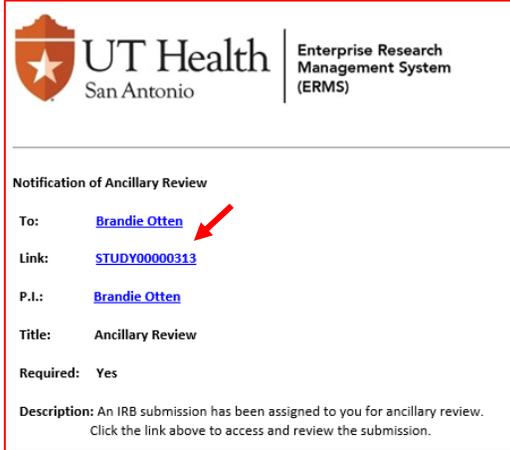


# Ancillary Review Quick Guide

## 1. Access Ancillary Review

- From email notification:



UT Health San Antonio Enterprise Research Management System (ERMS)

Notification of Ancillary Review

To: [Brandie Otten](#)

Link: [STUDY00000313](#)

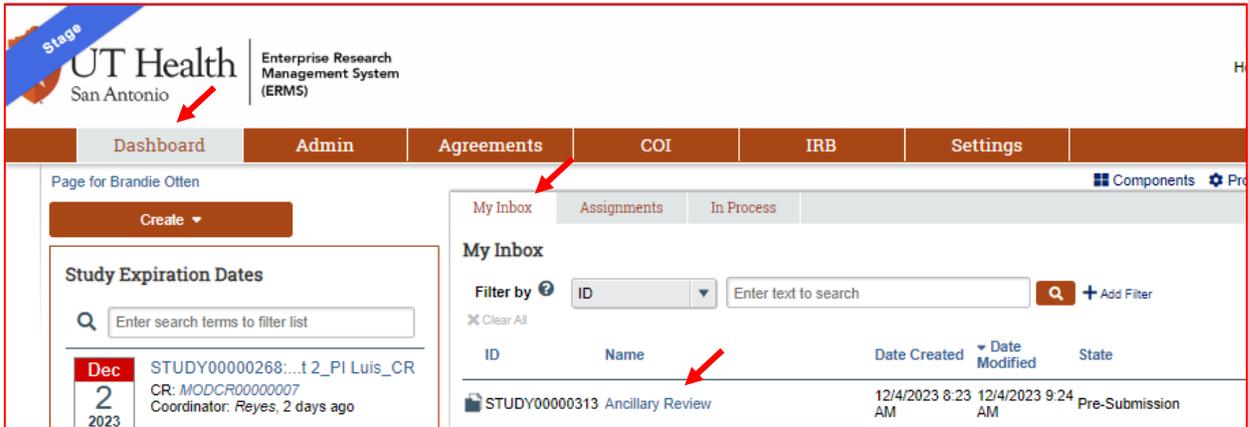
P.I.: [Brandie Otten](#)

Title: Ancillary Review

Required: Yes

Description: An IRB submission has been assigned to you for ancillary review. Click the link above to access and review the submission.

- From ERMS Dashboard



UT Health San Antonio Enterprise Research Management System (ERMS)

Dashboard Admin Agreements COI IRB Settings

Page for Brandie Otten

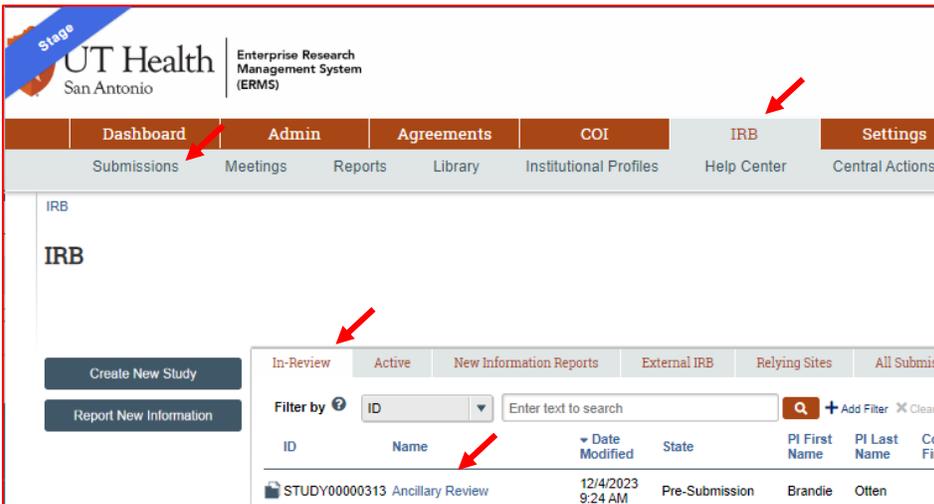
My Inbox Assignments In Process

My Inbox

Filter by ID Enter text to search

ID	Name	Date Created	Date Modified	State
STUDY00000313	Ancillary Review	12/4/2023 8:23 AM	12/4/2023 9:24 AM	Pre-Submission

- From ERMS IRB



UT Health San Antonio Enterprise Research Management System (ERMS)

Dashboard Admin Agreements COI IRB Settings

Submissions Meetings Reports Library Institutional Profiles Help Center Central Actions

IRB

In-Review Active New Information Reports External IRB Relying Sites All Submiss

Filter by ID Enter text to search

ID	Name	Date Modified	State	PI First Name	PI Last Name	Cod Firs
STUDY00000313	Ancillary Review	12/4/2023 9:24 AM	Pre-Submission	Brandie	Otten	

## 2. View Documents

**Dashboard** | **Agreements** | **COI** | **IRB** | Submissions | Meetings | Reports | Library | Institutional Profiles | Help Center

IRB > Ancillary Review

**Pre-Submission**

Last updated: 12/4/2023 2:55 PM

Principal investigator: Brandie Otten  
 Submission type: Initial Study  
 Primary contact: Brandie Otten  
 PI proxies:

IRB office: UT Health San Antonio IRB  
 IRB coordinator:

**Next Steps**

View Study  
 Printer Version

Submit Ancillary Review  
 Add Related Grant  
 Manage Related Agreements  
 Create Ad Hoc Certifications  
 Add Comment  
 Add Private Comment  
 Discard  
 Manage Tags

Workflow: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete  
 (Clarification Requested loops between Pre-Review and IRB Review; Modifications Required loops between IRB Review and Post-Review)

History | Funding | Contacts | COI | **Documents** | Reviews | Snapshots | Agreements | Training

Draft	Category	Final	Last Finalized	Document History
Protocol.docx	IRB Protocol			History

Draft	Category	Final	Last Finalized	Document History
Inst Form.docx	Application Form			History
inf_form.docx	Application Form			History
form_d.docx	Application Form			History
form_i_phone_script.doc	Recruitment Materials			History
form d.docx	Consent Form			History

## 3. Compare Documents

- Select History
- Select the documents to compare (for revised forms)
- Select Compare

**Submissions** | Meetings | Reports | Library | Institutional Profiles | Help Center | Central Actions

IRB > Submissions > New Study Documents > Modification / Update #1 for Study New Study Documents

**Pre-Review**

Entered IRB: 12/10/2023 10:04 AM  
 Last updated: 12/10/2023 10:07 AM

Principal investigator: Phil Bivens (pi2)  
 Submission type: Modification / Update  
 Primary contact: Brandie Otten

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

**Next Steps**

View Modification/CR  
 Printer Version

Submit Pre-Review  
 Request Pre-Review Clarification  
 Assign Coordinator  
 Manage Ancillary Reviews  
 Create Ad Hoc Certifications  
 Add Comment  
 Withdraw  
 Discard  
 Manage Tags

Workflow: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete  
 (Clarification Requested loops between Pre-Review and IRB Review; Modifications Required loops between IRB Review and Post-Review)

History | Contacts | COI | **Documents** | **Reviews** | Related RNIs | Snapshots | Training

Draft	Updated in Modification	Category	Final	Last Finalized	Document History
Drug Brochure.docx	No	Drug Attachment	Drug Brochure.docx	11/11/2023 12:02 AM	History
Form O.docx	No	Drug Attachment	Form O.docx	11/11/2023 12:02 AM	History
Protocol.docx	No	IRB Protocol	Protocol.pdf	11/11/2023 12:02 AM	History

Draft	Updated in Modification	Category	Final	Last Finalized	Document History
Form J.docx	Yes	HIPAA Waiver	Form J.pdf	11/11/2023 12:02 AM	History
Data Collection Form.docx	No	Data Collection Instrument	Data Collection Form.pdf	11/11/2023 12:02 AM	History
Flyer.docx	No	Recruitment Materials	Flyer.pdf	11/11/2023 12:02 AM	History
form_d.docx	No	Consent Form	form_d.pdf	11/11/2023 12:02 AM	History

**Resource History for Form J.docx**

Title: Form J.docx  
 File: Form J.docx  
 Owner: Brandie Otten  
 Author:  
 Content Type: Document  
 Version: 0.02  
 Description:

**History:**

Compare	Date	Version	Person	Action	Notes	Uploaded File
<input checked="" type="checkbox"/>	12/10/2023 10:06 AM	0.02	Brandie Otten	File Uploaded & Edited		Form J.docx
<input checked="" type="checkbox"/>	11/10/2023 11:59 PM	0.01	Brandie Otten	Created		Form J.docx

**Compare**

OK

#### 4. View Study

- Select View Study
- Select “Compare” to view changes in the ERMS application form (when applicable)

Approved

Entered IRB: 10/30/2023 2:58 PM  
Initial approval: 10/30/2023  
Initial effective: 10/30/2023  
Effective: 10/30/2023  
Last updated: 12/6/2023 4:32 PM

**Next Steps**

- View Study
- Printer Version
- Create Modification/CR
- Report New Information

UT Health San Antonio | Enterprise Research Management System (ERMS)

Compare

You Are Here: New Study Documents > Modification / Update #1 for S...

Reading: MOD00000080

Modification / Continuing Review / Study Closure

#### 5. Add Comment for PI/PI Proxy/POC, Study Team or IRB Coordinator

IRB > Ancillary Review

Pre-Submission

Last updated: 12/4/2023 2:45 PM

**Next Steps**

- View Study
- Printer Version
- Submit Ancillary Review
- Add Related Grant
- Manage Related Agreement
- Create Ad Hoc Certification
- Add Comment
- Add Private Comment
- Discard
- Manage Tags

**Add Comment**

Your comment is visible to anyone with access to this submission.

1. Comment:

2. Supporting documents:

- + Add
- Name
- Description
- There are no items to display

3. Who should receive an e-mail notification? ⓘ

- PI/PI Proxy/Primary Contact
- Study Team
- IRB Coordinator

OK Cancel

**Comments will be located under the history tab. Include the IRB Coordinator if the study team needs to provide clarifications (e.g. revised documents) within the application.**

#### 6. Finalize Ancillary Review

The screenshot shows the 'Submit Ancillary Review' form. Red arrows point to the following elements:

- 1. The 'Select the review you are submitting:' section, specifically the 'Organization' column with 'Alyssa Hernandez' and 'RSC/RDRC' selected.
- 2. The 'Do you accept the proposed submission?' section, with the 'Yes' radio button selected.
- 3. The 'Comments:' section, containing the text 'No issues. See attached approval letter.'
- 4. The 'Supporting documents:' section, with an arrow pointing to the '+ Add' button and another pointing to the 'Approval Letter.docx(0.01)' document.
- 5. The 'OK' and 'Cancel' buttons at the bottom right.

**Important: Updating an ancillary review will override any previous version. Previous versions will be stored under the "History" tab.**

The screenshot shows the 'STUDY0000320: Ancillary Review' page. It includes a navigation menu, a sidebar with 'Next Steps', a workflow diagram, and a table of reviews.

**Workflow Diagram:**

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

**Table of Ancillary Reviews:**

Review Type	Organization	Person	Reqd	Accepted	Comments	Docs
RSC/RDRC		Alyssa Hernandez	yes	yes	No issues. See attached approval letter.	Approval Letter.docx

Red arrows in the table point to the 'Review Type', 'Accepted', 'Comments', and 'Docs' columns.