AURA-IRB Continuing Review (CR)/ Termination Guidelines

Research Team (RT)

User: Research Team member (RT)

Purpose:
The following serves to aid Research Team members in the submission of a Continuing Review to AURA-IRB. Document includes:
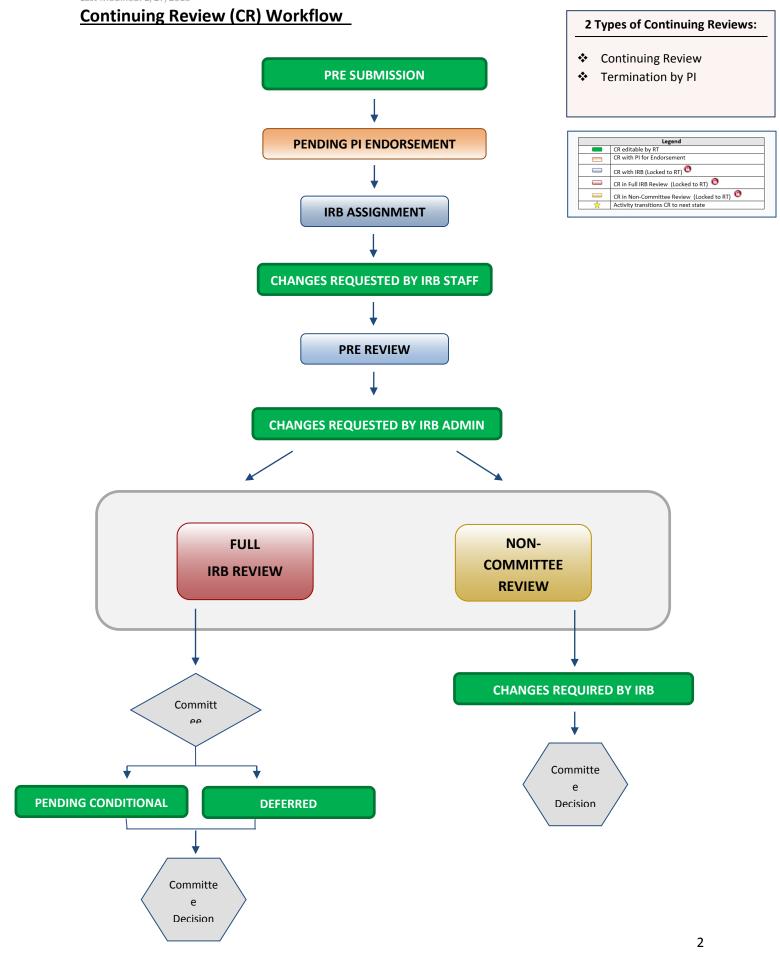
1. Workflow Overview (sequence of AURA-IRB States and owners in the process)
    a. State = status of the CR in the workflow; each State appears in AURA-IRB system.

2. Research Team 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

Acronyms	Title
PI	Principal Investigator
RT	Research Team/ Regulatory Contact
IRBS	Institutional Review Board Staff
IRBA	Institutional Review Board Administrator

Legend	
🟩	CR editable by RT
🟧	CR with PI for Endorsement
🟦	CR with IRB (Locked to RT) 🔒
🟥	CR in Full IRB Review (Locked to RT) 🔒
🟨	CR in Non-Committee Review (Locked to RT) 🔒
⭐	Activity transitions CR to next state

Continuing Review (CR) Workflow

2 Types of Continuing Reviews:

- ❖ Continuing Review
- ❖ Termination by PI

Legend	
🟩	CR editable by RT
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▭	CR in Full IRB Review (Locked to RT) 🔒
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⭐	Activity transitions CR to next state

PRE SUBMISSION

↓

PENDING PI ENDORSEMENT

↓

IRB ASSIGNMENT

↓

CHANGES REQUESTED BY IRB STAFF

↓

PRE REVIEW

↓

CHANGES REQUESTED BY IRB ADMIN

↙ ↘

FULL IRB REVIEW   **NON-COMMITTEE REVIEW**

↓ (Full IRB Review)

Committee

↓

PENDING CONDITIONAL   **DEFERRED**

↓

Committee Decision

↓ (Non-Committee Review)

CHANGES REQUIRED BY IRB

↓

Committee Decision

RT Checklist – Continuing Review

PRE SUBMISSION

☐ 1. Log into AURA IRB (http://aura.uchicago.edu)
   a. Select **IRB (on campus)** or **IRB (off campus)**
   b. Enter your CNET or UCHAD ID and password

☐ 2. Start a Continuing Review (CR)
   a. Locate approved study (All 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 in SmartForm
   d. Click "Finish" when complete

★ ☐ 3. Forward to PI for endorsement
   - Click **Forward to PI for Endorsement** (CR workspace - left)
     o Answer questions and click "Ok"

CR moves to PENDING PI ENDORSEMENT and cannot be edited unless PI requests changes.

★ ☐ 4. *If* PI requests changes
   a. Click name of the approved Study (All Protocols tab)
   b. Select Continuing Review tab and click on its name
   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. Select **Forward to PI for Endorsement**
      - Confirm submission and click "Ok"

When PI approves & submits to IRB, CR moves to IRB ASSIGNMENT where IRB Staff reviews. CR cannot be edited until IRB requests changes.

CHANGES REQUESTED BY IRB STAFF/ ADMIN

Upon receipt of e-mail notification "Changes Requested by IRB Staff/Admin"…

☐ 5. Select **Research Team Inbox** tab
   a. Click name of the CR and see comments or attached document with changes

b. Click **Edit Continuing Review**, and use Jump To menu to navigate and make edits in views
- Click "Save" after each edit; Click "Exit" to return to workspace

☆ *c.* Click **Submit Changes to IRB**, confirm submission and click "Ok"

CR moves back to ***IRB ASSIGNMENT or PRE-REVIEW*** *and cannot be edited. At Pre-Review, study 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"…

☐ 7. Select **Research Team 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"…

☐ 8. Select **Research Team 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 **Forward to PI for Re-Endorsement**, confirm submission and click "Ok"
   e. No changes requested, proceed to (f.)
      - If PI requests changes, see step #4. Upon receipt of PI approval proceed to (e.)

⭐   f.   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"…

☐   9.   Select **Research Team Inbox** tab
- a.   Click name of the CR
- b.   In History tab click "Sent Change Letter to PI" to view changes required and click "Exit" to return to workspace
- b.   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
- ⭐   b.   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)

States	Description
Pre Submission	SmartForm in progress
Pending PI Endorsement	CR ready for PI to endorsement and submit to IRB
Pending PI Re-Endorsement	CR has been deferred (requires major changes) and PI must re-endorse before changes submitted to IRB
IRB Assignment	IRB Staff reviews and assigns CR to IRB Administrator
Changes Requested by IRB Staff	CR returns to the RT for edits
Changes Requested by IRB Admin	CR returns to the RT for edits
Pre-Review	IRB Administrator reviews before forwarding for Full IRB Review or Non-Committee review
Changes Requested by IRB Administrator	IRB Administrator returns CR to RT for edits
Changes Required by IRB	CR returns to the RT for Non-Committee review edits
FULL IRB REVIEW States	
Awaiting Full IRB Review	CR requires full board review and has been assigned to IRB meeting agenda
Awaiting Full IRB Correspondence	IRB Administrator prepares committee determination letter to send to RT
Decision and Correspondence Review	RT addresses Committee Comments
NON-COMMITTEE REVIEW States **(Expedited & Exempt CR review)**	
In Non-Committee Review	CR reviewed by assigned IRB Reviewer (s)

Changes Required by Reviewer	IRB Reviewer(s) requests and forwards Change letter to RT for CR edits
Awaiting Non-Committee Correspondence	IRB Administrator prepares and sends IRB determination letter to PI

Committee Decision States	**Description**
Approved	CR approved by IRB
Pending Conditional	CR conditionally approved by IRB but requires minor changes
Deferred	CR requires major changes and re-review by IRB Committee
Terminated by PI	Approval Terminated
Rejected	CR rejected by IRB