

AURA-IRB Initial Submission Guidelines

Research Team (RT)

User: Research Team member (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

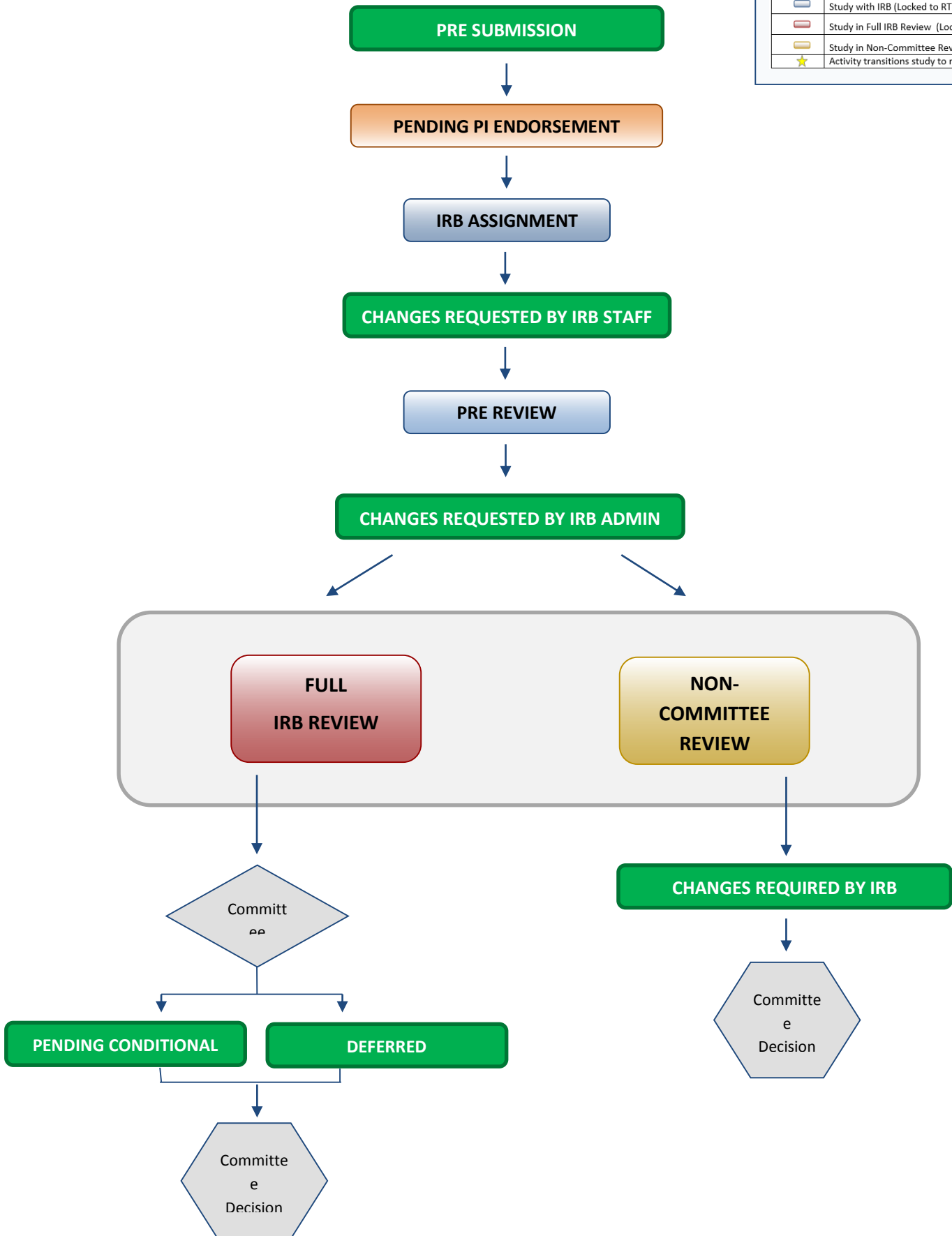
Acronyms and Legend

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
	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

Legend	
	Study editable by RT
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RT Checklist - Initial Submission

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 New Study
 - a. Click **New Study** (Study Workspace - left)
 - b. Enter all applicable information/ attachments. Navigate using “Continue” or “Jump To Menu” and click “Finish” in view 19.0 when complete

- ★ 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 awaits PI submission to IRB.*

- ★ 4. *If* PI requests changes
 - a. Click name of the Study (All Protocols tab)
 - b. Click **Edit Study** and use Jump To menu to navigate and make edits in views. Click “Save” after each edit; Click “Exit” to return to workspace
 - Inform PI that edits are complete and click “Ok”

*When PI approves & submits to IRB, study moves to **IRB ASSIGNMENT** where IRB Staff reviews. Study 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 Study and see comments or attached document with changes
 - b. Click **Edit Study** 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”

Study 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 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
 - b. 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
 - ★ b. 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
FULL IRB REVIEW States	
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

NON-COMMITTEE REVIEW States (Expedited & Exempt Study review)	
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
Committee Decision States	Description
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