Enterprise Research Management System (ERMS)
BULLETIN

UT Health San Antonio

Clinical trials submissions and ERMS

With the implementation of ERMS (Enterprise Research Management System) IRB and Agreements modules, there has been an update to the local review process.

- **CANCER RESEARCH**: Research teams are no longer required to submit studies to the Clinical Trials Portal, instead submit by email to mcc_startup@uthscsa.edu. This will begin the Cancer Center Process. Following CDST Review and Approval, MCC Regulatory Affairs will register the study in ERMS IRB on your behalf.
- **NON-CANCER RESEARCH**: Research teams are no longer required to submit studies to the Clinical Trials Portal, instead they can submit the study directly in ERMS. In ERMS a user will need to submit all studies to the IRB and will separately need to submit to Agreements when there is a research agreement associated to the study. The reviews for IRB and Agreements can be reviewed concurrently.

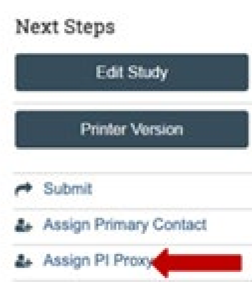
What does this mean for you:

- Study teams are no longer required to submit studies to the Clinical Trials Portal.
- VPR CTO clearance is no longer required for non-cancer research studies before submitting to the IRB. Submissions are initiated in ERMS.
- The reviews for IRB and Agreements can be reviewed concurrently.
    - NOTE: Each module requires a separate submission (Agreements and IRB).

The Research Operations Team believes that this revision to the process with help to expedite the time from the receipt of documents to first subject enrolled, while still maintaining safeguards in the approval process.

More helpful hints for ERMS-IRB users

How can my PI assign a Proxy?



- Click "Assign PI Proxy" on the *main* study page.
- Only the PI can assign a Proxy, and the Proxy must be a study team member.
- The Proxy can submit items on the PI's behalf, and multiple Proxies can be assigned.

How can I ensure my CITI training is showing up in ERMS?

- All study team members must complete CITI training.
- CITI training will only show up if you have affiliated with UT Health SA in CITI.
- Follow these instructions to update your affiliation in CITI.

How do I close a UT Health IRB study?

- Studies are closed by submitting a Continuing Review (CR).

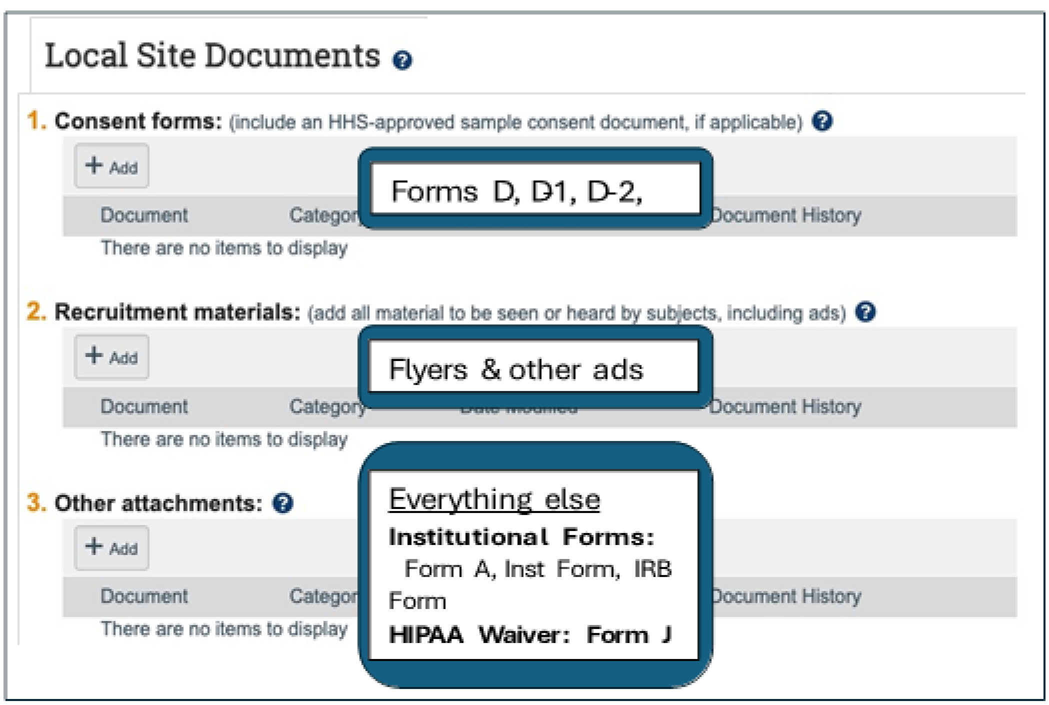
- If the top 4 items in CR smart form are checked, study will *automatically be closed*.

Where can I find more help?

- Find form templates in the Library
    - All studies (except non-regulated/non-human) require Form A & Inst Form
- Find Quick Guides in the Help Center:
    - *ERMS Overview*
    - *Updating Existing Documents*
    - *Adding Participating Sites*
    - *PI Proxy FAQ*
    - ...and many more!

Where do I upload all the Study Forms for Studies being Reviewed by UTHSA IRB?

- Upload the **Protocol *only*** under "Basic Study Information".
- Upload any Drug- or Device-related forms to the Drug/Device sections.
- All other study forms go under "Local Site Documents":



ERMS-COI Reviewer and Discloser Guides

Got a disclosure to make? Ever received an ERMS-COI notification and felt a bit lost? Here are some reasons why you get pinged:

1. You are associated with new research study.
2. Your profile is in the state of ‘Awaiting Profile Update.’
3. Your profile is in the state of ‘Action Required.’

But fret not! Check out these quick guides for handling ERMS-COI business:

For Reviewers:

1. Ancillary Review Guide for Management Plans

This guide describes how to review and approve management plans that have been sent to reviewers who have approval authority.

For Disclosers:

2. Accepting Your Management Plan

In the event of an external activity or financial interest that amounts to a conflict of interest, you will receive a formal request to review and accept a management plan. This comprehensive guide provides detailed steps to facilitate a seamless acceptance process.

3. Disclosure Submission Guide

Disclosure is mandatory for individuals engaged in the design, conduct, and reporting of research on a rolling annual. This guide outlines the necessary steps for disclosing any external activities or financial interests. Please note that you will need to address your disclosure profile even if you have nothing to report!

If you have questions about how to disclose or need to discuss a specific external activity or financial interest, we are happy to help you! Reach out to coi@uthscsa.edu

REMINDER - “Upon completion of the SmartForms the “Finish” button is clicked. You MUST then click on “Submit” for your ERMS transaction to be sent to the supporting office.”

**Note: Suggested browsers are Chrome, Firefox, or Safari 15+ to access links. If still unable to access link, verify your browser is updated and/or clear the browser cache.*