

# AURA-IRB Initial Submission Guidelines

## Research Team (RT)

**End Users:** Research Team (RT)

**Purpose:**











The following serves to aid Research Team members in the submission of new studies to AURA-IRB. Document includes:

1. Workflow Overview (sequence of AURA-IRB States and owners in the process)
  - a. State = status of the Study in the workflow; each State appears in AURA-IRB system.
2. Research Team Checklist (step-by-step guide for new study submission)
3. State Descriptions

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

### Acronyms and Legend

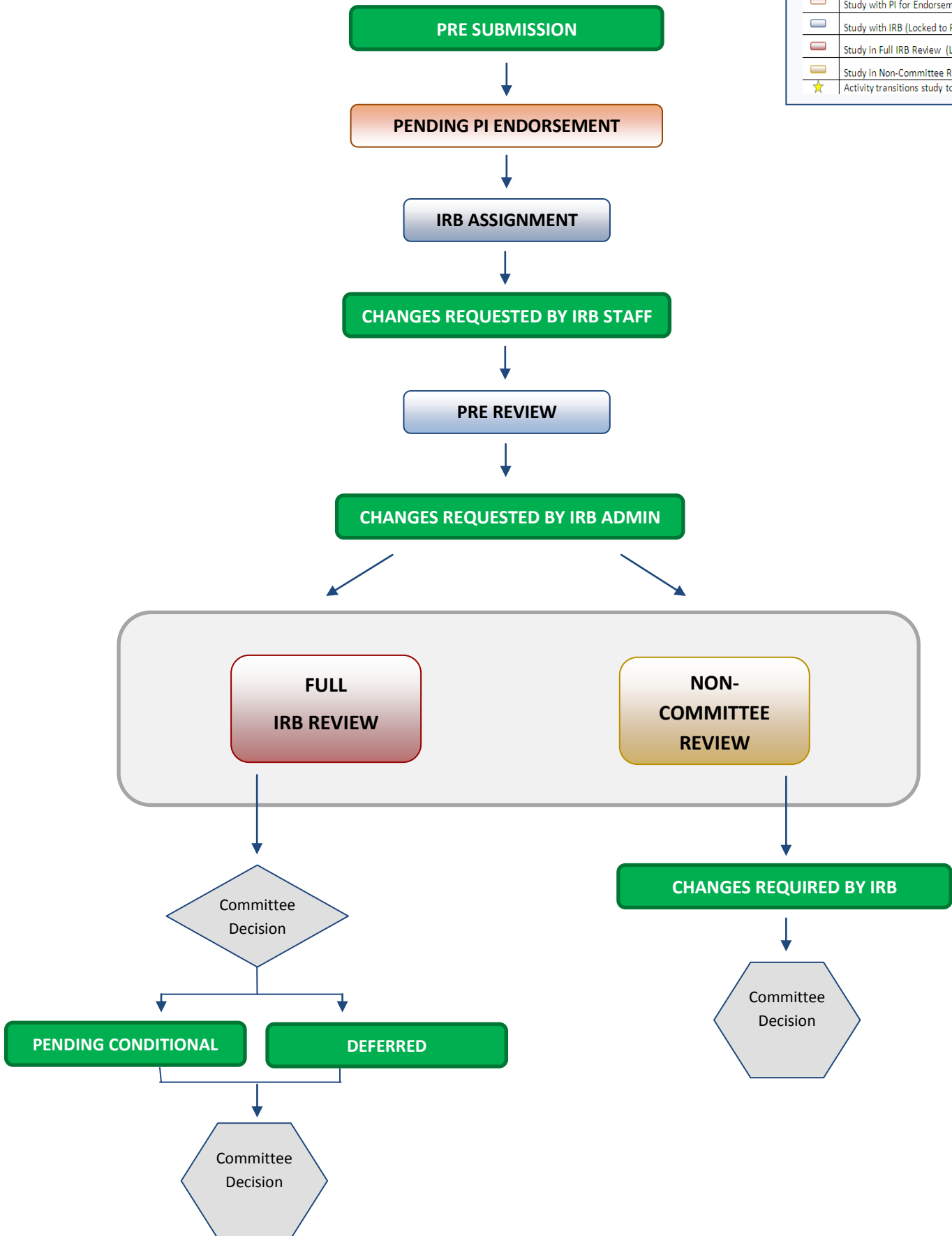
Acronyms	Title
PI	Principal Investigator
RT	Research Team/ Regulatory Contact
IRBS	Institutional Review Board Staff
IRBA	Institutional Review Board Administrator

Legend	
	Study editable by RT
	Study with PI for Endorsement (Locked to RT) 
	Study with IRB (Locked to RT) 
	Study in Full IRB Review (Locked to RT) 
	Study in Non-Committee Review (Locked to RT) 
	Activity transitions study to next state

# Initial Submission Workflow

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

Legend	
	Study editable by RT
	Study with PI for Endorsement (Locked to RT)
	Study with IRB (Locked to RT)
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# RT Checklist - Initial Submission

## 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 New Study
  - a. Click **New Study** (Study Workspace - left)  
Enter all applicable information/ attachments and click “Finish” when complete  
[\[See Quick Reference Guide\]](#)

- ★  3. Forward to PI for endorsement (*Study will lock; no edits allowed*)
  - a. Click **Forward to PI for Endorsement** (Study workspace - left)
    - Answer questions and click “Ok”

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

- ★  4. *If* PI requests changes
  - a. Click name of the Study (All Protocols tab)
  - b. Click “Change requested by PI” to review changes and click “Exit”
  - c. Click **Edit Study** 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”

*Study moves to **PENDING PI ENDORSEMENT** and cannot be edited. If PI requests changes, repeat Step #4. When PI approves & submits to IRB, study moves to **IRB ASSIGNMENT** where IRB Staff reviews. Study cannot be edited until IRB requests changes.*

## CHANGES REQUESTED BY IRB STAFF

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

- 5. Select **Research Team Inbox** tab
  - a. Click name of the Study

- b. Click **Edit Study**, 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”

Study moves back to **IRB ASSIGNMENT** for IRB Staff review and cannot be edited. If no additional changes, IRBS assigns IRBA to review. Study 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”...

- 6. Select **Research Team Inbox** tab
  - a. Click name of the Study
  - b. Click **Edit Study**, 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”

Study 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 STUDY REACHES ONE OF THE FOLLOWING COMMITTEE DECISION STATES, NO ADDITIONAL ACTION REQUIRED: APPROVED, EXEMPT, NOT HUMAN SUBJECTS RESEARCH, NOT ENGAGED, NOT RESEARCH, REJECTED**

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

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

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

Study 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.

## State Descriptions

(State = status of Study in AURA IRB)

States	Description
Pre Submission	SmartForm in progress
Pending PI Endorsement	Study 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 Study to IRB Administrator
Changes Requested by IRB Staff	Study returns to the RT for edits
Changes Requested by IRB Admin	Study 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 Study to RT for edits
Changes Required by IRB	Study returns to the RT for Non-Committee review edits
Ancillary Review Required	Ancillary review (e.g. CTRC, RADRAC, PBUC, HIRO, OCR, etc.) pending and must be completed prior to IRB Administrator assigns to Full IRB Review or Non-Committee review
Awaiting Ancillary Review	Final Ancillary review pending and to be completed prior to IRB Administrator decision correspondence
<b>FULL IRB REVIEW States</b>	
Awaiting Full IRB Review	Study 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

<b>NON-COMMITTEE REVIEW States (Expedited &amp; Exempt Study review)</b>	
In Non-Committee Review	Study reviewed by assigned IRB Reviewer (s)
Changes Required by Reviewer	IRB Reviewer(s) requests and forwards Change letter to RT for Study edits
Awaiting Non-Committee Correspondence	IRB Administrator prepares and sends IRB determination letter to PI
<b>Committee Decision States</b>	<b>Description</b>
Approved	Study approved by IRB
Pending Conditional	Study conditionally approved by IRB but requires minor changes
Deferred	Study requires major changes and re-review by IRB Committee
Exempt	Study exempt from IRB Review/ Approval and sent to Non-Committee Review
Not Human Subjects Research	Study does not qualify as human subjects research
Not Engaged	Study activities are such that UChicago is considered to be not engaged in research per current OHRP definitions
Not Research	Study does not qualify as research
Rejected	Study rejected by IRB