AURA-IRB Unanticipated Problems (UP) 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 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. **PI 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**

<table>
<thead>
<tr>
<th>Acronyms</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>RT</td>
<td>Research Team/ Regulatory Contact</td>
</tr>
<tr>
<td>IRBS</td>
<td>Institutional Review Board Staff</td>
</tr>
<tr>
<td>IRBA</td>
<td>Institutional Review Board Administrator</td>
</tr>
</tbody>
</table>

**Legend**

- UP editable by PI
- UP with IRB (Locked to PI)
- UP in Full IRB Review (Locked to PI)
- UP in Non-Committee Review (Locked to PI)
- Activity transitions UP to next state
Unanticipated Problem (UP) Workflow
(Click diagram for State descriptions or CLICK HERE)
PI Checklist – Unanticipated Problem

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 Unanticipated Problem (UP)
   a. Locate Approved study (in PI Protocols tab) and click on its name
   b. Click Unanticipated Problem (UP workspace - left)
   c. Enter all applicable information/ attachments [Insert link to Quick Reference Guide]
   d. Click “Finish” when complete

⭐ 3. Submit to IRB
   a. Click Submit to IRB (UP Workspace - left)
      a. Answer questions and click “Ok”

UP moves to IRB ASSIGNMENT where IRB Staff reviews. UP 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 UP
   b. Click Edit Unanticipated Problem, 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”

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

*UP moves back to PRE REVIEW, is assigned to Full IRB or Non-Committee review and continues through the workflow until committee reaches a decision.*

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**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.**

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**FURTHER INFORMATION REQUESTED**

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

- 6. Select **PI 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)

<table>
<thead>
<tr>
<th>States</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre Submission</td>
<td>SmartForm in progress</td>
</tr>
<tr>
<td>IRB Assignment</td>
<td>IRB Staff reviews and assigns UP to IRB Administrator</td>
</tr>
<tr>
<td>Changes Requested by IRB Staff</td>
<td>UP returns to the PI for edits</td>
</tr>
<tr>
<td>Changes Requested by IRB Admin</td>
<td>UP returns to the PI for edits</td>
</tr>
<tr>
<td>Pre-Review</td>
<td>IRB Administrator reviews before forwarding for Full IRB Review or Non-Committee review</td>
</tr>
<tr>
<td>Changes Requested by IRB Administrator</td>
<td>IRB Administrator returns UP to PI for edits</td>
</tr>
</tbody>
</table>

**FULL IRB REVIEW States**

<table>
<thead>
<tr>
<th>States</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awaiting Full IRB Review</td>
<td>UP requires full board review and has been assigned to IRB meeting agenda</td>
</tr>
<tr>
<td>Awaiting Full IRB Correspondence</td>
<td>IRB Administrator prepares committee determination letter to send to PI</td>
</tr>
<tr>
<td>Decision and Correspondence Review</td>
<td>PI addresses Committee Comments</td>
</tr>
</tbody>
</table>

**NON-COMMITTEE REVIEW States**

(Expedited & Exempt UP review)

<table>
<thead>
<tr>
<th>States</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Non-Committee Review</td>
<td>UP reviewed by assigned IRB Reviewer(s)</td>
</tr>
<tr>
<td>Awaiting Non-Committee Correspondence</td>
<td>IRB Administrator prepares and sends IRB determination letter to PI</td>
</tr>
</tbody>
</table>

**Committee Decision States**

<table>
<thead>
<tr>
<th>States</th>
<th>Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledged</td>
<td>Acknowledged by IRB; IRB reports UP to OHRP-FDA</td>
</tr>
<tr>
<td>No Action Required</td>
<td>No additional action is required</td>
</tr>
<tr>
<td>Further Information Required</td>
<td>UP returns to the PI for edits</td>
</tr>
</tbody>
</table>