

AURA-IRB Amendment Guidelines

Research Team (RT)

User: Research Team member (RT)

Purpose:










The following serves to aid Research Team members 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. Research Team Checklist (step-by-step guide for Amendment submissions)
3. State Descriptions

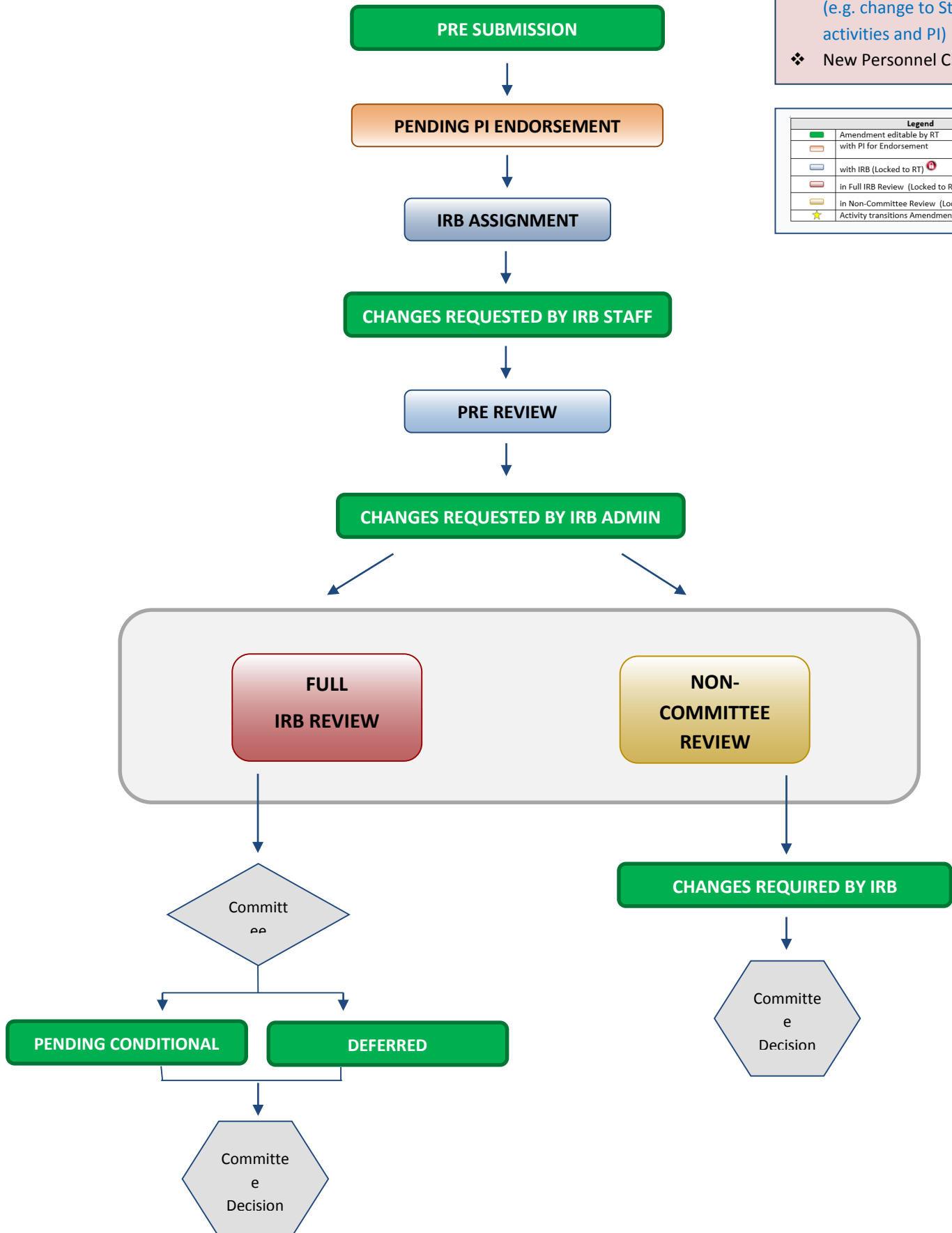
Use bookmarks to your left to navigate to the above mentioned sections.

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 RT
	with PI for Endorsement
	with IRB (Locked to RT) 
	in Full IRB Review (Locked to RT) 
	in Non-Committee Review (Locked to RT) 
	Activity transitions Amendment to next state

Amendment Workflow



2 Types of Study Amendments:

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

Legend	
■	Amendment editable by RT with PI for Endorsement
■	with IRB (Locked to RT) ¹
■	In Full IRB Review (Locked to RT) ²
■	In Non-Committee Review (Locked to RT) ³
★	Activity transitions Amendment to next state

RT Checklist – Amendments

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 an Amendment
 - a. Locate Approved study (All Protocols tab) and click on its name
 - **New Personnel Change** (Amendment workspace - left)
 - o Add or delete new personal and click Finish
 - **Full Amendment** (Amendment workspace - left)
 - o Complete Smartform to inform IRB of the changes you are making.
 - o View 1.9 Summary of Changes and Steps, click **Modified Study SmartForm** to make changes to main study. Click “Save” after every edit, then “Exit” when complete to return to view 1.9
 - c. Click “Finish”

 - ★ 3. Forward to PI for endorsement
 - a. Click **Forward to PI for Endorsement** (Amendment workspace - left)
 - Answer questions and click “OK”
- Amendment moves to **PENDING PI ENDORSEMENT** and awaits PI submission to IRB.*
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- ★ 4. *If* PI requests changes
 - a. Click name of the approved Study (All Protocols tab)
 - b. Select Amendments tab and click on its name
 - 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. Select **Forward to PI for Endorsement**
 - Confirm submission and click “OK”

*When PI approves & submits to IRB, Amendment moves to **IRB ASSIGNMENT** where IRB Staff reviews. Amendment cannot be edited unless 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 Amendment and see comments or attached document with changes
 - b. Click **Edit Amendment** 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”

Amendment moves back to **IRB ASSIGNMENT** or **PRE-REVIEW** and cannot be edited. At Pre-Review, Amendment 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”...

- 7. Select **Research Team 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”...

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

- 9. Select **Research Team Inbox** tab
 - a. Click name of the Amendment
 - b. In History tab click “Sent Change Letter to PI” to view changes required and click “Exit” to return to workspace
 - b. 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
 - ★ b. 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
Pending PI Endorsement	Amendment ready for PI to endorsement and submit to IRB
Pending PI Re-Endorsement	Study has been deferred (requires major changes) and PI must re-endorse before changes submitted to IRB
IRB Assignment	IRB Staff reviews and assigns Amendment to IRB Administrator
Changes Requested by IRB Staff	Amendment returns to the RT for edits
Changes Requested by IRB Admin	Amendment 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 Amendment to RT for edits
Changes Required by IRB	Amendment returns to the RT 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 RT
Decision and Correspondence Review	RT 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 RT 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