Submit a Designated Review

Recording your decision completes the designated review and moves the submission forward in the review process.

1. From the submission workspace, click Submit Designated Review.

Completing the Designated Review

Record the determinations, review level, and other important information.

1. Select the appropriate determination

2. For Phase 1 applications, indicate N/A as the risk level
3. Select the special determinations and waivers that apply to the submission

Special determinations and waivers:
- Emergency Use
- Expanded Access
- Humanitarian Use Device
- Right to Try

a. When you select the special determinations and waivers, additional boxes will appear where you will attest that the submission meets that requirement and note other elements of the submission

Note: Checking these boxes are required, because this is where the final determinations for the study is made. This language will auto populate regulatory determination language into the approval letter.

4. For Phase I applications that require only chair concurrence, select Expedited

5. Then select Chair Concurrence
Once IRB Chair Concurrence is selected, you cannot select any other categories as they do not apply to chair concurrences.

6. Indicate if continuing review is required, and if it is required provide a rationale.

<table>
<thead>
<tr>
<th>Continuing Review is required for:</th>
<th>Continuing Review is NOT required for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Is continuing review required? *</td>
<td>4. * Is continuing review required?</td>
</tr>
<tr>
<td>〇 Yes 〇 No Clear</td>
<td>〇 Yes 〇 No Clear</td>
</tr>
<tr>
<td>* Rationale for continuing review requirement:</td>
<td></td>
</tr>
</tbody>
</table>

|                                                                                               |                                                    |
| Expanded Access submissions reviewed by the Full Board                                         | Right to Try                                       |
| Humanitarian Use Device submissions reviewed by the Full Board                                 | Emergency Use                                      |
|                                                                                               | Expanded Access submissions with Chair Concurrence |

BruinIRB will auto populate the approval date with the first designated reviewer action. OHRPP staff will verify the expiration date or anniversary date upon study approval.

- For studies that require CR, OHRPP staff will set an expiration date.

![Expiration Date](image1)

- For studies that do not require CR, OHRPP staff will set an anniversary date. This will trigger the annual PI assurances.

![Anniversary Date](image2)

7. Click Yes if you are ready to submit your review. If not, click No, and the information you entered will be saved. You can submit your review later. If you said Yes, the submission moves to the IRB coordinator’s inbox so the coordinator can send a determination letter to the PI.