

# AURA-IRB Unanticipated Problems (UP) Guidelines

## Research Team (RT)

**User:** Research Team member (RT)

**Purpose:**










The following serves to aid Research Team members in the submission of Unanticipated Problems (UP) to AURA-IRB. Document includes:

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

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

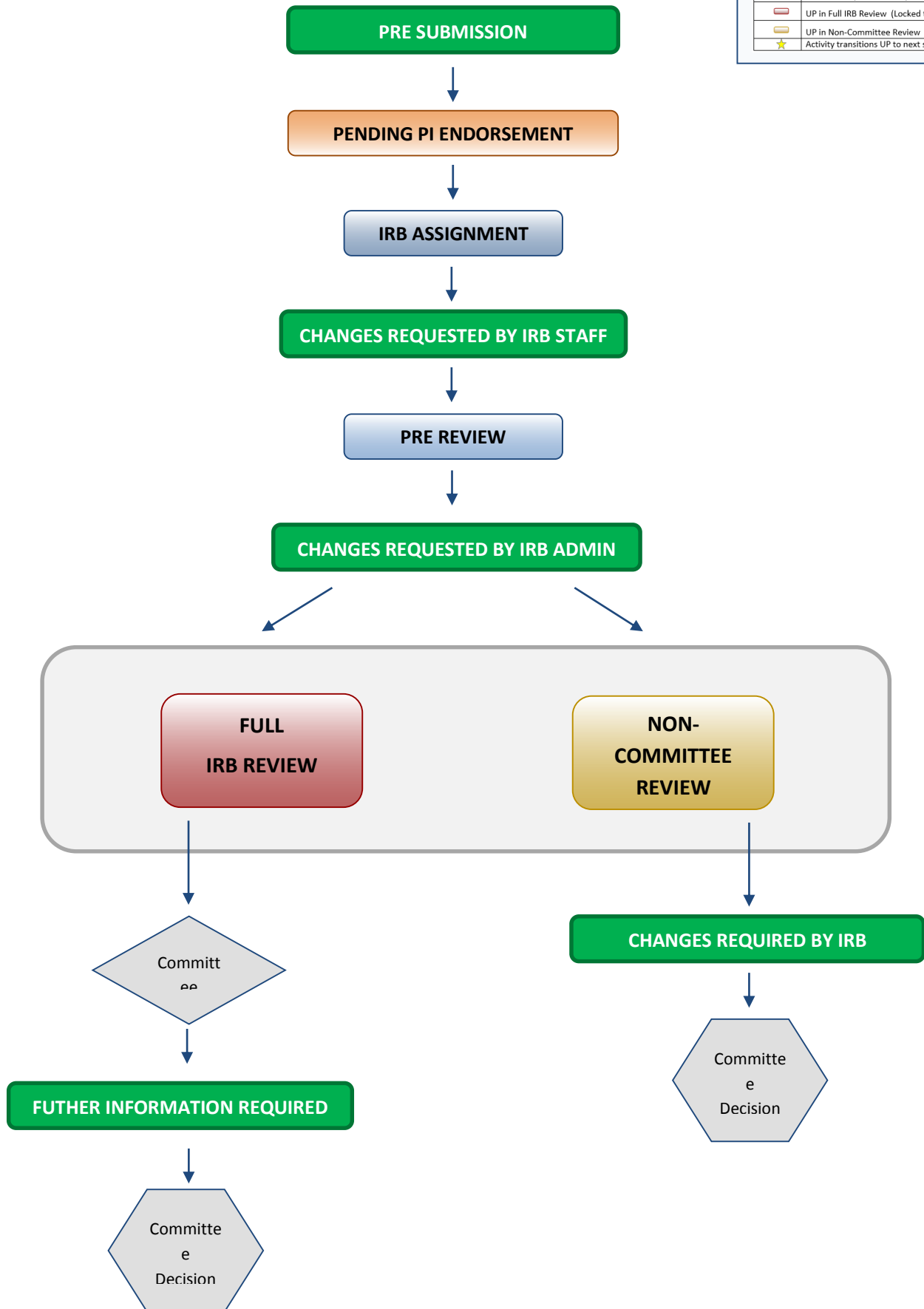
### Acronyms and Legend

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

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

# Unanticipated Problem (UP) Workflow

| Legend                                                                                     |                                                        |
|--------------------------------------------------------------------------------------------|--------------------------------------------------------|
| <span style="background-color: green; border: 1px solid black; padding: 2px;"> </span>     | UP editable by RT                                      |
| <span style="background-color: orange; border: 1px solid black; padding: 2px;"> </span>    | UP with PI for Endorsement                             |
| <span style="background-color: lightblue; border: 1px solid black; padding: 2px;"> </span> | UP with IRB (Locked to RT) <sup>1</sup>                |
| <span style="background-color: red; border: 1px solid black; padding: 2px;"> </span>       | UP in Full IRB Review (Locked to RT) <sup>1</sup>      |
| <span style="background-color: yellow; border: 1px solid black; padding: 2px;"> </span>    | UP in Non-Committee Review (Locked to RT) <sup>1</sup> |
| <span style="color: blue;">★</span>                                                        | Activity transitions UP to next state                  |



# RT Checklist – Unanticipated Problem

## 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 Unanticipated Problem (UP)
  - a. Locate Approved study (All Protocols tab) and click on its name
  - b. Click **Unanticipated Problem** (UP workspace - left)
  - c. Enter all applicable information/ attachments
  - d. Click “Finish” when complete
  
- ★  3. Forward to PI for endorsement
  - a. Click **Forward to PI for Endorsement** (UP workspace - left)
    - Confirm submission and click “Ok”

UP moves to **PENDING PI ENDORSEMENT** and awaits PI submission to IRB.

- ★  4. *If* PI requests changes
  - a. Click name of the approved Study (All Protocols tab)
  - b. Select **Unanticipated Problems** tab click name of UP
  - c. Click **Edit Unanticipated Problem** 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, UP moves to **IRB ASSIGNMENT** where IRB Staff reviews. UP 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 UP and see comments or attached document with changes
  - b. Click **Edit Unanticipated Problem** 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”

UP 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 UP REACHES ONE OF THE FOLLOWING COMMITTEE DECISION STATES, NO ADDITIONAL ACTION REQUIRED: ACKNOWLEDGED, NO ACTION REQUIRED, REPORT TO OHRP-FDA**

**IF THE UP REACHES THE FOLLOWING STATE, PROCEED AS FOLLOWS.**

## FURTHER INFORMATION REQUESTED

Upon receipt of e-mail notification “Further information required”...

- 7. Select **Research Team Inbox** tab
  - a. Click name of UP
  - b. In History tab click “Sent Change Letter to PI” to view changes required and click “Exit” to return to workspace
    - Click **Edit Unanticipated Problem** and use Jump To: 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”

UP 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 UP in AURA IRB)

| <b>States</b>                                                             | <b>Description</b>                                                                                   |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Pre Submission                                                            | SmartForm in progress                                                                                |
| Pending PI Endorsement                                                    | UP ready for PI to endorsement and submit to IRB                                                     |
| Pending PI Re-Endorsement                                                 | UP has been deferred (requires major changes) and PI must re-endorse before changes submitted to IRB |
| IRB Assignment                                                            | IRB Staff reviews and assigns UP to IRB Administrator                                                |
| Changes Requested by IRB Staff                                            | UP returns to the RT for edits                                                                       |
| Changes Requested by IRB Admin                                            | UP 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 UP to RT for edits                                                         |
| <b>FULL IRB REVIEW States</b>                                             |                                                                                                      |
| Awaiting Full IRB Review                                                  | UP 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<br/>(Expedited &amp; Exempt UP review)</b> |                                                                                                      |
| In Non-Committee Review                                                   | UP reviewed by assigned IRB Reviewer (s)                                                             |
| Awaiting Non-Committee Correspondence                                     | IRB Administrator prepares and sends IRB determination letter to PI                                  |
| <b>Committee Decision States</b>                                          |                                                                                                      |
| <b>Descriptions</b>                                                       |                                                                                                      |
| Acknowledged                                                              | Acknowledged by IRB; IRB reports UP to OHRP-FDA                                                      |
| No Action Required                                                        | No additional action required                                                                        |
| Further Information Required                                              | UP returns to the RT for edits                                                                       |

