Typical UFA Review Workflow by State

All previous actions taken on an UFA are displayed on the Recent Activity list at the bottom of the UFA Workspace.

OTT Processing (Part 1)

Role: OTT  Tab: Unassigned
1. Open the applicable UFA from the UFAs list by clicking its name.

From the Manage Data menu:
2. Click Manage Sponsors. Review sponsor information and edit if necessary.
   a. Click Update (the initial information was entered by the Project Team).
   b. Enter Name (name of the sponsor as entered on the UFA Worksheet).
   c. Select sponsor Type.
   d. If known, enter the ID number for the sponsor
      OR
      2a. Click Select.
      2b. Enter search criteria.
      2c. Click Find.
      2d. Select Sponsor.
      2e. Click OK.
      OR
      Select Not Found if you cannot find the Sponsor ID after searching for it.
3. Enter Notes (optional).
4. Click Save.
5. Click OK.
6. Click Project Representative. Select appropriate project rep. Click OK.

OTT Processing (Part 2)

Role: OTT  Tab: Inbox
1. Open the applicable UFA from the UFAs list by clicking its name.
2. Review the Sponsor Info, Draft Documents and Recent Activity (including any notes/comments) listed on the UFA Workspace.
3. Click Display UFA Summary.
4. Review and verify:
   - Sponsor Contact Information
   - Routing and Processing Instructions
   - Project Information
   - PI Signatures
5. Click OK.
6. If the agreement or the Project Team indicate that clinical data and/or patient record data are being shared, click Send for Compliance Review. Otherwise, continue with step 7.

Note: When sent for compliance review, the state of the UFA changes to HIPAA Review. When compliance review is completed, the record will return to the state of OTT Processing.
7. Click Negotiation in Progress from the Activities menu.
8. Attach any documents by clicking Add and post any comments.

Note: Any comments entered appear in the Recent Activity list.
9. Click OK.

The state of the UFA changes to Negotiation in Progress.
Negotiation in Progress

Role: OTT Tab: In Negotiation
While the terms of the UFA are being negotiated, all associated actions should be recorded by clicking Record Action in the Activities menu.
1. Click the radio button to record the latest action taken.
2. Enter any comments (optional).
3. Click Add to attach any documents (optional).
4. Click OK.
Note: All Recorded Actions will appear in the Recent Activities list.

Record Agreement Dates

Negotiation in Progress

Role: OTT Tab: In Negotiation
1. Click Record Processing Steps from the Activities menu.
2. Enter the Agreement Start Date, and End Date.

FOIA Letter

Role: OTT Tab: In Negotiation
1. Click the Create FOIA Letter activity.
2. Click the drop-down menu and select the time period, and then click OK. The FOIA workspace opens.
3. If desired, click Edit FOIA Letter and make changes.
4. Click the Route to FOIA Office activity.
5. Verify the Letter Date is correct or enter a new date in the field, and enter Comments if desired.
6. Click OK.

Send to PI for Signature

Negotiation in Progress

Role: OTT Tab: In Negotiation
1. Click Send to PI for Signature from the Activities menu.
2. Enter any comments for the PI (optional).
3. Click Add to attach the signed contract if ink signature is not required.
4. Click OK.
The state of the UFA changes to PI Sign Contract.
Note: Once the PI returns the signed contract to OTT, the state will change to OTT Processing - PI Approved.

OTT Processing—PI Approved

OTT Processing—PI Approved

Role: OTT Tab: Inbox
The final required activities are determined by whether or not the sponsor signature has been obtained. If the sponsor signature has not yet been obtained, complete the steps below. If the sponsor signature has already been obtained, skip to Log Fully Executed Contract.

Partially Executed Contract Sent to Sponsor

OTT Processing—

Role: OTT Tab: Inbox
1. Click Partially Executed Contract Sent to Sponsor from the Activities menu.
2. Enter any comments (optional).
3. Attach the contract by clicking Add.
The state of the UFA changes to Awaiting Sponsor Signature.
Once the sponsor signature has been obtained, complete the Log Fully Executed Contract to activate the project.

Log Fully Executed Contract

Awaiting Sponsor

Role: OTT Tab: With Sponsor
1. Click Log Fully Executed Contract from the Activities menu.
2. Enter the date the contract was fully executed (the date the final signature was obtained) (required).
3. Attach the final contract by clicking Add.
Note: The document will then be located in the Final Documents list.
4. Click OK.
The state of the UFA changes to Active.