

ERMS – IRB Module

Vice President for Research Town Hall

November 15, 2023

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Agenda

- ERMS and Implementation Update
- Overview of ERMS-IRB Module
- How to access additional information
- ERMS-IRB Demonstration
- Important Deadlines
- Questions

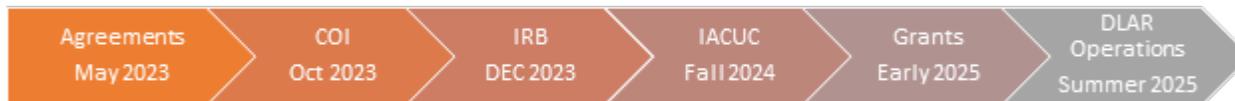
Note: Slides will be made available on the VPR ERMS website and the ERMS SharePoint site.

ERMS Overview

The Enterprise Research Management System (ERMS) is a comprehensive and integrated software solution to create an information portal for research administrative support, relieve administrative burden and free up time for mission-focused activities.

ERMS is part of our commitment to provide:

- Exceptional research administration service delivery
- Increased transparency and improved user experience
- Automated workflows



ERMS – IRB Module

- Will replace current email submissions and access to approved documents through ORCA – December 2023
- Purpose:
 - Manage human subjects research protocols within the IRB Office
 - Single electronic regulatory system for internal and external IRB studies
- Comply with federal, state, and institutional requirements
- *Change Impact:* Single point of entry system, integrated management of regulatory accountability processes, data reporting and extraction.

Dashboard	Admin	Agreements	COI	IRB		
Submissions	Meetings	Reports	Library	Institutional Profiles	Help Center	Central Actions

ERMS – IRB Module: Terminology

- **IRB Reliance Coordinator** – formerly OCR analyst; administrative team dedicated to coordination of protocols reviewed by an external IRB.
- **IRB Coordinator**– formerly IRB analyst; administrative team dedicated to coordination of protocols reviewed by UT Health SA IRB.
- **Modification** – Amendment; any change in study involving protocol, procedures, personnel, or other item requiring IRB/IRB office review.
- **Reportable New Information (RNI)** – Prompt Report; report by PI or study team notifying the institution and the designated IRB when specific issues are identified, e.g., noncompliance, unanticipated problem, etc.
- **Clarification Requests** – when an IRB coordinator requests additional information from the study team.
- **Ancillary Review** – study review conducted in parallel by an ancillary office, e.g., Radiation Safety, University Health
- **pSite** – participating site; external study location engaged in study under UT Health SA IRB oversight

Dashboard	Admin	Agreements	COI	IRB		
Submissions	Meetings	Reports	Library	Institutional Profiles	Help Center	Central Actions

ERMS Log-In From My UT Health

The screenshot shows a SharePoint page with an orange header. The header includes the UT Health San Antonio logo, the text "SharePoint", and a user profile for "Summers, Kimberl...". Below the header, there are three news items on the left and two "Quick Links" sections on the right. The first news item is titled "Annual Liver Cancer Symposium Returns to San Antonio to Address At-Risk Communities and Major Advances" (10/16/2023). The second is "Join the fun during Spirit Week Oct. 16-20! People. Power. Partnerships." (10/06/2023). The third is "Leaders mark LEAP graduation" (10/05/2023). The first "Quick Links" section contains icons for My Service Center, Epic/Clinical Support Services, Paycheck W2/W4 Direct_Deposit, Business Community, Parking Updates, and UT Health Learns. The second "Quick Links" section contains icons for Maps, HR, Scheduling, Kronos, ERMS, and Workers_Comp. A blue arrow points to the ERMS icon in the second section. The UT Health logo is visible at the bottom right of the page content.

ERMS Log-In From UT Health Connect Research

UT Health San Antonio

SharePoint Search this site Summers, Kimberl

Researcher Resources Home Study and Grant Support Human Resources and People Purchases and Travel IT Support & Facilities Profile, Tenure & Training

Study and Grant Support

IT Support and Facilities Management

Profile, Tenure and Training

Welcome to the UT Health San Antonio Connect Research and Lab Resources

The portal is to support the unique operational needs of research and your lab.

UT Health Policies - HOP

Have Feedback on the Site?

Send Your Feedback or Suggestions
Email: vpr-it@uthscsa.edu or Phone: 210-450-6666

Academic Research Resources

- Core Labs
- Office of Sponsored Programs (OSP)
- Office of Sponsored Programs (OSP) Intranet
- Environmental Health and Safety (EHS) Plans & Resources
- Laboratory Animal Resources (DLAR)
- Animal Research Compliance (ARC)
- Office of the Institutional Review Board (IRB)
- Graduate School of Biomedical Sciences
- The Libraries
- Office of Postdoctoral Affairs (OPA)
- Visiting Student Policy
- Summer Programs
- Programs for Students and Volunteers - Office of Recruitment
- Office of Recruitment and Science Outreach
- Conflict of Interest (COI)
- ERMS Resources
- Research, Ethics, and Compliance Training | CITI Program
- Council of Principal Investigators (CPI)

Research Systems

- Clayuse
- ERMS Login
- Effort Certification (ECRT)
- ilab

Teaching and Programs

- Catalogue
- Canvas Information & Login
- Courseleaf - Instructions and
- CIM, Course Inventory

ERMS SharePoint Site

UT Health San Antonio SharePoint

ERMS-Enterprise Research Management System Home Site Pages Bulletins ERMS University Page ERMS Sign-In ERMS Suite Training Videos

Welcome to the ERMS SharePoint Site!

This site contains information about the ERMS suite and all modules within the suite. Information within this site may also be found on the [VPR's main website page](#).

When implementation is completed (CY2025) the following modules will be available on a single platform:

- Agreements (e.g., contracts, MOUs, data use agreements) (Completed May 2023)
- Conflict of Interest & Conflict of Commitment (Completed October 2023)
- Institutional Review Board (December 2023)
- Grants Management
- Institutional Animal Care & Use Committee (IACUC)
- Laboratory Animal Management

For general ERMS questions, email ermshelp@uthscsa.edu.

Welcome! ERMS - Transforming Research Management
LEARN MORE →

ERMS - Agreements Module

ERMS - COI/COC Module

Your feedback counts!

Log into ERMS

UT Health San Antonio
Office of the Vice President for Research

ERMS-Enterprise Research Management S...

ERMS – IRB Module: Information

ERMS - Enterprise Research Management System

Transforming Research Management

ERMS is UT Health San Antonio's implementation of the Huron Research Suite, a comprehensive software solution designed to relieve administrative burden and free up time for mission-focused activities. ERMS assists in transforming business processes to facilitate exceptional research administration service delivery, increase transparency, and automate workflows.

When implementation is completed (CY2025) the following modules will be available on a single platform:

- Agreements (e.g., contracts, MOUs, data use agreements)
- Conflict of Interest & Conflict of Commitment
- Institutional Review Board
- Grants Management
- Institutional Animal Care & Use Committee (IACUC)
- Laboratory Animal Management



[Ask a question?](#)

[Log into ERMS](#)

[Feedback Form](#)

ERMS Support

ermshelp@uthscsa.edu
210-450-6666
Technical Help: vpr-it@uthscsa.edu

Agreements Module (Live May 2023) ▾

COI & COC Module (Go-live October 2023) ▾

IRB Module (Coming Soon 2023) ▾

Bulletins and Communications ▾

General FAQ ▾

Find additional information and updates:

- Online
- Email bulletins
- Contact us via phone or email



Email: IRB@uthscsa.edu or
IRBReliance@uthscsa.edu

<https://www.uthscsa.edu/vpr/services/erms>

ERMS Dashboard

UT Single Sign On (SSO)

The screenshot shows the ERMS Dashboard for Phil Bivens (pi2). The dashboard includes a navigation bar with tabs for Dashboard, Agreements, COI, and IRB. A 'Create' button is visible in the top left. The main content area is divided into sections: 'Study Expiration Dates' (with a search bar and a calendar showing Dec 2, 2023), 'Recently Viewed' (with a list of recent studies), and 'My Inbox' (with a table of study items). The 'My Inbox' table has columns for ID, Name, Date Created, Date Modified, State, and Coordinator. A search bar and filter options are located above the table. A 'Help' button is in the top right, and an 'Export to CSV' button is in the bottom right. A legend on the right side of the dashboard explains the numbered callouts:

- 1: UT Health San Antonio logo
- 2: My Inbox tab
- 3: Filter by dropdown
- 4: Search bar
- 5: Create button
- 6: Study Expiration Dates section
- 7: Recently Viewed section
- 8: Help button
- 9: Export to CSV button

ID	Name	Date Created	Date Modified	State	Coordinator
DP00000084	Disclosure Profile for Phil Bivens (pi2)	9/13/2023 4:52 PM	10/19/2023 2:01 AM	Action Required	Phil Bivens (pi2)
STUDY00000019	ADH PROJ-00103669-13 Test	9/1/2023 9:57 AM	10/18/2023 10:19 AM	Pre-Submission	
STUDY00000027	BT - Agreement	9/11/2023 5:07 PM	9/11/2023 5:08 PM	Pre-Submission	
STUDY00000026	BT4	9/11/2023 2:39 PM	9/11/2023 5:05 PM	Pre-Submission	
MOD00000011	Modification / Update #1 for Study BT	9/11/2023 4:49 PM	9/11/2023 4:50 PM	Pre-Submission	
STUDY00000025	BT3 MSS	9/11/2023 2:37 PM	9/11/2023 2:37 PM	Pre-Submission	
STUDY00000024	BT2	9/11/2023 2:25 PM	9/11/2023 2:35 PM	Pre-Submission	

ERMS IRB Module

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2) | Switch User

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

IRB

IRB

Search

4 Create New Study | Report New Information

2 In-Review | Active | New Information Reports | External IRB | Relying Sites | All Submissions | Archived

Filter by ID | Enter text to search | + Add Filter | X Clear All

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Submission Type
STUDY00000019ADH PROJ-00103669-13	Test	10/18/2023 10:19 AM	Pre-Submission	Rebecca	Simms (pi)			Initial Study
CR00000003	Continuing Review for Study BT	10/5/2023 11:55 AM	Committee Review	Phil	Bivens (pi2)			Continuing Review

3 Export to CSV

- 3**
- **In-Review:** Submissions undergoing UT Health SA IRB review.
 - **Active:** All approved UT Health SA IRB studies.
 - **New Information Reports:** All Reportable New Information (RNI) submissions, in any state.
 - **External IRB:** All submissions undergoing External IRB Reliance review, in any state.
 - **Relying Sites:** All participating sites relying on UT Health SA IRB as the single IRB of record.
 - **All Submissions:** All submissions, in any state.
 - **Archived:** All closed, disapproved, discarded, and terminated submissions.

Create New Study – UT Health SA IRB

The screenshot shows the 'Enterprise Research Management System (ERMS)' interface. At the top left is the UT Health San Antonio logo. Below it, a navigation menu highlights 'Basic Study Information' with a blue arrow. The main content area is titled 'Creating New: IRB Submission' and 'Basic Study Information'. It contains four numbered sections:

- 1. * Title of study:** A text input field with the placeholder text 'Long Title'.
- 2. * Short title:** A text input field with the placeholder text 'Short Title'.
- 3. * Brief description:** A larger text input field with the placeholder text 'Brief Description'.
- 4. * What kind of study is this?:** Two radio button options: 'Multi-site or Collaborative study' (unselected) and 'Single-site study' (selected). Below these is a 'Clear' link.

? Short Title

- Select a short title for your study. You can use the sponsor's short title or any other unique name. As a guideline, keep it shorter than 50 characters.
- The short title identifies the study throughout the IRB system, such as in your inbox and in the IRB's list of submissions to review.

? Brief Description

- In a few words, summarize the central question the research is intended to answer (e.g. primary objects / methods used).
- For example: This is a <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine...

? Kind of Study

- A multi-site or collaborative research study is one where two or more institutions collaborate to complete the research outlined in a specific protocol. **Must select when participating sites are relying on UT Health SA IRB as the sIRB of record.**
- A single-site study is one where all research activities occur at one institution. List studies involving affiliate sites (VA, UH) as a single-site study.

Basic Study Information

5. * Will an external IRB act as the IRB of record for this study?

Yes No [Clear](#)

6. * Will your IRB act as the single IRB of record for other participating sites?

Yes No [Clear](#)

7. * Local principal investigator:

Phil Bivens (pi2)

8. * Which IRB should oversee this study?

External IRB Reliance
 UT Health San Antonio IRB
[Clear](#)

9. * Attach the protocol:

Document	Category	Date Modified	Document History
There are no items to display			

Exit Save Continue

External IRB of Record

Select 'Yes' if using an external IRB of record (e.g. Advarra, WCG IRB, UTSW).

Is Your IRB the IRB of Record?

Select 'Yes' if the IRB at your institution will be responsible for reviewing this submission on behalf of all sites participating in this study.

Local Principal Investigator

Select the local principal investigator for this study or participating site. If this is a multi-site or collaborative research study for which your IRB will be serving as the IRB of record, then select the name of the principal investigator responsible for the entire conduct of the study. You will enter individual site principal investigators on the site records.

IRB to Oversee Study

- Select External IRB Reliance if using an external IRB of record (e.g. Advarra, WCG IRB, UTSW).
- Select UT Health San Antonio IRB if using the local UT Health SA IRB as the IRB of record.

Attach the Protocol

Attach protocol using the template from the following diagram:

Protocol Template Diagram

🔗 **Attach the Protocol** - Attach protocol using the template from the following diagram:

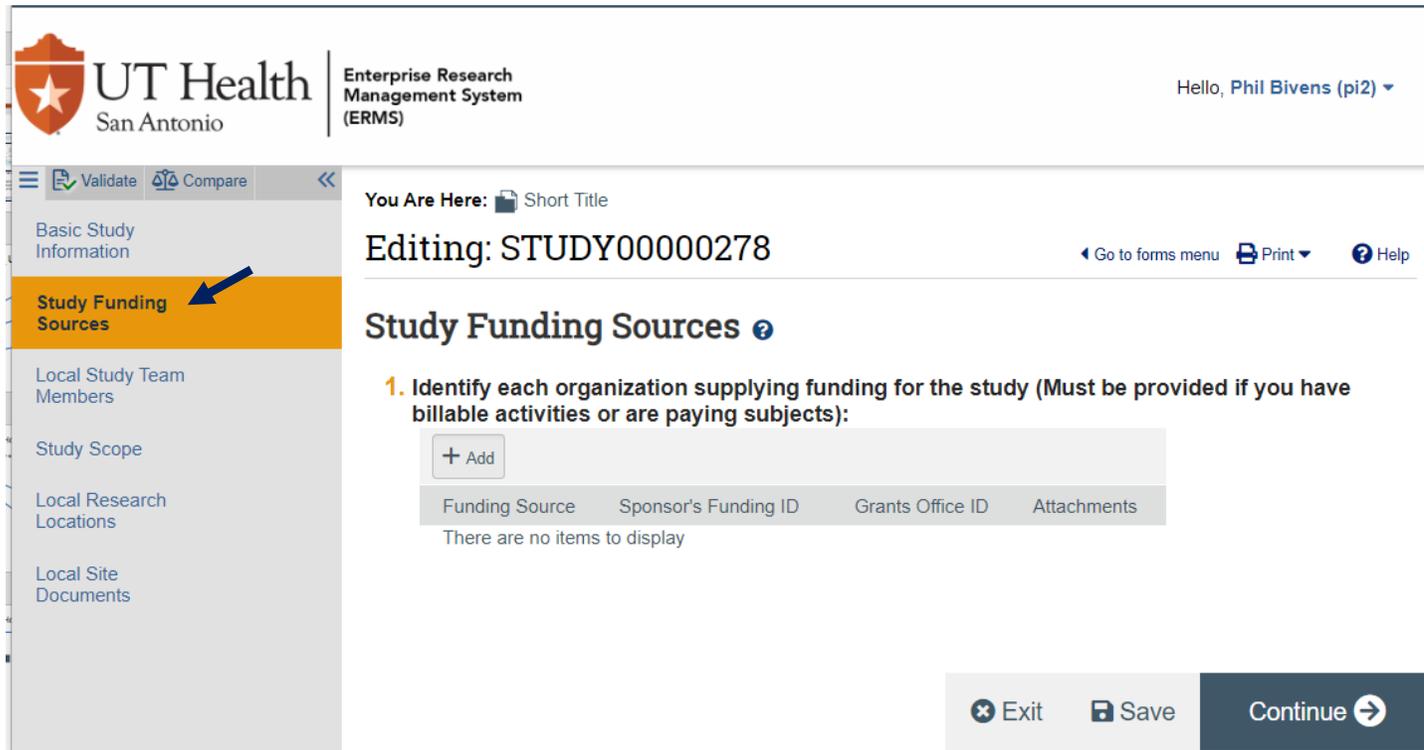
Non-human subjects or non-regulated research	Exempt Determination	Expedited Review non-experimental	Expedited Review experimental	Full Board Review	Investigator-Sponsor	Emergency Use of Investigational Agent
IRB Office Review		IRB Approval			IRB Notification	
Examples: -Quality Improvement -Health surveillance -Program evaluation -Use of deidentified data or specimens -Use of commercially available samples or publicly available data	Examples: -Chart reviews -Surveys -Comparing educational methods -Benign behavioral interventions -Research on specimens collected for other purposes	Examples: -Collection of blood by venipuncture -Collection of non-invasive biological specimens -Collection of non-invasive measurements -In-vitro diagnostic testing	Examples: -Use of minimal risk experimental procedures including approved drugs or devices which do not require IND or IDE	Examples: -All greater than minimal risk research -Clinical trials -Any research use involving radiation -Any research use of invasive procedures	Examples: -FDA IND or IDE held by local investigator	Use the below checklists to determine whether the use of the drug or device qualifies as Emergency Use
<u>HRP-503a – Template – Protocol – Nonhuman determination</u>	<u>HRP-503b – Template – Protocol – Exempt Research</u>	<u>HRP-503c – Template – Protocol – Expedited Study non-experimental</u>	<u>HRP-503d – Template – Protocol – Expedited Study experimental</u>	<u>HRP-503 – Template – Protocol – Full Board Study</u>	<u>HRP-503e – Template – Protocol – Investigator IND/IDE</u>	<u>HRP-503f – Template – Drug Emergency Use</u> <u>HRP-503g – Template – Device Emergency Use</u>



UT Health
San Antonio

Enterprise Research Management System (ERMS)

Study Funding Sources



UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2) ▾

Validate Compare <<

You Are Here: 📄 Short Title

Editing: STUDY00000278 [Go to forms menu](#) [Print](#) [Help](#)

Study Funding Sources ⓘ

1. Identify each organization supplying funding for the study (Must be provided if you have billable activities or are paying subjects):

[+ Add](#)

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

[✕ Exit](#) [💾 Save](#) [Continue ➔](#)

🔗 Funding Sources Page

Identify all external funding sources, such as industry sponsors and government agencies. If funding comes from a specific internal funding program, also identify that funding source.

Local Study Team Members - Internal

? Role in research

Select at least one option from Group A and Group B, if applicable.

- Group A = study roles for engaged personnel
- Group B = research sites
- Group C = non-engaged personnel, as applicable

All other non-engaged personnel should be added under "Manage Guest List".

? Study Team Members

UT Health SA employees	Add UT Health SA employees who will be interacting with human subjects or accessing identifiable private information (engaged in research) Add UT Health SA employees who will be the custodian, payor, and department representative for participant payments (if applicable). Add UT Health SA employee who will be the billing contact for the study (if applicable).
UH employees	Do not add UH employees. They will be listed on a separate UH specific personnel form.
VA/WOC employees	Do not add VA/WOC employees. They will be listed within the VA IRBNet application.
IMPORTANT: Do not list study team members from other sites for a multi-site study. Other sites involved in multi-site studies will add their own information about local study team members.	

Tips: If you have difficulty finding the person in the list, try typing the beginning of the first or last name. Contact the IRB staff for assistance if a person is not listed in the system.

Local Study Team Members - External

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2)

Validate Compare

You Are Here: Short Title

Editing: STUDY00000278 | Go to forms menu | Print | Help

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

+ Add

Name	Roles	Involved in Consent	E-mail	Phone
There are no items to display				

2. External team member information: ?

+ Add

Name	Description
There are no items to display	

Exit Save Continue



External Team Member Information

DO	DON'T
<ul style="list-style-type: none">List University Health employees (e.g. @uhtx.com email) on the University Health Personnel Form.	<ul style="list-style-type: none">Do not add UT Health San Antonio employees. "UH Research Activities" should be selected in the study team member roles if applicable.Do not add VA employees/WOCs. They will be listed within the VA IRBNet application and should <u>not</u> be included here. Add study team members from other sites for a multi-site study. Other sites involved in multi-site studies will add their own information about local study team members.

IMPORTANT: Do not add information about team members you were able to select in the previous question. For people listed in the system, the information should be added to their profiles in the system instead.

Study Scope

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2)

Validate Compare

You Are Here: Short Title

Editing: STUDY00000278

Go to forms menu Print Help

Study Scope

- * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**
 Yes No [Clear](#)
- * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**
 Yes No [Clear](#)

Exit Save Continue



Study Scope Page (Drugs and Devices)

Answering 'Yes' will create forms for drugs and/or devices.

You can use the navigation element located on the left of the page to skip between the drugs and/or devices forms. You can also exit the form and return later to add information before submitting the study for review.



Drug or Biologic Used?

"Specify the use of" means the protocol requires one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is considered standard of care.

Example: If the protocol indicates that "Subjects in group 1 **will take** 650 mg of aspirin in response to a headache," the use of aspirin is specified by the protocol. In contrast, if the protocol indicates that "Subjects in group 1 **may take** 650 mg of aspirin in response to a headache," the use of aspirin is not specified by the protocol.

Local Research Locations

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2)

Validate Compare

You Are Here: Short Title

Editing: STUDY00000278

Go to forms menu Print Help

Local Research Locations

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

+ Add

Location	Contact	Phone	Email
There are no items to display			

Select Research Location SEL

Filter by Location Name [] Go Clear

Location Name

- Mays Cancer Center
- University Health
- UT Health SA
- VA South Texas Veterans Health Care System

OK Cancel

Exit Save Continue



Local Research Locations Page

- Identify UT Health SA and affiliate research locations where research activities will be conducted or overseen by the local investigator (i.e., UH, VA, MCC).
- Do NOT add locations outside UT Health SA and affiliates here. Other sites under the local investigator will be added in a separate section.

Drugs

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2)

You Are Here: Short Title

Editing: STUDY00000278

Drugs

- List all drugs, biologics, foods, and dietary supplements to be used in the study:**
+ Add

Generic Name	Brand Name	Drug Type	Attachment Name
There are no items to display			
- Will the study be conducted under any IND numbers?**
 Yes No [Clear](#)
- Attach files:** (such as IND or other information that was not attached for a specific drug)
+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Exit Save Continue



Drugs Page

Identify all drugs to be used on human subjects as part of this study. Include all information the IRB needs to identify and evaluate any investigational new drug.

For studies being reviewed by UT Health SA IRB, an IND letter is required for all investigational drugs. Complete and upload a **Form O** for all off-label use of a drug requesting an exemption. Include files related to this drug (i.e. package insert, investigator brochure).



Study Conducted Under IND

For studies being reviewed by UT Health SA IRB, an IND letter is required for all investigational drugs. Complete and upload a **Form O** for all off-label use of a drug requesting an exemption.



Attach Files For Drugs

Attach files related to this drug (i.e. package insert, investigator brochure). Complete and upload a **Form O** for all off-label use of a drug requesting an exemption.

Devices

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2)

You Are Here: Short Title

Editing: STUDY00000278

Devices

- Select each device the study will use as an HUD or evaluate for safety or effectiveness:**
+ Add

Device	Humanitarian Use Device	Attachment Name
There are no items to display		
- Device exemptions applicable to this study:**
 - IDE number
 - HDE number
 - Claim of abbreviated IDE (nonsignificant risk device)
 - Exempt from IDE requirements[Clear](#)
- Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device)
+ Add

Document	Category	Date Modified	Document History
There are no items to display			

Exit Save Continue



Devices Page

Identify all devices to be used as an HUD or evaluated for safety and effectiveness on human subjects as part of this study. Include all information the IRB needs to identify and evaluate any device with exemptions or claimed exemptions.

Attach files related to this device (i.e. FDA exemption status, FDA cleared labeling information, device brochure, instruction manual, or information from the manufacturer describing the device). For studies reviewed by UT Health SA IRB, a **Form P** Investigational Use of a Device must be completed and uploaded for a claim of abbreviated IDE (nonsignificant risk device) or exemption from IDE requirements.



Device Exemptions

For studies reviewed by UT Health SA IRB, a **Form P** Investigational Use of a Device must be completed and uploaded for a claim of abbreviated IDE (nonsignificant risk device) or exemption from IDE requirements.



Attach Files for Devices

For studies being reviewed by the UT Health SA IRB, a Sponsor or FDA IDE letter or FDA HDE letter is required for all investigational devices that do not meet abbreviated or exemption requirements. Complete and upload a **Form P** for all claims of abbreviated IDE (nonsignificant risk device) or exemption from IDE requests.

Local Site Documents

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2)

Validate Compare

You Are Here: Short Title

Editing: STUDY0000278

Go to forms menu Print Help

Local Site Documents

- 1. Consent forms:** (include an HHS-approved sample consent document, if applicable) [?](#)

Document	Category	Date Modified	Document History
There are no items to display			
- 2. Recruitment materials:** (add all material to be seen or heard by subjects, including ads) [?](#)

Document	Category	Date Modified	Document History
There are no items to display			
- 3. Other attachments:** [?](#)

Document	Category	Date Modified	Document History
There are no items to display			

Suggested attachments:

- UT Health SA sites: Add from the document library, the UT Health SA Institutional Form and any applicable forms referenced within the document. NOTE: This form is REQUIRED for all studies unless a nonhuman research determination is made.
- For non-UT Health SA sites: Add from the document library, the Protocol Specific Site Form.

Exit Save Continue



Consent Forms

Upload site specific consent form from sponsor or utilize appropriate UT Health SA template informed consent located within the [Library](#).



Recruitment Materials

Add all UT Health SA specific material to be seen or heard by subjects, including ads.



Other Attachments

Add the [UT Health SA Institutional Form](#) and [UT Health SA IRB Application](#) and any applicable forms referenced within the document. Forms are in the [Library](#) under Templates.

NOTE: The institutional form is REQUIRED for all studies unless a non-human research determination is made. The IRB application is REQUIRED for all non-exempt UT Health IRB studies.

Create New Study – External IRB Reliance

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2)

Validate Compare

You Are Here: Short Title

Editing: STU00000278

Go to forms menu Print Help

Basic Site Information

- Basic Study Information
- Basic Site Information
- External IRB
- Study Funding Sources
- Additional Local Funding Sources
- Local Study Team Members
- Study Scope
- Local Research Locations
- Drugs
- Devices
- Study-Related Documents
- Local Site Documents

Basic Local Site Information

1. * Brief description of activities this site will perform: (enter "ALL" if this site will perform all procedures in the protocol)

Exit Save Continue

? Brief Description of Activities This Site Will Perform

In a few words, summarize your activities as a participating site in this multi-site or collaborative research study. If your site will be conducting all portions of the research, type "ALL." If your site will be conducting only certain portions of the research, include a summary.

For example: This study includes both adults and children as research subjects; however, at this site, we will include only children. Therefore, we will conduct only those procedures related to children.

External IRB

The screenshot shows the ERMS interface. At the top left is the UT Health San Antonio logo. To its right is the text "Enterprise Research Management System (ERMS)" and a user greeting "Hello, Phil Bivens (pi2)". Below the logo is a navigation menu with items like "Basic Site Information", "External IRB" (highlighted with a blue arrow), "Study Funding Sources", "Additional Local Funding Sources", "Local Study Team Members", "Study Scope", "Local Research Locations", "Drugs", "Devices", "Study-Related Documents", and "Local Site Documents". The main content area is titled "Editing: STUDY0000278" and "External IRB". It contains three numbered steps: 1. "* External IRB:" with a dropdown menu; 2. "External study ID:" with a text input field; 3. "Specify the reason the study should be reviewed by an external IRB:" with a large text area. At the bottom right are three buttons: "Exit", "Save", and "Continue" (highlighted with a blue arrow).

- External IRB
Select the IRB outside your institution that will act as the IRB of record for this study. If you cannot find the external IRB in the list, contact IRBReliance@uthscsa.edu for assistance.

Additional Local Funding Sources

The screenshot shows the Enterprise Research Management System (ERMS) interface. At the top left is the UT Health San Antonio logo. To its right, it says 'Enterprise Research Management System (ERMS)'. Further right, it says 'Hello, Phil Bivens (pi2)'. Below the logo, there are navigation icons for 'Validate' and 'Compare'. A left-hand navigation menu is visible, with 'Additional Local Funding Sources' highlighted in orange and indicated by a blue arrow. The main content area shows 'You Are Here: Short Title' and 'Editing: STUDY00000278'. Below this, the title 'Additional Local Funding Sources' is displayed. A numbered instruction reads: '1. Identify each organization supplying funding for the local site:'. Below the instruction is a '+ Add' button and a table with columns: 'Funding Source', 'Sponsor's Funding ID', 'Grants Office ID', and 'Attachments'. The table is currently empty, with the text 'There are no items to display' below it. At the bottom of the interface, there are three buttons: 'Exit', 'Save', and 'Continue' (which is highlighted in dark blue and indicated by a blue arrow).

Study-Related Documents

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Phil Bivens (pi2)

Validate Compare

You Are Here: Short Title

Editing: STUDY00000278

Go to forms menu Print Help

Study-Related Documents

- 1. Consent form templates:** (include an HHS-approved sample consent document, if applicable) ?
+ Add

Document	Category	Date Modified	Document History
There are no items to display			
- 2. Recruitment material templates:** (add templates for all material to be seen or heard by subjects, including ads) ?
+ Add

Document	Category	Date Modified	Document History
There are no items to display			
- 3. Other attachments:**
+ Add

Document	Category	Date Modified	Document History
There are no items to display			

i Suggested attachments:

- Sponsor provided CRFs
- Data collection instruments, forms, tools
- Sponsor provided lab and/or pharmacy manuals
- Local manuals for labs and/or pharmacy
- Other Sponsor or lead PI documents not attached on previous forms

Exit Save Continue

? Study-Related Documents - Consent form templates

- Add sponsor or lead PI approved template(s), if available.
- Do **not** add UT Health SA specific informed consent here. It will be uploaded under Local Site Documents.

? Study-Related Documents - Recruitment material templates

- Add all material to be seen or heard by subjects, including ads, provided by the sponsor or lead PI.
- Do **not** add UT Health SA specific materials here. They will be uploaded under Local Site Documents

Protocol Status and Submission – UT Health SA IRB

The screenshot displays the ERMS interface for study BT4. The top navigation bar includes 'Dashboard', 'Agreements', 'COI', and 'IRB'. The 'IRB' section is active, showing 'Submissions', 'Meetings', 'Reports', 'Library', and 'Help Center'. The study details for 'STUDY00000026: BT4' are shown, including the principal investigator (Phil Bivens), submission type (Initial Study), and primary contact (Phil Bivens). A flowchart illustrates the submission process: Pre-Submission (highlighted in orange) leads to Pre-Review, which can lead to IRB Review or Clarification Requested. IRB Review can lead to Post-Review or Clarification Requested. Post-Review can lead to Review Complete or Modifications Required. Clarification Requested can lead to Pre-Review or IRB Review. Modifications Required can lead to Post-Review. The 'Submit' button in the left sidebar is highlighted with a red box.

Pre-Submission: Means you haven't submitted the study. You can open it, and then finish and submit it for review.

Pre-Review: Under review with IRB Coordinator. **Study team can no longer edit study unless it is returned by IRB Coordinator for clarifications.**

IRB Review: Assigned to expedited reviewer or full board meeting.

Post-Review: IRB Coordinator finalizes review.

Review Complete: Study review complete. Notification send to PI, PI Proxy, and POC.

Clarification Requested: Changes requested by the IRB Coordinator or IRB Expedited Reviewer.

Modification Required: Changes required by the convened IRB.

Edit Study

If you feel something has been incorrectly filled out, or a person was not added, this will allow you to revise your application prior to submission.

Adding a PI Proxy

This function will allow the addition of a PI Proxy. A PI Proxy has the ability to act on behalf of the PI. **Only a PI or a PI Proxy may submit a study.**

Note: If you wish to add an individual a PI Proxy, this person must be listed as a Local Study Team Member

Submit

Once all applicable information has been provided, and a Contact/PI Proxy has been assigned, you may now submit your study.

Protocol Status and Submission – External IRB Reliance

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

Dashboard | Agreements | COI | IRB

Submissions | Meetings | Reports | Library | Help Center

IRB > Submissions > BT - Agreement

Pre-Submission STUDY00000027: BT - Agreement

Last updated: 9/11/2023 5:08 PM

Principal investigator: Phil Bivens (pi2)
Submission type: Initial Study
Primary contact: Phil Bivens (pi2)
PI proxies:

IRB office: External IRB Reliance
IRB coordinator:
External study ID:

Next Steps

- Edit Study
- Printer Version
- Submit** ⭐
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews

Flowchart: Pre-Submission → Pre-Review → Pending sIRB Review → Post-Review → Review Complete. Clarification Requested and Modifications Required are also shown as part of the process.

Pre-Submission: Means you haven't submitted the study. You can open it, and then finish and submit it for review.

Pre-Review: Confirm reliance.

- The IRB Reliance Coordinator will confirm external IRB reliance, moving the study from the Pre-Review state to the Pending sIRB Review state.
- An email notification will be generated and sent to the PI, PI Proxy, and POC.
- A comment will be sent to the study team for pending items while awaiting sIRB review.

Pending sIRB Review: Record sIRB Decision.

- Once the sIRB makes a determination, the IRB coordinator records the sIRB determination, moving the study from the Pending sIRB Review state to the Review Complete state.

Review Complete: Study review complete. An acknowledgement letter is generated for approval to activate the study at UT Health SA after sIRB determination and all institutional requirements are met.

Clarification Requested: Changes requested by the IRB Reliance Coordinator.

Modification Required: Will not use. Decision by sIRB will not be recorded until approved.

Submit ⭐

Once all applicable information has been provided, and a Contact/PI Proxy has been assigned, you may now submit your study.

Clarifications Requested

① Click the **History** tab and review the Clarification Requested activity.

Note: If the reviewer attached a document, a link to open it appears on the History tab.



History Funding Contacts Docu

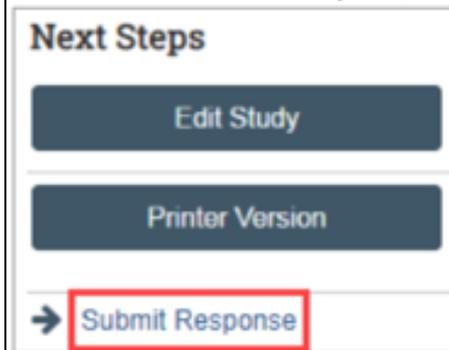
Filter by [?] Activity ▾ Enter text to s

Activity

← Clarification Requested

Please upload revised consent forms for the study.

② On the submission workspace, click **Submit Response**.



Next Steps

Edit Study

Printer Version

→ Submit Response

Approval Documents

IRB > Submissions > New Study Documents Admin View Help

Approved

STUDY00000280: New Study Documents

Entered IRB: 11/11/2023 12:00 AM
 Initial approval: 11/11/2023
 Initial effective: 11/11/2023
 Effective: 11/11/2023
 Last updated: 11/11/2023 12:03 AM

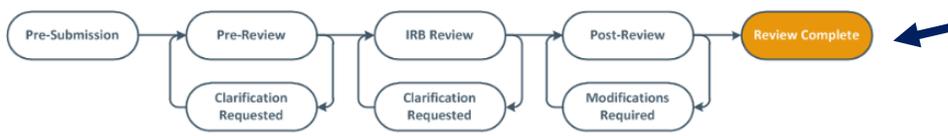
Principal investigator: Phil Bivens (pi2)
Submission type: Initial Study
Primary contact: Brandie Otten
PI proxies: Brandie Otten

IRB office: UT Health San Antonio IRB
IRB coordinator: Patricia Alexander
Letter:  Correspondence_for_STUDY00000280.pdf(0.01) ...
Regulatory authority: 2018 Requirements

Next Steps

- View Study
- Printer Version

-  Send Letter
-  Prepare Letter
- Submit Designated Review
-  Assign Coordinator
-  Assign Primary Contact
-  Assign PI Proxy
-  Manage Ancillary Reviews
-  Manage Guest List
-  Add Related Grant
-  Manage Related Agreements



History
Funding
Contacts
COI
Documents
Follow-on Submissions
Reviews
Snapshots
Agreements
Training

Study Related Documents				
Draft	Category	Final	Last Finalized	Document History
Drug Brochure.docx	Drug Attachment	Drug Brochure.docx	11/11/2023 12:02 AM	History
Form O.docx	Drug Attachment	Form O.docx	11/11/2023 12:02 AM	History
Form O.docx	Drug Attachment	Form O.docx	11/11/2023 12:02 AM	History
Protocol.docx	IRB Protocol	Protocol.pdf	11/11/2023 12:02 AM	History
Site Related Documents				
Draft	Category	Final	Last Finalized	Document History
Form J.docx	HIPAA Waiver	Form J.pdf	11/11/2023 12:02 AM	History
Data Collection Form.docx	Data Collection Instrument	Data Collection Form.pdf	11/11/2023 12:02 AM	History
Flyer.docx	Recruitment Materials	Flyer.pdf	11/11/2023 12:02 AM	History
form_d.docx	Consent Form	form_d.pdf	11/11/2023 12:02 AM	History

Study Information

The screenshot displays the ERMS interface for a study titled "STUDY00000280: New Study Documents". The status is "Approved". Key information includes:

- Entered IRB:** 11/11/2023 12:00 AM
- Initial approval:** 11/11/2023
- Initial effective:** 11/11/2023
- Effective:** 11/11/2023
- Last updated:** 11/11/2023 12:03 AM
- Principal investigator:** Phil Bivens (pi2)
- Submission type:** Initial Study
- Primary contact:** Brandie Otten
- PI proxies:** Brandie Otten
- IRB office:** UT Health San Antonio IRB
- IRB coordinator:** Patricia Alexander
- Letter:** Correspondence_for_STUDY00000280.pdf(0.01) ...
- Regulatory authority:** 2018 Requirements

The "Next Steps" section includes buttons for "View Study", "Printer Version", "Create Modification/CR", and "Report New Information". A workflow diagram shows stages: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete, with sub-steps for Clarification Requested and Modifications Required.

The "History" tab is active, showing a table of activity:

Activity	Author	Activity Date
Letter Sent	Otten, Brandie	11/11/2023 12:03 AM
Correspondence_for_STUDY00000280.pdf		

History: lists the activity taken on a submission including any comments, attachments, or correspondence added.

Funding: lists funding sources and related grant information.

Contacts: lists PI, study team, and guests who can view the submission.

COI: listed related disclosure profiles.

Documents: lists study and site related documents.

Follow-on Submissions: lists continuing reviews, modifications, RNIs, and external IRB updates.

Reviews: lists ancillary reviews.

Snapshots: lists the history of submission contents.

Agreements: lists related agreements.

Training: lists study team related training

Add Participating Sites

The screenshot shows the ERMS interface for a Multi-site Study (MSS). The top navigation bar includes 'Dashboard', 'Admin', 'Agreements', 'COI', 'IRB', and 'Settings'. The main content area displays the study details for 'STUDY00000279: Multi-site Study (MSS)'. A sidebar on the left lists 'Next Steps' with options like 'View Study', 'Printer Version', 'Create Modification/CR', 'Report New Information', 'Send Letter', 'Prepare Letter', 'Submit Designated Review', and 'Add Participating Sites'. The 'Add Participating Sites' option is highlighted with a red box and a blue arrow. Below the sidebar is a flowchart showing the review process: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. A table below the flowchart shows activity logs for the study.

Activity	Author	Activity Date
IRB Coordinator Assigned	Otten, Brandie	11/10/2023 11:40 PM
Assigned to Patricia Alexander		
Letter Sent	Otten, Brandie	11/10/2023 11:39 PM

The screenshot shows the 'Add Participating Sites' dialog box. It has a title bar 'Add Participating Sites' and a main area with a heading '1. * Add participating sites:'. Below the heading are two input fields: 'Institutional Profile' and 'Principal Investigator'. Each field has a red asterisk and a search icon. There is an '+ Add' button below the fields and 'OK' and 'Cancel' buttons at the bottom right.

Note: IRB Coordinator will confirm site(s) and site PI(s) for selection.

Add / Manage participating sites when non-affiliated sites are relying on UT Health SA IRB as the sIRB of record.

Ancillary Reviews

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 > Submissions > Test

Pre-Submission STUDY00000283: Test

Last updated: 11/15/2023 8:34 AM

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
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews**
- Manage Guest List
- Submit Ancillary Review
- Add Related Grant
- Manage Related Agreements
- Create Ad Hoc Certifications
- Add Comment
- Add Private Comment
- Copy Submission
- Discard
- Manage Tags

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested → Clarification Requested → Modifications Required

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

There is no Pre-Review to display at this time.
 There is no Non-Committee Review to display at this time.
 There is no Committee Review to display at this time.

Ancillary Reviews

Review Type	Organization	Person	Reqd	Accepted	Comments	Docs
Billing Risk		Jeannette Watterson	no	yes	This study has a billing risk.	
Participant Payment		Jeannette Watterson	no	yes	Approved.	Inst B.pdf

There are no Committee Member Review Comments to show at this time.

Add Ancillary Review

- * Select either an organization or a person as reviewer:**
 Organization:
 Person:
- Review type:**
- Billing Risk**
 IBC
 Institutional Review-UH
 Institutional Review-VA
 IT Security Review
 Participant Payment
 Privacy Review
 Protocol Development and Feasibility
 Protocol Review
 Research Compliance
 Review for High Risk Data Sharing
 RSC/RDRC

★ IRB Coordinator will add appropriate ancillary reviews even though the 'Manage Ancillary Reviews' button is accessible by study team.

Agreements

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 > Test Re-Authentication Prompts 10.5 Removal

Pre-Review STUDY0000045: Test Re-Authentication Prompts 10.5 Removal

Entered IRB: 9/26/2023 4:13 PM
Last updated: 11/11/2023 12:48 AM

Principal investigator: Phil Bivens (pi2)
Submission type: Initial Study
Primary contact: Phil Bivens (pi2)
PI proxies:

IRB office: UT Health San Antonio IRB
IRB coordinator:

Next Steps

View Study
Printer Version

Submit Pre-Review
Request Pre-Review Clarification
Assign Coordinator
Assign Primary Contact
Assign PI Proxy
Assign IRB
Manage Ancillary Reviews
Manage Guest List
Add Related Grant
Manage Related Agreements

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete
Clarification Requested → IRB Review → Clarification Requested → IRB Review → Post-Review → Review Complete
Modifications Required → Post-Review → Review Complete

History Funding Contacts COI Documents IRB Assignment Details Reviews Snapshots Agreements Training

Related Agreements

Filter by ID Enter text to search + Add Filter X Clear All

ID	Name	PI Last	PI First	Agreement Status
MTA00000130	BB Test Agreement 1	Aavik	Torgeir	Pre-Submission

1 items page 1 of 1

★ PI/Study Team should add appropriate linked agreements using 'Manage Related Agreements' button. IRB Coordinator can add later if needed.

Conflict of Interest - COI

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

Hello, Brandie Otten ▾

Switch User

Dashboard | Admin | Agreements | COI | IRB | Settings

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

IRB > Test Re-Authentication Prompts 10.5 Removal

Pre-Review

Entered IRB: 9/26/2023 4:13 PM
Last updated: 11/11/2023 12:48 AM

Next Steps

- View Study
- Printer Version
- Submit Pre-Review
- Request Pre-Review Clarification
- Assign Coordinator
- Assign Primary Contact
- Assign PI Proxy
- Assign IRB
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Manage Related Agreements
- Create Ad Hoc Certifications

STUDY0000045: Test Re-Authentication Prompts 10.5 Removal

Principal investigator: Phil Bivens (pi2)
Submission type: Initial Study
Primary contact: Phil Bivens (pi2)
PI proxies:

IRB office: UT Health San Antonio IRB
IRB coordinator:

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested (between Pre-Submission and Pre-Review, IRB Review and Post-Review)

Modifications Required (between Post-Review and Review Complete)

History | Funding | Contacts | **COI** | Documents | IRB Assignment Details | Reviews | Snapshots | Agreements | Training

Open Certifications

Filter by: Discloser First N [Enter text to search] [Add Filter] [Clear All]

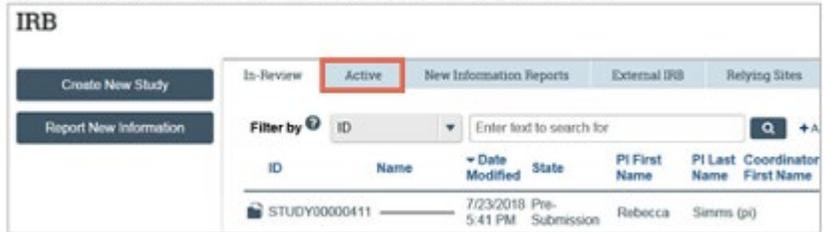
Discloser First Name	Discloser Last Name	Date Created	Status	Last Profile Update Date
Phil	Bivens (pi2)	9/26/2023 4:13 PM	Awaiting Profile Update	

1 items | page 1 of 1 | 10 / page

★ 'Create Ad Hoc Certifications' button only viewable to IRB Coordinator.

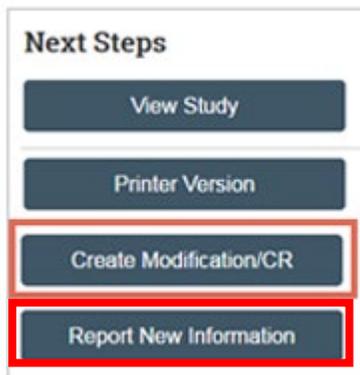
Follow-on Submissions – UT Health SA IRB

- ① On the IRB page, click the **Active** tab and open the approved study.



The screenshot shows the IRB system interface. On the left, there are buttons for 'Create New Study' and 'Report New Information'. The main area has tabs for 'In-Review', 'Active', 'New Information Reports', 'External IRB', and 'Relisting Sites'. The 'Active' tab is highlighted with a red box. Below the tabs is a search bar and a table of studies. The table has columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name. One study is listed with ID 'STUDY00000411', Name 'Pre-Submission', Date Modified '7/23/2018 5:41 PM', State 'Rebecca', and Coordinator 'Simms (pi)'.

- ② Click the **Create Modification/CR** or **Report New Information** button.



The screenshot shows a 'Next Steps' menu with four buttons: 'View Study', 'Printer Version', 'Create Modification/CR', and 'Report New Information'. The 'Create Modification/CR' and 'Report New Information' buttons are highlighted with red boxes.

- ③
- Complete the pages.
 - Click Continue to move through the pages and Finish on the last page.
 - From the workspace, click Submit.

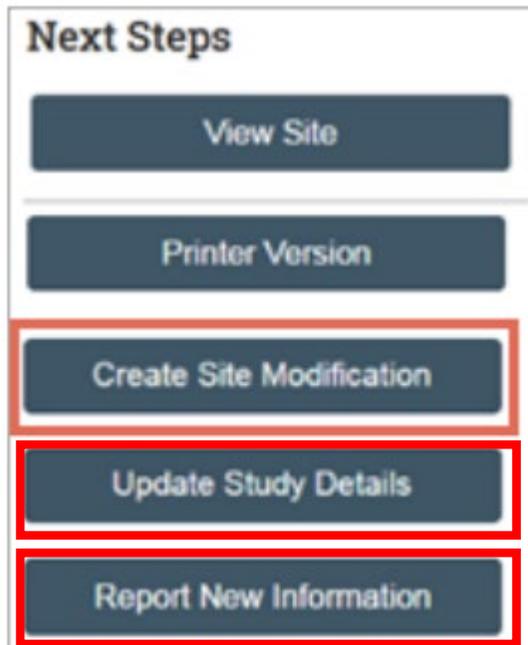
Follow-on Submissions – External IRB Reliance

① Click the **External IRB** tab and open the study.

③

- Complete the pages.
- Click Continue to move through the pages and Finish on the last page.
- From the workspace, click Submit or Finalize Updates.

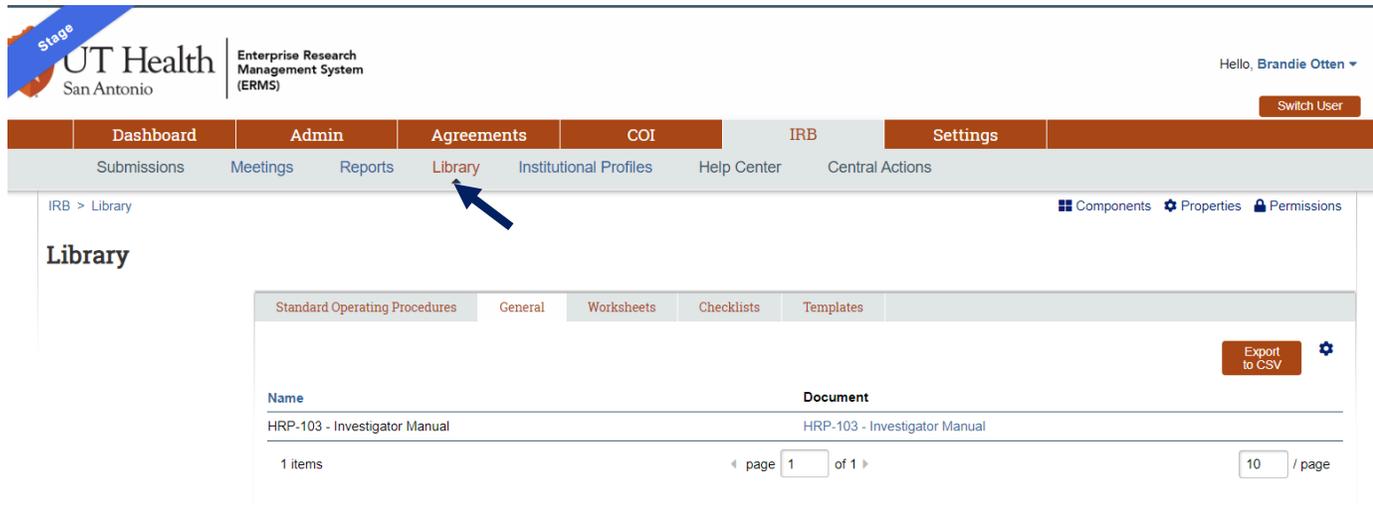
② Click the **Create Modification/CR** or **Report New Information** button.



Create Site Modification: to update submission information such as a PI change that requires external IRB review.

Update Study Details: to update submission information such as a personnel change that does not require external IRB review.

Library and Help Center



The screenshot shows the ERMS interface with the 'Library' tab selected in the top navigation bar. A blue arrow points to the 'Library' tab. The page title is 'Library'. Below the title, there are tabs for 'Standard Operating Procedures', 'General', 'Worksheets', 'Checklists', and 'Templates'. The 'Standard Operating Procedures' tab is active. A table lists documents, with one entry: 'HRP-103 - Investigator Manual'. The table has columns for 'Name' and 'Document'. Below the table, it shows '1 items' and a pagination control for 'page 1 of 1' with '10 / page'.

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Brandie Otten | Switch User

Dashboard Admin **Agreements** COI IRB Settings

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

IRB > Library Components Properties Permissions

Library

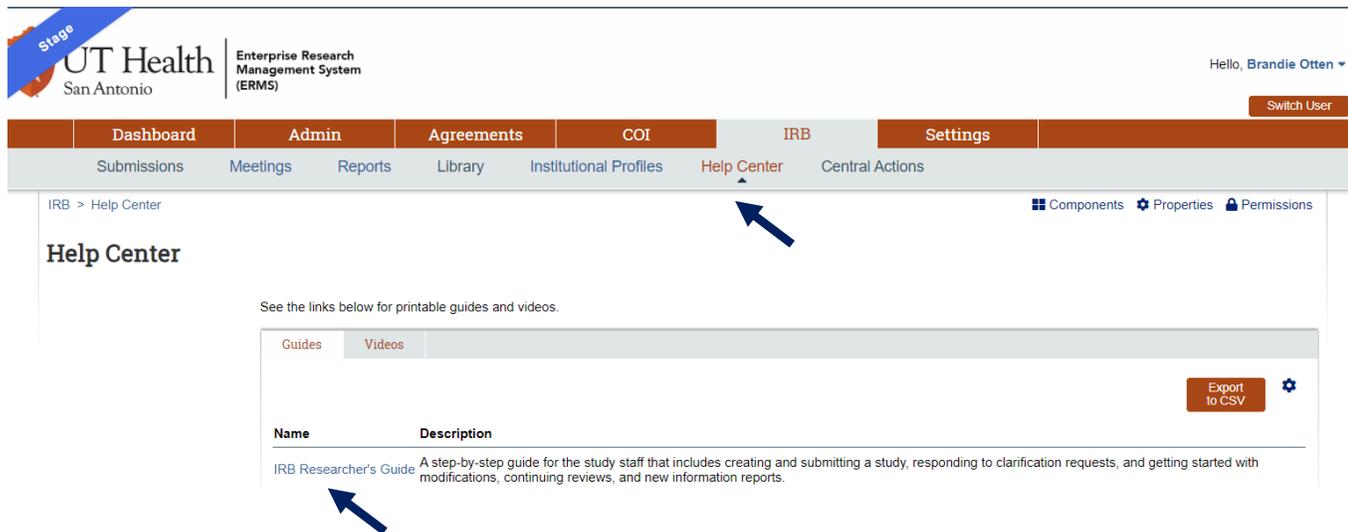
Standard Operating Procedures General Worksheets Checklists Templates

Export to CSV

Name	Document
HRP-103 - Investigator Manual	HRP-103 - Investigator Manual

1 items | page 1 of 1 | 10 / page

Standard Operating Procedures: All IRB and External IRB Reliance SOPs
General: Investigator Handbook and FAQs
Worksheets: Help documents for IRB reviewers.
Checklists: IRB reviewer determinations.
Templates: IRB submission forms and templates.



The screenshot shows the ERMS interface with the 'Help Center' tab selected in the top navigation bar. A blue arrow points to the 'Help Center' tab. The page title is 'Help Center'. Below the title, there are tabs for 'Guides' and 'Videos'. The 'Guides' tab is active. A table lists guides, with one entry: 'IRB Researcher's Guide'. The table has columns for 'Name' and 'Description'. Below the table, it shows '1 items' and a pagination control for 'page 1 of 1' with '10 / page'.

UT Health San Antonio | Enterprise Research Management System (ERMS) | Hello, Brandie Otten | Switch User

Dashboard Admin Agreements COI IRB **Settings**

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

IRB > Help Center Components Properties Permissions

Help Center

See the links below for printable guides and videos.

Guides **Videos**

Export to CSV

Name	Description
IRB Researcher's Guide	A step-by-step guide for the study staff that includes creating and submitting a study, responding to clarification requests, and getting started with modifications, continuing reviews, and new information reports.

1 items | page 1 of 1 | 10 / page

Guides: How to and Quick Start guides.
Videos: Overview of submission and/or review processes.

Important Changes

- ❖ All submissions initiated in ERMS
 - *previously through REDCap for clinical trials and prompt reporting or via the current email process*
- ❖ Coverage Analysis is no longer part of the IRB files
- ❖ Institutional form revised (removed ERMS questions)
- ❖ No Personnel Form (Inst M)
- ❖ No institutional activation letter for UT Health IRB studies
- ❖ Participant payment roles added to ERMS application
- ❖ All sIRB approvals and approved documents for external IRB studies submitted in ERMS
 - *previously only required when involving institutional changes*
- ❖ Continuing review submission includes study closure
- ❖ ERMS requires UT single sign-on
 - *previously allowed non-UT accounts*



Important Deadlines



Dec 11

**** ERMS Go Live ****

All submissions will be processed through ERMS

November 2023						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
19	20	21	22 Deadline for submission of all new studies via current email process	23 Holiday	24 Holiday	25
26	27	28	29	30	Transition active and pending studies to ERMS *	
December 2023						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					1 Deadline for submission of other business items via current email process	2
3	4 Emergency submission ONLY	5 Emergency submission ONLY	6 Emergency submission ONLY	7 Emergency submission ONLY	8 Emergency submission ONLY	9
	Transition active and pending studies to ERMS *					
10	11  ** ERMS Go Live ** All submissions will be processed through ERMS	12	13	14	15	16

* Non-exempt UT Health SA IRB and external IRB studies

Thank you!

Questions?

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