

## ERMS Overview Quick-Guide

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**Actions:**

Action	PI of a Protocol	PI Proxy	Protocol Team
Create a new Protocol	X	X	X
Edit a Protocol	X	X	X
Submit a Protocol	X	X	
Submit Clarifications	X	X	
Create a follow-on submission	X	X	X
Submit a follow-on submission	X	X	
Assign PI Proxies	X		

## Submission States:

State of the Submission	Description
<b>Acknowledged</b>	A completed Report of New Information (RNI) that has been reviewed by the UT Health San Antonio IRB in which they have determined that further review is not required.
<b>Active</b>	An approved site relying on UT Health San Antonio IRB or an approved protocol under an external IRB purview.
<b>Approved</b>	An approved submission or a protocol.
<b>Clarifications Requested</b>	A request for a clarification or a revision to the submission by the IRB Coordinator or IRB Designated Reviewer.
<b>Committee Review</b>	A submission scheduled for a convened IRB committee review.
<b>Deferred</b>	IRB committee is unable to approve research and the IRB suggests modifications that might make the research approvable.
<b>Discarded</b>	Permanently removed submission.
<b>Inactive</b>	A site submission that has been deactivated (either no longer under IRB purview or discarded, never officially added to the protocol).
<b>Invitation Pending</b>	Request by IRB Coordinator to add a non-affiliated site to an approved protocol under UT Health San Antonio IRB purview.
<b>Modifications Required</b>	IRB committee members require specific modifications to the research before approval can be finalized.
<b>Modifications Submitted</b>	Modifications returned for IRB review.
<b>Non-Committee Review</b>	Submission undergoing an IRB review via an expedited review procedure.
<b>Post-Review</b>	Transition state where the IRB determination has been made and correspondence to the investigator is pending;
<b>Pre-Review</b>	IRB Coordinator conducting administrative review.
<b>Pre-Review Completed</b>	Ready for IRB review.
<b>Pre-Submission</b>	Not yet submitted for review.
<b>Updating Study</b>	Minor updates to an external IRB that do not require sIRB. A letter will not be generated.
<b>Awaiting Site Materials</b>	Waiting for participating site (pSite) specific documentation.

## How to Locate a Protocol:

In ERMS, clicking the **IRB** tab will direct you to the main study workspace. Here, you may navigate to the appropriate tabs to locate your protocol.

The screenshot shows the ERMS interface with the **IRB** tab selected. The top navigation bar includes **Dashboard**, **Agreements**, **COI**, and **IRB**. Below this, there are sub-tabs: **Submissions**, **Meetings**, **Reports**, **Library**, **Institutional Profiles**, and **Help Center**. The main content area shows a list of submissions with filters for **In-Review**, **Active**, **New Information Reports**, **External IRB**, **Relying Sites**, **All Submissions**, **IRB Exchange**, and **Archived**. A search filter is applied: **Approved UT Health San Antonio IRB protocols**. The table below lists the submissions:

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name
STUDY00000197	ADH MSS - pSite Exchange Test	12/5/2023 10:08 AM	Approved	Ashley	Hicks	Brandie	Otten
STUDY00000322	PPW Track Changes	12/4/2023 5:23 PM	Approved	Jason	Bates	Brandie	Otten
STUDY00000317	Test Study 12-04-23	12/4/2023 4:23 PM	Approved	Celia	Aviles	Celia	Aviles

## Protocols under UT Health San Antonio Purview:

The screenshots displayed below will provide a description of the information available in the protocol record. This includes the Documents tab, and the Reviews tab.

The screenshot shows a protocol record for an **Active** submission. Key details include:

- Entered IRB:** 12/4/2023 10:15 AM
- Last updated:** 12/5/2023 8:45 AM
- Principal investigator:** Alyssa Hernandez
- Lead principal investigator:** IRB Site
- Submission type:** IRB Site
- Primary contact:** Alyssa Hernandez
- PI proxies:** Stephen Luis
- PI proxies (Lead site):** Stephen Luis
- IRB office:** External IRB Reliance
- IRB coordinator:** Alyssa Hernandez
- Letter:** [Correspondence\\_for\\_STUDY00000314.pdf\(0.01\)](#)
- Regulatory authority:** 2018 Requirements
- External study ID:** cz

**Next Steps:** View Study, Printer Version, Create Site Modification, Update Study Details, Report New Information, Assign Coordinator.

**Activity Log:**

Activity	Author	Activity Date
Modification MOD00000069: Closed (Discarded) Modification: MOD00000069	Luis, Stephen	12/5/2023 8:45 AM
Modification MOD00000069 Opened Modification: MOD00000069	Luis, Stephen	12/5/2023 8:44 AM

## Documents Tab:

**Study Related Documents**

Draft	Category	Final	Document History

**Site Related Documents**

Draft	Category	Final	Last Finalized	Document History

Documents in the Final column are the official versions approved by the IRB.

Documents in the Draft column are the versions submitted for review.

## Reviews Tab:

The details of any ancillary reviews are available in the Reviews tab of the main study workspace and within each submission workspace.

If ancillary reviews are created, all information regarding these reviews will be displayed here.

Supporting documents regarding these ancillary reviews will also be located here.

## Collaborative/Multi-center Studies:

The following is a workspace for collaborative/multi-center studies. For this type of study, there will be an additional tab located between the Documents and Follow-on Submissions labeled **Sites**.

**Approved**

Entered IRB: 10/23/2023 2:13 PM  
Initial approval: 10/23/2023  
Initial effective: 10/23/2023  
Effective: 10/23/2023  
Last updated: 12/5/2023 10:08 AM

**Principal investigator:** Ashley Hicks  
**Submission type:** Initial Study  
**Primary contact:** Ashley Hicks  
**PI proxies:**

**IRB office:** UT Health San Antonio IRB  
**IRB coordinator:** Brandie Otten  
**Letter:** [Correspondence\\_for\\_STUDY00000197.pdf\(0.01\) ...](#)  
**Regulatory authority:** 2018 Requirements

**Next Steps**

- View Study
- Printer Version
- Report New Information
- Assign Coordinator
- Add Related Grant
- Manage Related Agreements
- Create Ad Hoc Certifications
- Add Comment

**STUDY00000197: ADH MSS - pSite Exchange Test**

```

    graph LR
      A[Pre-Submission] --> B[Pre-Review]
      B --> C[IRB Review]
      C --> D[Post-Review]
      D --> E[Review Complete]
      B --> B1[Clarification Requested]
      B1 --> B
      C --> C1[Clarification Requested]
      C1 --> C
      D --> D1[Modifications Required]
      D1 --> D
  
```

**Sites**

ID	Name	SmartForm Institution	Principal Investigator	State	FWA Number
SITE00000012	QUANTUM LEAP HEALTHCARE COLLABORATIVE Participating Site for ADH MSS - pSite Exchange Test	QUANTUM LEAP HEALTHCARE COLLABORATIVE	Howard Watson	Awaiting Site Materials	

Selecting the Sites tab will display all pending, inactive, and active sites.

Selecting the name of the site will open a site workspace as shown in the screenshot shown on the next page.

## Site Workspace:

**Awaiting Site Materials**

Last updated: 12/5/2023 3:31 PM

**Next Steps**

[Edit Site](#)

[Printer Version](#)

The electronic application can be accessed by clicking [View Site](#) or [Printer Version](#)

[Add Comment](#)

[Add Private Comment](#)

[Discard](#)

[Manage Tags](#)

### SITE0000012: QUANTUM LEAP HEALTHCARE COLLABORATIVE Participating Site for ADH MSS - pSite Exchange Test

**Principal investigator:** Howard Watson  
**Submission type:** IRB Site  
**Primary contact:**  
**PI proxies:**

**IRB office:** UT Health San Antonio IRB  
**IRB coordinator:**  
**Regulatory authority:** 2018 Requirements  
**Study:** STUDY00000197

**Institution:** QUANTUM LEAP HEALTHCARE COLLABORATIVE

If available, site-specific approval documentation can also be located here.

Selecting the link above will allow you to return to the main study workspace.

Site specific documents and subsequent submissions are available in this space.

Activity	Author	Activity Date
Updated from	Luis, Stephen	12/5/2023 3:31 PM

## Protocols under External IRB Purview:

Note: the documents in the record for a study under external IRB purview may not be the most recently approved versions by the reviewing IRB.

**Active**

Entered IRB: 12/7/2023 3:11 PM  
Initial approval: 12/7/2023  
Initial effective: 12/7/2026  
Effective: 12/7/2023  
Approval end: 12/31/2026  
Last updated: 12/7/2023 3:25 PM

**Next Steps**

Approval and expiration dates as assigned by the reviewing IRB will be displayed here.

[Create Site Modification](#)

[Update Study Details](#)

[Report New Information](#)

[Send Letter](#)

### STUDY00000328: Mr. ...

**Principal investigator:** Stephen Luis  
**Lead principal investigator:** Alyssa Hernandez  
**Submission type:** IRB Site  
**Primary contact:** Alyssa Hernandez  
**PI proxies:** Alyssa Hernandez  
**PI proxies (Lead site):**  
**External IRB:** GREEN FIELDS UNIVERSITY

**IRB office:** External IRB Reliance  
**IRB coordinator:** Alyssa Hernandez  
**Letter:** Letter(0.01) ...  
**Regulatory authority:** 2018 Requirements + FDA  
**External study ID:** Mr. ... Frost

Acknowledgement of the External IRB oversight. Authorization to use the external IRB can be located in the **History** tab.

Activity	Author	Activity Date
Research Location Notified	Hernandez, Alyssa	12/7/2023 3:25 P