Enterprise Research Management System (ERMS)
BULLETIN

UT Health San Antonio

Help for Students using ERMS-IRB

Most students should have access to ERMS.

When logging in, students should use their uthscsa.edu email (without "livemail", e.g., Jane.Doe@livemail.uthscsa.edu will be Jane.Doe@uthscsa.edu).

The password will be the student's Canvas password.

When updating study personnel, if a student is not found in ERMS, contact IRBReliance@uthscsa.edu for assistance.

Updates on Participant Payments

New ClinCard payment policy: Any participants who have not provided a Taxpayer Identification Number (TIN) or SSN will automatically have 24% withheld from ClinCard payments for tax purposes. The Consent Form template, available in the ERMS-IRB Templates, has been revised to include this information.

New Participant Payment Form: A new Participant Payment Form has **replaced** the old Inst B and participant payment workbook and integrates all info into a single file. This Excel form will be available in the ERMS-IRB Library, and has a tab with instructions. VPR-CTO will continue to review participant payments, confirming payment schedules, reimbursement amounts, and personnel training through the Ancillary Review function of ERMS-IRB. The final, signed version of the form will be sent to the study team. **All changes to previously approved studies require a study modification in ERMS** – this includes changes to PID, staffing, and/or payment schedules. Questions? Contact VPRCTO@uthscsa.edu

New protocol forms in ERMS-IRB!

Visit the ERMS-IRB Help Center to view our new Color Diagram of protocol documents required (see below). This tool shows the forms required for each study type. Many forms have been updated in recent months. You can find all forms in the Templates tab of the ERMS-IRB Library.

Risk Based Decision Support Tool with ERMS Requirements

Non-human subjects or non-regulated research	**Exempt Determination**	**Minimal Risk non-experimental**	**Minimal Risk experimental**	**Greater Than Minimal Risk Review**	**Investigator-Sponsor**	**Emergency Use of Investigational Agent**
IRB Office Review		IRB Approval (Expedited or Full Board)				IRB Notification
Examples: -Quality Improvement -Health surveillanc	Examples: -Chart reviews -Observational only studies -Surveys -Comparing	Examples: -Chart reviews -Observational studies	Examples: -Minimal risk experimental interventio	Examples: -All greater than minimal risk	Examples: -FDA regulated Investigational Product	Use the below checklists to determine whether the use of the drug or device

e -Program evaluation -Use of deidentified data or specimens -Use of commercially available samples or publicly available data	educational methods -Benign behavioral interventions -Research on specimens *collected for other purposes*	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	ns and non-invasive procedures (Note: if your experimental intervention is a behavioral intervention it may qualify for an exempt determination)	research -Clinical trials -Any research use of invasive procedures	clinical trials (IND or IDE) held by local investigator	qualifies as Emergency Use
HRP-503 Protocol Templates Required for ERMS IRB Submission:						
HRP 503a Not Regulated Human Research Determination	**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-503j – Drug Emergency Use Checklist HRP-503i – Device Emergency Use Checklist **HRP-503h**– IRB Emergency Use Notification
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 in these forms.						

	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	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	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 at: UT ERMS Templates tab

What information is required in ERMS-Agreements Smart Forms?

Put simply – ALL OF IT!

You may have noticed a red asterisk (*) on certain Smart Form questions, indicating a response is required. Blank entries on required responses will prevent you from saving your work and advancing to the next step, while blanks in other responses will not. However, please do not misunderstand – *all* information contained in the Smart Forms is required!

Every Smart Form question is an essential piece of information for processing your agreement request, even though you will not see a red asterisk (*) on every question. This allows for maximum flexibility – we understand that Smart Forms might not always be completed in one sitting or might require some input from others. The Smart Forms are designed to accommodate this flexibility; however, remember that all responses are equally important, and any unanswered questions will cause delays and result in a Clarification Request, which will require your action before we can process your agreement any further.

Help us to help you – please ensure that every question is answered, every time, regardless of red asterisks. If needed, you can always save your work and return later to complete the Smart Forms. And when you have provided all responses and have clicked Finish on your SmartForms and return to the Agreement Request Workspace, *don't forget to hit Submit*!

Please contact contracts@uthscsa.edu with any questions or for assistance with the ERMS-Agreements module.

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.*