GEORGETOWN UNIVERSITY

INSTITUTIONAL REVIEW BOARD

Electronic Research and Information Compliance (eRIC)

Investigator and Study Staff Manual Quick Reference

Checking the Status of an Application and Responding to Requested Changes

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Checking the Status of an Application and Responding to Requested Changes

Once the study application has been submitted to the IRB, the application is automatically routed to the required people in the review process. As part of the study team, you will receive notifications from the system indicating the completion of certain elements of the review process or requesting changes to be made to the application. You can also check the progress of your application by opening the study workspace in eRIC.

Receiving Progress Notifications

The eRIC system automatically generates email notifications and sends them to the study team when significant events have occurred in the review process. In addition, the study team will receive notifications at the following times:

- Confirmation that the new study application has been submitted
- Receipt of study application in the IRB office
- Official action letter from the IRB (letting the study team know whether the study submission has been approved, disapproved, approved with contingencies, deferred, suspended, terminated, etc.)
- Reminders of upcoming continuing review deadlines (90 days, 60 days, 30 days, and 2 weeks advance reminders)

It is important that your email address recorded in the eRIC system is current, since the system uses this email address to send notifications about review progress. You can update your information at any time by clicking on the link to your account in the upper right corner of the screen.

Viewing and Responding to Requested Changes or Clarifications

The study team will receive automated email notification when a study submission is sent back to them for requested changes or clarifications.

Editing an Application

A study application may be edited before it is submitted (during Pre-submission) or any time changes are requested by reviewers or the IRB. The study will appear under the My Inbox tab in all of these occasions.

To open a study to make changes:

1. From your personal folder, click on the title of the study you wish to select
2. In the study workspace, click the _Edit Study_ button. The first study application screen appears in edit mode.

3. Make any necessary changes and save the study by clicking the _Save or Continue_ button

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The table below outlines the essential steps for viewing and responding to requested changes or clarifications:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Log: 09:00 - Information for Protocol Review (Study Description)</td>
<td>PI, Alex</td>
</tr>
<tr>
<td>Change Log: 12:09 - Type of Consent</td>
<td>PI, Alex</td>
</tr>
<tr>
<td>Change Log: 09:00 - Information for Protocol Review (Study Description)</td>
<td>PI, Alex</td>
</tr>
<tr>
<td>Study: Approvable Pending Minor Changes</td>
<td>IRB, Alex</td>
</tr>
<tr>
<td>Study Approved by Department</td>
<td>DA, Alex</td>
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<tr>
<td>Study Submitted for Review</td>
<td>PI, Alex</td>
</tr>
<tr>
<td>Created Study</td>
<td>PI, Alex</td>
</tr>
</tbody>
</table>

Click on the “View Correspondence Letter” link in the history log to view the IRB contingency letter for the study.
To edit your study, and make requested changes and/or clarifications, please click on the Edit Study button on the left side of the screen to navigate to the smartform.

Click on the arrow next to “Reviewer Notes” at the top of the screen to display the requested changes and/or clarifications.
The reviewer’s notes and requests for changes and/or clarifications will be listed. Please make any necessary changes in the study application. Once you have done so, please click on the link “Click here to respond” to provide a required response.

After you click on the “Click here to respond” link, a window will open directing you to “Respond to reviewer notes”. In the “Type” field, please select whether the change request was completed, not completed, or whether your response is providing information. In the “Response” text box, please write your
response to the requested change here, detailing the change made or your reason for disputing it. When finished, click “OK”.

To view additional reviewer notes, click the “Next” button located next to “Reviewer notes” at the top of the page. Once you have finished making all requested changes and/or clarifications to the study application and responded to the change requests, save your changes and exit out of the study application.
In the study workspace area, click **Submit Changes** to submit your response to the requested changes and/or clarifications to the IRB.

Changes can be submitted to the IRB by any team member.
At any time, you may view the reviewer’s notes and request for changes and/or clarifications (and, where applicable, your response to the notes/requests) under the **Reviewer Notes** tab.