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 ********** ★**New Self-Certification Tool for Non-Regulated or Not Human Subjects Research**	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-900e – Form J – HIPAA Waiver (UT IRB)	• HRP-211a – Form A • HRP-211b – Institutional Form • HRP-211c – IRB Supplemental Form • HRP-900e – Form J – HIPAA Waiver (UT IRB) 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.