 1 for IRB Study #IRB00000101</td>
<td>5/1/2</td>
</tr>
<tr>
<td>📈 REV00000024</td>
<td>Review of: Review Test 2</td>
<td>3/30/2</td>
</tr>
</tbody>
</table>

   This will open the review workspace.

4. The review workspace will provide basic information about the item to be reviewed such as Type of Review (Study, Amendment, Continuing Review, Reportable Event) and Review Classification (Full, Expedited, Exempt)
5. Click **Update Review** on the left hand side of the workspace to open the review SmartForm.

6. To proceed, click **Continue >** in either the top or bottom right side of the form. This will step you through the review SmartForm.

7. Sample page of the review SmartForm:

   **IRB Review of Research Design**

   IRB Research Design

   1.0 * Does the Lay Summary adequately describe the
      - Yes  - No  - Clear
   2.0 * Is the Protocol Documentation provided completely
      - Yes  - No  - Clear
   3.0 * Does the Protocol Documentation provide statistical
      - Yes  - No  - Clear

8. Each page of the review SmartForm will provide the name of the area being reviewed:

   **IRB Review of Research Design**

   A link to the page of the study, amendment, continuing review or reportable event that contains the actual information being reviewed:

   IRB Research Design

   The item to be reviewed will open in a new browser window. Once you are in the item to be reviewed, you may use the **Continue >** icon or the “Jump To” drop down to navigate within that item. To close this item, just close the new window.

   An a set of questions to answers about the information being reviewed:
## 1.0 * Does the Lay Summary adequately
- Yes
- No
- Clear

## 2.0 * Is the Protocol Documentation provided
- Yes
- No
- Clear

## 3.0 * Does the Protocol Documentation provide
- Yes
- No
- Clear

### 9. Each page has 2 standard questions:

- **Points for discussion at the meeting** - is a place for you to place notes or reminders as to items to be discussed at the meeting.
- **Comments for the PI letter** - is a place for you to place comments that you feel should be included in correspondence to the study team.

### 10. The drop down box will allow you to navigate to a summary of all Points for Discussion and Comments for the PI letter.

### 11. There is a final page for each review classification:

#### IRB Review of Full Board Final Page

<table>
<thead>
<tr>
<th>1.0</th>
<th>Recommendation: (select one)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Approval- no changes needed</td>
</tr>
<tr>
<td></td>
<td>Pending- minor changes needed that may be reviewed</td>
</tr>
<tr>
<td></td>
<td>Deferred- substantive clarifications, protocol modifications</td>
</tr>
<tr>
<td></td>
<td>Disapproved- cannot be approved</td>
</tr>
<tr>
<td></td>
<td>Clear</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.0</th>
<th>Risk Recommendation: (select one)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HIGH Risk</td>
</tr>
<tr>
<td></td>
<td>STANDARD Risk</td>
</tr>
<tr>
<td></td>
<td>Clear</td>
</tr>
</tbody>
</table>

### 12. On the final page, once you are through with your review click Finish. This will take you back to the review workspace. To submit your review, click Submit Review on the left hand side of the review workspace.

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**eIRB location:** http://eresearch.emory.edu/emory