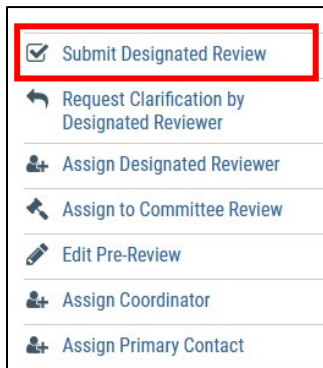


**Quick Reference Guide: Completing Designated Review for Non-Committee Review in BruinIRB – Phase I (07/2022)**

**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

1. \* **Determination:**

Name

Approved

Modifications Required to Secure "Approved"

Not Human Research

Modifications Required to Secure "Not Human Research"

Human Research, Not Engaged

Modifications Required to Secure "Human Research, Not Engaged"

2. For Phase 1 applications, indicate **N/A** as the risk level

**2. Risk Level: ?**

Greater than minimal risk

No greater than minimal risk

N/A

[Clear](#)

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

**a. Humanitarian Use Device**

HUD submission with a research

HUD submission with no research component

This submission meets the Humanitarian Use Device (HUD) criteria under 21 CFR 814.3(n).

**b. Emergency Use**

This submission meets the Emergency Use approval criteria under 21 CFR 56.104(c).

**c. Right to Try**

This submission meets the Right to Try criteria under Federal Law 115-176 and California Law Section 11548.

**d. Expanded Access**

This submission meets the Expanded Access approval criteria under 21 CFR Part 312.

*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**

**4. \* Review level:**

Name

Exempt

Expedited

5. Then select **Chair Concurrence**

(8)(a) Long-term follow-up

(8)(b) No subjects enrolled

(8)(c) Data analysis

(9) Convened IRB determined minimal risk

IRB 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.

<p><i>Continuing Review is required for:</i></p> <div style="border: 1px solid black; padding: 5px;"> <p><b>* Is continuing review required?</b> ?</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> </div> <p><b>* Rationale for continuing review requirement:</b></p> <div style="border: 1px solid gray; height: 20px; width: 100%;"></div>	<p><i>Continuing Review is <b>NOT</b> required for:</i></p> <div style="border: 1px solid black; padding: 5px;"> <p><b>4. * Is continuing review required?</b></p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No <a href="#">Clear</a></p> </div>
<p><i>Expanded Access submissions reviewed by the Full Board</i></p>	<p><i>Right to Try</i></p>
<p><i>Humanitarian Use Device submissions reviewed by the Full Board</i></p>	<p><i>Emergency Use</i></p>
	<p><i>Expanded Access submissions with Chair Concurrence</i></p>

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.

**5. Dates:**

Approval date: ?

4/30/2021

Last day of approval period: ?

4/29/2022

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

**5. Dates:**

Approval date: ?

4/30/2021

Last day of approval period: ?

Anniversary Date:

4/29/2022

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.