

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

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






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

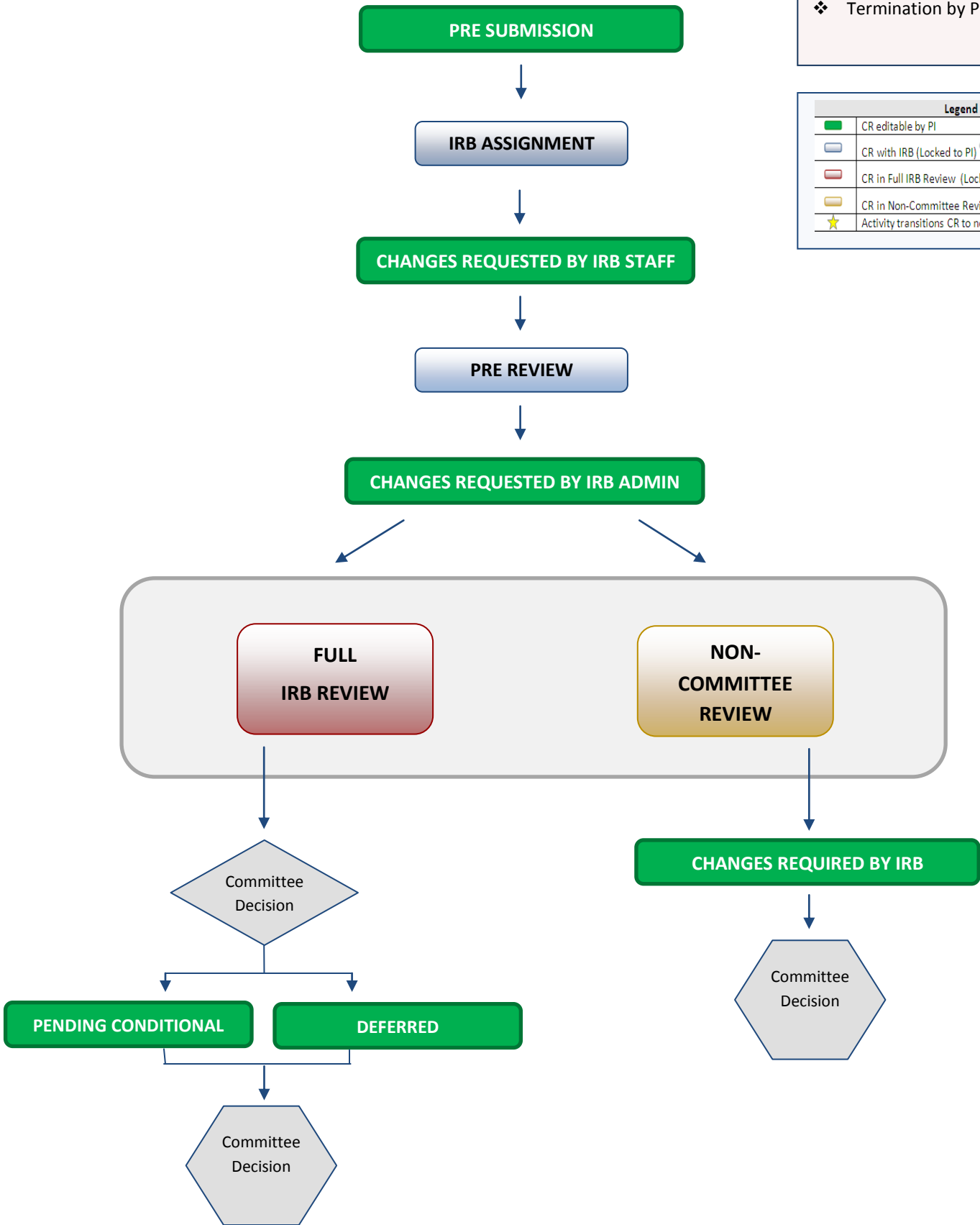
Continuing Review (CR) Workflow

(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



PI Checklist – Continuing Review

PRE SUBMISSION

- 1. Log into AURA IRB (<http://aura.uchicago.edu>)
Off-site? Go to <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)

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 PI for edits
Changes Requested by IRB Admin	CR returns to the PI 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 PI for edits
Changes Required by IRB	CR returns to the PI 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 PI
Decision and Correspondence Review	PI 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 PI 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