



**UT Southwestern**  
Medical Center

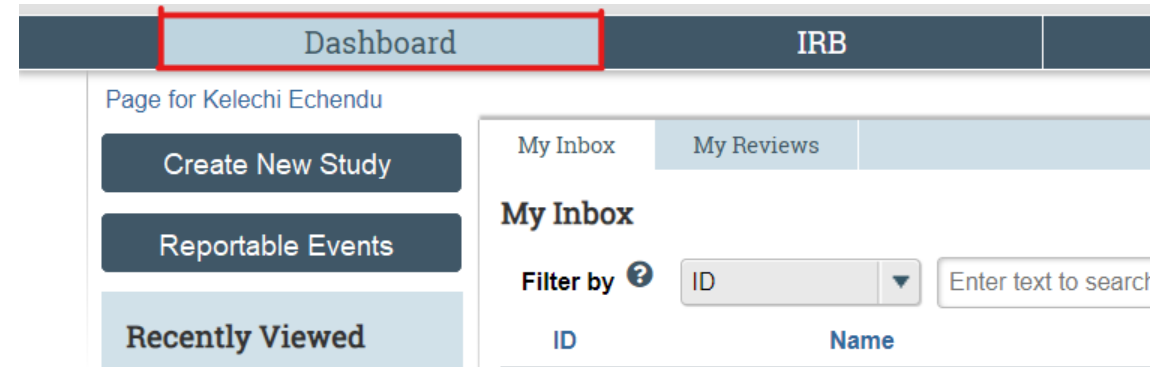
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# Navigating the UTSW ETHOS Workspace

*Human Research Protection Program*

# Dashboard Workspace

- When you log in with your UTSW credentials, your landing page will be your Dashboard. The Dashboard is where you can access items and perform basic tasks.



# Navigating the Dashboard

Activities you may perform from the Dashboard:

- **Create a New Study:** activity to create a new project
- **Reportable Events (RE):** activity to create a new RE
- **My Inbox:** items (i.e. New Studies, MODs, CR / AUs / NSCs, REs) that require attention or require you to take action.
- **My Reviews:** Items that are assigned to you for review (i.e. ancillary reviews, committee reviews). A subset of item in “My Inbox”.
- **Post Review:** Items that need to be out processed. This is used to be “**awaiting correspondence**” in the old eIRB system.
- **Recently Viewed:**
  - **Recent:** all recently viewed items
  - **Pinned:** pinned items in the recently viewed section for quick and easy access.

Page for Kimberly Hawkins

Buttons: Create New Study, Reportable Events

Recently Viewed: Recent, Pinned

Navigation: My Inbox, My Reviews, Post-Review

My Inbox

Filter by ? ID [dropdown] Enter text to

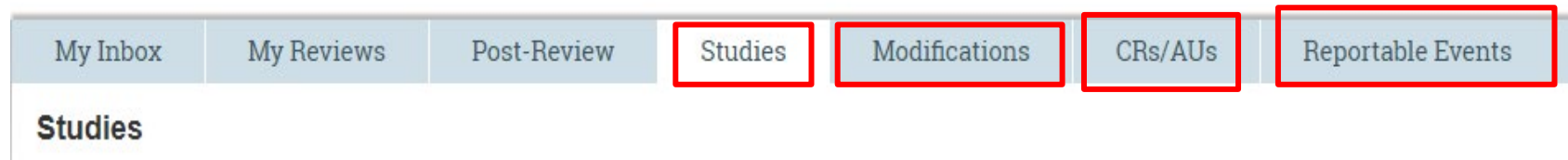
ID	Name
STUDY00001139	NRR - KF

The screenshot shows a user interface for Kimberly Hawkins. On the left, there are two large buttons: 'Create New Study' and 'Reportable Events'. Below them is a 'Recently Viewed' section with 'Recent' and 'Pinned' sub-sections. On the right, there are three tabs: 'My Inbox', 'My Reviews', and 'Post-Review'. Below the tabs is a 'My Inbox' section with a 'Filter by' dropdown set to 'ID' and a search input field. A table below shows a single entry with ID 'STUDY00001139' and Name 'NRR - KF'.

# Navigating the Dashboard

The Dashboard also includes the following:

- You are able to view the **Studies**, **Modifications**, **CRs/AUs**, and **Reportable Events** that require attention or require you to take action.



# Study Workspace

- Once you open a submission, you will see the study workspace.
- Your Study Workspace allows you to edit your application, smartforms (e.g., modifications, CR, etc), and view the history of your submission. Continue to the next slide to learn more about the functionality of the Study Workspace.

## Pre-Submission

Last updated: 7/9/2024 1:39 PM

### Next Steps

- Edit Study
- Printer Version
- Add Reliance Institute Information
- Add Comment
- Manage Guest List
- Copy Submission
- Discard
- Create Velos Study

## STUDY00001107: Test KE

Principal Investigator: Abdelrahim Abdel  
Submission Type: Initial Study

IRB Office: IRB 1  
IRB Coordinator:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; B --> C[IRB Review]; B --> D[Clarification Requested]; C --> E[Post-Review]; C --> D; D --> B; D --> C; E --> F[Review Complete]; E --> G[Stipulations Required]; G --> E;
```

History | Contacts | Documents | Reviews | Snapshots | Modifications | Continuing Reviews | Reportable Events

Filter by Activity  + Add Filter ✕ Clear All

Activity	Author	Activity Date
Study Created	Echendu, Kelechi	5/15/2024 12:36 PM

# Study Workspace

The Study Workspace also shows study review history, approval status, etc. *See next slide for detailed description of each tab.*

## STUDY00001151: Test Study 1

Principal Investigator: Madhukar Trivedi

Submission Type: Initial Study

IRB Office: IRB 1

IRB Coordinator:

Letter:

 Correspondence\_for\_STUDY00001151.pdf(0.01) ...

Regulatory authority: Revised Common Rule



Navigation tabs: 1 History, 2 Contacts, 3 Documents, 4 Approval Status, 5 Reviews, 6 Determinations, 7 Snapshots, 8 Modifications, 9 Continuing Reviews, 10 ...

Filter by: Activity (dropdown), Enter text to search (input), Add Filter, Clear All

Activity Author

Reportable Events, Determination Snapshot, Activity Date (dropdown)

# Study Workspace

1. **History:** This tab lists the activity taken on a submission including any comments, attachments, or correspondence added.
2. **Contacts:** This tab lists all study Team and Guest contact information and financial interest.
3. **Documents:** This tab includes all study related and site related documents.
4. **Approval Status:** This tab shows the approval status of ancillary reviews, performance site approvals, greenlight, etc.
5. **Reviews:** This tab displays review information's such as pre-review, committee, designated review, etc
6. **Determinations:** This tab displays committee review or designated review determinations.
7. **Snapshots:** Provides a snapshot of the entire study at different states of the submission (e.g., approved stated, pre-submission state).
8. **Modifications:** This tab displays modifications associated with the study.
9. **Continuing Reviews:** This tab displays continuing reviews associated with the study.
10. **Reportable Events:** This tab displays reportable events associated with the study.
11. **Determinations Snapshot:** Provides a snapshot of the determinations.

# Study Workspace: Submission Workflow

- Submission may be various states in the workflow (flowchart). The workflow informs the user where the submission is at any given time throughout the review process up until approval.
- Continue to the next slide to learn more about the functionality of the Study Workspace.





# Study Submission Workflow

## STUDY00000949: Test study for Snapshots Title

**Principal Investigator:** Bethanie Abram

**Submission Type:** Initial Study

**IRB Office:** IRB 1

**IRB Coordinator:**

**Regulatory authority:** Revised Common Rule



# Study Submission Workflow

- **Pre-submission:** In this state, the study has not been submitted to HRPP/IRB for review. The study still sits with the PI /research team.

## Pre-Submission

### Next Steps

Edit Study

Printer Version

Submit

Manage Ancillary Reviews

Submit Ancillary Review

Cancel Ancillary Reviews

Add Reliance Institute Information



After you have completed all the pages, you may submit the submission

Other study activities in **Pre-Submission state** include:

- Faculty Sponsor Review
- Clarification Requested Faculty Sponsor
- CRU Review
- Clarification Requested CRU Review

# Study Submission Workflow

- **Pre-Review:** In Pre-Review state, the study is submitted and is with the HRPP/IRB office for review.
  - If the HRPP/IRB Reviewer sends the study back to the study team for changes, the state changes to “**Clarifications Requested**”

Pre-Review

## Next Steps

Edit Study

Printer Version

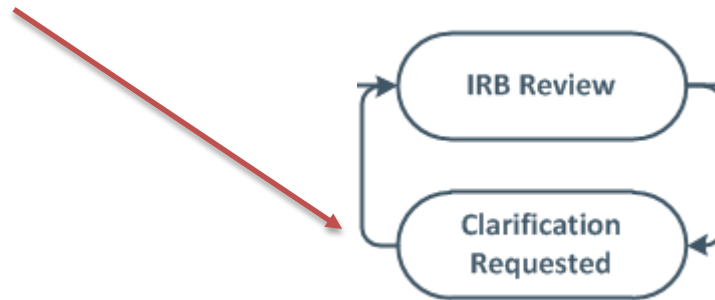
Submit Pre-Review

Request Pre-Review Clarification

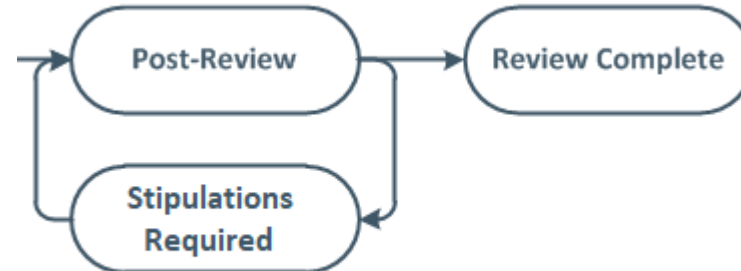


# Study Submission Workflow

- **IRB Review:** In this state, the study is assigned for review by the IRB (**Committee Review**) or Designated Review (**Non-Committee Review**).
  - If the IRB or Designated Reviewer sends the study back to the study team for changes (modifications), the state changes to **“Clarifications Requested.”**



- **Post Review:** The study has been reviewed and the determination letter will be generated.
  - If the determination specified in the IRB Review is “Approved with Stipulations”, then on executing the “Send letter” activity the state of study changes to ‘**Stipulations Required**’ state.
  - If there are no stipulations, then the study state changes to “**Review Complete**”



# Study Submission Workflow

- **Review Complete:** The review of the submission is complete, and the study is now active / approved.

