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

<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 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

PRE SUBMISSION

PENDING PI ENDORSEMENT

IRB ASSIGNMENT

CHANGES REQUESTED BY IRB STAFF

PRE REVIEW

CHANGES REQUESTED BY IRB ADMIN

FULL IRB REVIEW

NON-COMMITTEE REVIEW

FURTHER INFORMATION REQUIRED

Committee Decision

CHANGES REQUIRED BY IRB

Committee Decision

Legend:
- UP with PI for Endorsement
- UP with PI for Endorsement (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
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.**

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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**

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**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”…

- **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)

<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>Pending PI Endorsement</td>
<td>UP ready for PI to endorsement and submit to IRB</td>
</tr>
<tr>
<td>Pending PI Re-Endorsement</td>
<td>UP has been deferred (requires major changes) and PI must re-endorse before changes submitted to IRB</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 RT for edits</td>
</tr>
<tr>
<td>Changes Requested by IRB Admin</td>
<td>UP returns to the RT 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 RT 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 RT</td>
</tr>
<tr>
<td>Decision and Correspondence Review</td>
<td>RT 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>Descriptions</th>
<th>Acknowledged Acknowledged by IRB; IRB reports UP to OHRP-FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Action Required</td>
<td>No additional action required</td>
</tr>
<tr>
<td>Further Information Required</td>
<td>UP returns to the RT for edits</td>
</tr>
</tbody>
</table>