Enterprise Research Management System (ERMS) – IRB Module FAQ

Contents

What studies have been transferred into ERMS from ORCA?

- UT IRB Expedited and Full Board studies.
- External IRB studies.

Note: Non-regulated Human Research and Exempt Studies were not transferred to ERMS. A New Study submission in ERMS will be required to modify an exempt study. Documents for studies remain accessible in ORCA. Studies in ERMS should be updated during the first modification. The original protocol number should be added to the end of the "Short Title" for reference.

Where do I submit my study?

ERMS is the single entry point for all study submissions. Clinical trials and prompt reports are no longer submitted to REDCap.

Will the coverage analysis be part of the IRB application?

No. The coverage analysis will be maintained in the Clinical Trials Office.

How will the Clinical Trials Office review my application?

The Clinical Trials Office will be assigned an ancillary review in ERMS.

How do I log in to ERMS?

ERMS requires UT single sign-on. Contact IRB@uthscsa.edu or IRBReliance@uthscsa.edu if you are unable to access the system.

Do I need an Institutional Activation letter for UT Health San Antonio IRB Studies?

No. Institutional review will be conducted alongside the regulatory review, and approval will be issued in a single notification. *Note: An institutional activation letter will still be issued for external IRB studies.*

What forms do I submit in ERMS (For UT IRB and External IRB)?

- For a UT IRB Study:

Risk Based Decision Support Tool with ERMS Requirements

Non-Regulated or Not Human Subjects Research	**Exempt Determination**	**Minimal Risk Non-Experimental**	**Minimal Risk Experimental**	**Greater Than Minimal Risk**	**Investigator-Sponsor**	**Emergency Use of Investigational Agent**
IRB Office Review		**IRB Approval (Expedited or Full Board)**				IRB Notification
Examples: -Quality Improvement (QI) -Health surveillance -Program evaluation -Use of deidentified data or specimens -Use of commercially available samples or publicly available data	Examples: -Chart reviews -Observational only studies -Surveys -Comparing educational methods -Benign behavioral interventions -Research on specimens *collected for other purposes*	Examples: -Chart reviews -Observational studies with non-invasive procedures such as: -Collection of blood by venipuncture -Collection of non-invasive biological specimens -Collection of non-invasive measurements -In-vitro diagnostic testing	Examples: -Minimal risk experimental interventions and non-invasive procedures (Note: if your experimental intervention is a behavioral intervention it may qualify for an exempt determination)	Examples: -All greater than minimal risk research -Clinical trials -Any research use of invasive procedures	Examples: -FDA regulated Investigational Product clinical trials (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
	• Checklist: Minimal Risk Study Start-up			• Checklist: Greater than Minimal Risk Study Start-up • Checklist: FDA IND/IDE Study Start-up • Checklist: Sponsored Clinical Trial (CT) Start-up		• HRP-503j – Drug Emergency Use Checklist • HRP-503i – Device Emergency Use Checklist
HRP-503 Protocol Templates for ERMS IRB Submission:						
• HRP-503a – QI Project • HRP-503k – Not Regulated Human Research (other than QI)	• HRP-503b – Minimal Risk - Exempt • HRP-503f – Minimal Risk, Chart Review	• HRP-503c – Minimal Risk Study, Non-Experimental • HRP-503f – Minimal Risk, Chart Review	• HRP-503d – Minimal Risk Study, Experimental	• HRP-503 – Greater than Minimal Risk Study	• HRP-503e– Investigator IND/IDE	• HRP-503h – IRB Emergency Use Notification • HRP-503g – Emergency Use Certification
Other Required Attachments – Select "*Institutional Supplements*" as the Category: Reference the section of the protocol if applicable. **Do not copy and paste** the responses from the protocol into these forms.						

• HRP-211e – Request for Not Regulated Human Research Determination	• HRP-211a – Form A • HRP-211b – Institutional Form • HRP-211d – Request for Determination of Exempt Research	• HRP-211a – Form A • HRP-211b – Institutional Form • HRP-211c – IRB Supplemental Form If applicable: • HRP-211f – Local Repository Description	• HRP-211a – Form A • HRP-211b – Institutional Form • HRP-211c – IRB Supplemental Form If applicable: • HRP-211f – Local Repository Description	• HRP-211a – Form A • HRP-211b – Institutional Form • HRP-211c – IRB Supplemental Form	• HRP-211a – Form A • HRP-211b – Institutional Form • HRP-211c – IRB Supplemental Form	**Do not** submit Emergency Use in ERMS. Submit to IRB@uthscsa.edu.

All Documents Located in the templates tab.

- For an External IRB Study:

  - HRP-211a – Form A
  - HRP-211b – Institutional Form
  - External IRB-approved consent form
    - Incorporate HRP-901a - Local Context Information and HIPAA (using tracked changes).
      For NCI CIRB studies only, use HRP-901b – NCI CIRB Boilerplate language.
  - Protocol

Include additional forms as annotated in the Institutional Supplemental forms. All forms are in the ERMS-IRB Library under Templates.

Do not include a HIPAA waiver or HIPAA authorization unless the sIRB of record will not act as the privacy board and provide these reviews. Most IRBs will provide these reviews, including commercial IRBs such as WCG IRB and Advarra.

What changes are required for External IRB Submissions?

All changes, including sIRB approvals and approved documents, must be submitted in ERMS.

What roles do study team members have?

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		

Who receives automatic notifications and letters?

PI, PI Proxies, and POC. *Note: Study team will be notified if selected when Adding Comment.*

What roles does a guest have?

Guests may view the Protocol, its status, and all associated documents.