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

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<th>Agreements</th>
<th>COI</th>
<th>IRB</th>
<th>IACUC</th>
<th>Grants</th>
<th>DLAR Operations</th>
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<td>Oct 2023</td>
<td>DEC 2023</td>
<td>Fall 2024</td>
<td>Early 2025</td>
<td>Summer 2025</td>
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</table>
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.
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
ERMS Log-In From My UT Health
ERMS Log-In From UT Health Connect Research
ERMS – IRB Module: Information

Find additional information and updates:

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

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

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

- **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

**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

6. Will your IRB act as the single IRB of record for other participating sites?
   - Yes
   - No

7. Local principal investigator:
   - Phil Bivens

8. Which IRB should oversee this study?
   - External IRB Reliance
   - UT Health San Antonio IRB

9. Attach the protocol:
   - Add

   Document | Category | Date Modified | Document History
   -------- | -------- |-------------- |-------------------
   None

   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:

<table>
<thead>
<tr>
<th>Non-human subjects or non-regulated research</th>
<th>Exempt Determination</th>
<th>Expedited Review non-experimental</th>
<th>Expedited Review experimental</th>
<th>Full Board Review</th>
<th>Investigator-Sponsor</th>
<th>Emergency Use of Investigational Agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Office Review</td>
<td>IRB Approval</td>
<td>IRB Notification</td>
<td></td>
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</tbody>
</table>

**Examples:**
- Quality Improvement
- Health surveillance
- Program evaluation
- Use of de-identified data or specimens
- Use of commercially available samples or publicly available data

**IRB Office Review:**
- Examples:
  - Chart reviews
  - Surveys
  - Comparing educational methods
  - Benign behavioral interventions
  - Research on specimens collected for other purposes

**IRB Approval:**
- Examples:
  - Collection of blood by venipuncture
  - Collection of non-invasive biological specimens
  - Collection of non-invasive measurements
  - In-vitro diagnostic testing

**IRB Notification:**
- Examples:
  - All greater than minimal risk research
  - Clinical trials
  - Any research use involving radiation
  - Any research use of invasive procedures
  - 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:**

**HRP-503a - Template - Protocol - Nonhuman determination**

**HRP-503b - Template - Protocol - Exempt Research**

**HRP-503c - Template - Protocol - Expedited Study non-experimental**

**HRP-503d - Template - Protocol - Expedited Study experimental**

**HRP-503 - Template - Protocol - Full Board Study**

**HRP-503e - Template - Protocol - Investigator IND/IDE**

**HRP-503f - Template - Drug Emergency Use**

**HRP-503g - Template - Device Emergency Use**
Study Funding Sources

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

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".
Local Study Team Members - External

**External Team Member Information**

**DO**

- List University Health employees (e.g. @uthsc.com email) on the University Health Personnel Form.

**DONT**

- 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 not 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 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

- 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 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.
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.

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.

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

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

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

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

1. Identify each organization supplying funding for the local site:

- [ ]

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Sponsor's Funding ID</th>
<th>Grants Office ID</th>
<th>Attachments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

There are no items to display.
Study-Related Documents

- **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

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 one PI or a PI Proxy may submit a study.

Note: If you wish to add an individual as 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 or PI Proxy has been assigned, you may now submit your study.
Protocol Status and Submission – External IRB Reliance

**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.
   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
Study Information

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

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

Note: IRB Coordinator will confirm site(s) and site PI(s) for selection.
IRB Coordinator will add appropriate ancillary reviews even though the ‘Manage Ancillary Reviews’ button is accessible by study team.
Agreements

π PI/Study Team should add appropriate linked agreements using ‘Manage Related Agreements’ button. IRB Coordinator can add later if needed.
Conflict of Interest - COI

‘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.

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

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.

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

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.

**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

**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.

**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

* Non-exempt UT Health SA IRB and external IRB studies
Thank you!

Questions?

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