

AURA-IRB Amendment 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 Amendments to AURA-IRB. Document includes:

1. Workflow Overview (sequence of AURA-IRB States and owners in the process)
 - a. State = status of the Amendment in the workflow; each State appears in AURA-IRB system.
2. PI Checklist (step-by-step guide for Amendment 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	
	Amendment editable by PI
	Amendment with IRB (Locked to PI) 
	Amendment in Full IRB Review (Locked to PI) 
	Amendment in Non-Committee Review (Locked to PI) 
	Activity transitions Amendment to next state

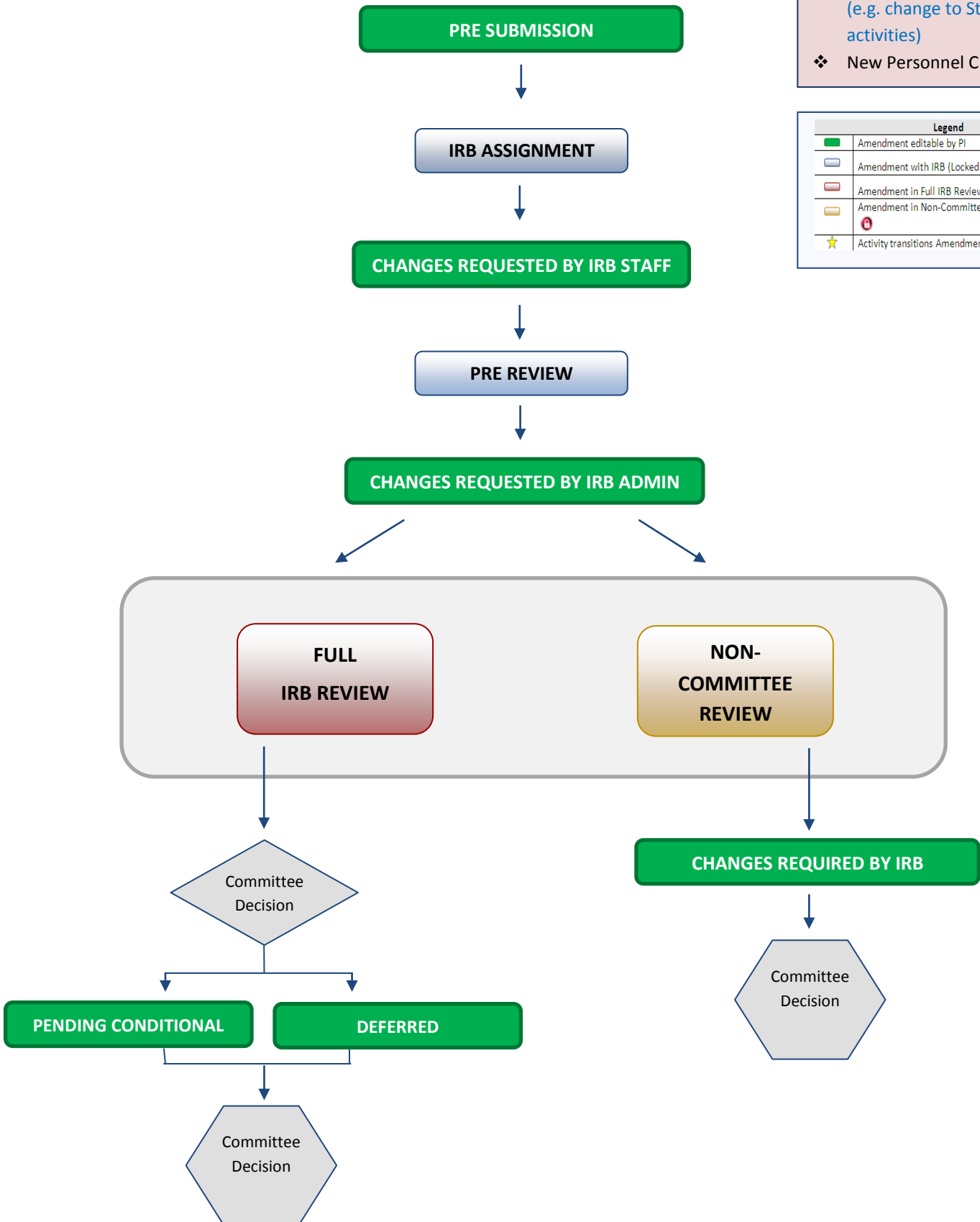
Amendment Workflow

(Click diagram for State descriptions or [CLICK HERE](#))

2 Types of Study Amendments:

- ❖ New Amendment
(e.g. change to Study activities)
- ❖ New Personnel Change

Legend	
	Amendment editable by PI
	Amendment with IRB (Locked to PI)
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	Activity transitions Amendment to next state



PI Checklist – Amendments

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 an Amendment
 - a. Locate Approved study (in PI Protocols tab) and click on its name
 - b. Click **New Amendment** or **New Personnel Change** (Amendment workspace - left)
 - Enter all applicable information/ attachments *[Insert link to Quick Reference Guide]*
 - c. Click **Modified Study SmartForm** (view 1.9) to make changes to main study. Click “Save” after every edit, then “Exit” when complete to return to view 1.9
 - d. Click “Finish”

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

Amendment moves to **IRB ASSIGNMENT** where IRB Staff reviews. Amendment 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 Amendment
 - b. Click **Edit Amendment**, 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”

Amendment moves back to **IRB ASSIGNMENT** for IRB Staff review and cannot be edited. If no additional changes, IRBS assigns IRBA to review. Amendment 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 Amendment
 - b. Click **Edit Amendment**, 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”

Amendment 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 AMENDMENT REACHES ONE OF THE FOLLOWING COMMITTEE DECISION STATES, NO ADDITIONAL ACTION REQUIRED: APPROVED, EXEMPT, REJECTED

IF THE AMENDMENT 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 Amendment
 - b. In History tab click “View correspondence letter” to view pending conditional letter with IRB changes
 - c. Click **Edit Amendment** 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”

Amendment 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 Amendment
 - b. In History tab click “View correspondence letter” to view deferral letter
 - c. Click **Edit Amendment** 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”

Amendment 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 Amendment
 - b. In History tab click “Sent Change Letter to PI” to view changes required and click “Exit” to return to workspace
 - c. Click **Edit Amendment** 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”

Amendment 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 Amendment in AURA IRB)

States	Description
Pre Submission	SmartForm in progress
IRB Assignment	IRB Staff reviews and assigns Amendment to IRB Administrator
Changes Requested by IRB Staff	Amendment returns to the PI for edits
Changes Requested by IRB Admin	Amendment 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 Amendment to PI for edits
Changes Required by IRB	Amendment returns to the PI for Non-Committee review edits
FULL IRB REVIEW States	
Awaiting Full IRB Review	Amendment 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 Amendment review)	
In Non-Committee Review	Amendment reviewed by assigned IRB Reviewer (s)
Changes Required by Reviewer	IRB Reviewer(s) requests and forwards Change letter to PI for Amendment edits

Awaiting Non-Committee Correspondence	IRB Administrator prepares and sends IRB determination letter to PI
Committee Decision States	Description
Approved	Amendment approved by IRB
Pending Conditional	Amendment conditionally approved by IRB but requires minor changes
Deferred	Amendment requires major changes and re-review by IRB Committee
Exempt	Amendment exempt from IRB Review/ Approval and sent to Non-Committee Review
Rejected	Amendment rejected by IRB