AURA-IRB Continuing Review (CR)/ Termination Guidelines

Principal Investigators (PI)

End Users: Principal Investigators (PI) who enter studies.

Purpose:
The following serves to aid Principal Investigators (PI) in the submission of a Continuing Review to AURA-IRB. Document includes:

1. Workflow Overview (sequence of AURA-IRB States and owners in the process)
   a. State = status of the CR in the workflow; each State appears in AURA-IRB system.

2. PI Checklist (step-by-step guide for Continuing Review submissions)

3. State Descriptions

Use bookmarks to your left to navigate to the above mentioned sections.

Acronyms and Legend

<table>
<thead>
<tr>
<th>Acronyms</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>RT</td>
<td>Research Team/ Regulatory Contact</td>
</tr>
<tr>
<td>IRBS</td>
<td>Institutional Review Board Staff</td>
</tr>
<tr>
<td>IRBA</td>
<td>Institutional Review Board Administrator</td>
</tr>
</tbody>
</table>

Legend

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Green</td>
<td>CR editable by PI</td>
</tr>
<tr>
<td>Light Blue</td>
<td>CR with IRB (Locked to PI)</td>
</tr>
<tr>
<td>Red</td>
<td>CR in Full IRB Review (Locked to PI)</td>
</tr>
<tr>
<td>Yellow</td>
<td>CR in Non-Committee Review (Locked to PI)</td>
</tr>
<tr>
<td>Yellow Star</td>
<td>Activity transitions CR to next state</td>
</tr>
</tbody>
</table>
Continuing Review (CR) Workflow
(Click diagram for State descriptions or CLICK HERE)

2 Types of Continuing Reviews:
- Continuing Review
- Termination by PI

Legend:
- CR editable by PI
- CR with IRB (Locked to PI)
- CR in Full IRB Review (Locked to PI)
- CR in Non-Committee Review (Locked to PI)
- Activity transitions CR to next state

PRE SUBMISSION

IRB ASSIGNMENT

CHANGES REQUESTED BY IRB STAFF

PRE REVIEW

CHANGES REQUESTED BY IRB ADMIN

FULL IRB REVIEW

NON-COMMITTEE REVIEW

Committee Decision

PENDING CONDITIONAL

DEFERRED

Committee Decision

Committee Decision

Committee Decision

CHANGES REQUIRED BY IRB
PI Checklist – Continuing Review

PRE SUBMISSION

☐ 1. Log into AURA IRB ([http://aura.uchicago.edu](http://aura.uchicago.edu))
   Off-site? Go to [https://cvpn.uchicago.edu/+CSCOE+/logon.html](https://cvpn.uchicago.edu/+CSCOE+/logon.html) first, then visit link above
   a. Select AURA IRB Login
   b. Enter your CNET or UCHAD ID and password

☐ 2. Start a Continuing Review (CR)
   a. Locate Approved study (in PI Protocols tab) and click on its name
   b. Click New Continuing Review or Termination by PI (CR workspace - left)
   c. Enter all applicable information/ attachments [Insert link to Quick Reference Guide]
   d. Click “Finish” when complete

★ 3. Submit to IRB
   a. Click Submit to IRB (CR Workspace - left)
      a. Answer questions and click “Ok”

CR moves to IRB ASSIGNMENT where IRB Staff reviews. CR cannot be edited until IRB requests changes.

CHANGES REQUESTED BY IRB STAFF

Upon receipt of e-mail notification “Changes Requested by IRB Staff”…

☐ 4. Select PI Inbox tab
   a. Click name of the CR
   b. Click Edit Continuing Review, then click Reviewer Notes icon (top left) to view and make changes. Use “Next” & “Previous” buttons to review notes, make changes, then “Exit” to return to workspace
   ★ c. Click Submit Changes to IRB, confirm submission and click “Ok”

CR moves back to IRB ASSIGNMENT for IRB Staff review and cannot be edited. If no additional changes, IRBS assigns IRBA to review. CR moves to PRE REVIEW and cannot be edited until IRBA requests changes.
CHANGES REQUESTED BY IRB ADMIN

Upon receipt of e-mail notification “Changes Requested by IRB Admin”…

☐ 5. Select PI Inbox tab
   a. Click name of the CR
   b. Click Edit Continuing Review, then click Reviewer Notes icon (top left) to view and make changes. Use “Next” & “Previous” buttons to review notes, make changes, then “Exit” to return to workspace
   ★ c. Click Submit Changes to IRB, confirm submission and click “Ok”

CR moves back to PRE REVIEW, is assigned to Full IRB or Non-Committee review and continues through the workflow until committee reaches a decision.

IF THE CR REACHES ONE OF THE FOLLOWING COMMITTEE DECISION STATES, NO ADDITIONAL ACTION REQUIRED:
APPROVED, TERMINATED BY PI, REJECTED

IF THE CR REACHES ONE OF THE FOLLOWING STATES, PROCEED AS FOLLOWS.

PENDING CONDITIONAL

Upon receipt of e-mail notification “Pending Conditional Response Required”…

☐ 6. Select PI Inbox tab
   a. Click name of the CR
   b. In History tab click “View correspondence letter” to view pending conditional letter with IRB changes
   c. Click Edit Continuing Review and use Jump To: to navigate and make edits in views
      - Click “Save” after each edit; Click “Exit” to return to workspace
   ★ d. Click Submit Changes to IRB, confirm submission and click “Ok”

CR moves back to PRE REVIEW, is assigned to Full IRB or Non-Committee review and continues through the workflow until committee reaches a final decision.

DEFERRED

Upon receipt of e-mail notification “Deferred Response Required”…

☐ 7. Select PI Inbox tab
   a. Click name of the CR
b. In History tab click “View correspondence letter” to view deferral letter
c. Click Edit Continuing Review and use Jump To: to navigate and make edits in views
   - Click “Save” after each edit; Click “Exit” to return to workspace
★ d. Click Submit Changes to IRB, confirm submission and click “Ok”

CR moves back to PRE REVIEW, is assigned to Full IRB or Non-Committee review and continues through the workflow until committee reaches a final decision.

CHANGES REQUIRED BY IRB

Upon receipt of e-mail notification “Changes required by IRB”…

☐ 8. Select PI Inbox tab
   a. Click name of CR
   b. In History tab click “Sent Change Letter to PI” to view changes required and click “Exit” to return to workspace
   c. Click Edit Continuing Review and use Jump To: to navigate and make edits in views
      - Click “Save” after each edit; Click “Exit” to return to workspace
★ d. Click Submit Changes to IRB, confirm submission and click “Ok”

CR moves back to PRE REVIEW, is assigned to Full IRB or Non-Committee review for review and continues through the workflow until committee reaches a final decision.
# State Descriptions

(State = status of CR in AURA IRB)

<table>
<thead>
<tr>
<th>States</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre Submission</td>
<td>SmartForm in progress</td>
</tr>
<tr>
<td>Pending PI Endorsement</td>
<td>CR ready for PI to endorsement and submit to IRB</td>
</tr>
<tr>
<td>Pending PI Re-Endorsement</td>
<td>CR has been deferred (requires major changes) and PI must re-endorse before changes submitted to IRB</td>
</tr>
<tr>
<td>IRB Assignment</td>
<td>IRB Staff reviews and assigns CR to IRB Administrator</td>
</tr>
<tr>
<td>Changes Requested by IRB Staff</td>
<td>CR returns to the PI for edits</td>
</tr>
<tr>
<td>Changes Requested by IRB Admin</td>
<td>CR returns to the PI for edits</td>
</tr>
<tr>
<td>Pre-Review</td>
<td>IRB Administrator reviews before forwarding for Full IRB Review or Non-Committee review</td>
</tr>
<tr>
<td>Changes Requested by IRB Administrator</td>
<td>IRB Administrator returns CR to PI for edits</td>
</tr>
<tr>
<td>Changes Required by IRB</td>
<td>CR returns to the PI for Non-Committee review edits</td>
</tr>
</tbody>
</table>

**FULL IRB REVIEW States**

<table>
<thead>
<tr>
<th>States</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awaiting Full IRB Review</td>
<td>CR requires full board review and has been assigned to IRB meeting agenda</td>
</tr>
<tr>
<td>Awaiting Full IRB Correspondence</td>
<td>IRB Administrator prepares committee determination letter to send to PI</td>
</tr>
<tr>
<td>Decision and Correspondence Review</td>
<td>PI addresses Committee Comments</td>
</tr>
</tbody>
</table>

**NON-COMMITTEE REVIEW States**

(Expedited & Exempt CR review)

<table>
<thead>
<tr>
<th>States</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Non-Committee Review</td>
<td>CR reviewed by assigned IRB Reviewer (s)</td>
</tr>
<tr>
<td>Changes Required by Reviewer</td>
<td>IRB Reviewer(s) requests and forwards Change letter to PI for CR edits</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Awaiting Non-Committee Correspondence</td>
<td>IRB Administrator prepares and sends IRB determination letter to PI</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Committee Decision States</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>CR approved by IRB</td>
</tr>
<tr>
<td>Pending Conditional</td>
<td>CR conditionally approved by IRB but requires minor changes</td>
</tr>
<tr>
<td>Deferred</td>
<td>CR requires major changes and re-review by IRB Committee</td>
</tr>
<tr>
<td>Terminated by PI</td>
<td>Approval Terminated</td>
</tr>
<tr>
<td>Rejected</td>
<td>CR rejected by IRB</td>
</tr>
</tbody>
</table>