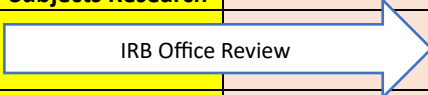
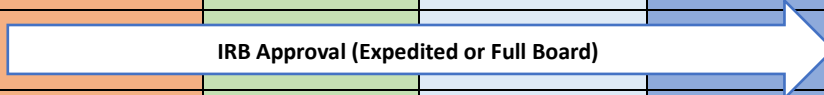
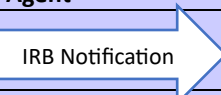


## Risk Based Decision Support Tool with ERMS Requirements

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
						
<p>Examples:</p> <ul style="list-style-type: none"> <li>-Quality Improvement (QI)</li> <li>-Health surveillance</li> <li>-Program evaluation</li> <li>-Use of deidentified data or specimens</li> <li>-Use of commercially available samples or publicly available data</li> </ul>	<p>Examples:</p> <ul style="list-style-type: none"> <li>-Chart reviews</li> <li>-Observational only studies</li> <li>-Surveys</li> <li>-Comparing educational methods</li> <li>-Benign behavioral interventions</li> <li>-Research on specimens <i>collected for other purposes</i></li> </ul>	<p>Examples:</p> <ul style="list-style-type: none"> <li>-Chart reviews</li> <li>-Observational studies with non-invasive procedures such as:                             <ul style="list-style-type: none"> <li>-Collection of blood by venipuncture</li> <li>-Collection of non-invasive biological specimens</li> <li>-Collection of non-invasive measurements</li> <li>-In-vitro diagnostic testing</li> </ul> </li> </ul>	<p>Examples:</p> <ul style="list-style-type: none"> <li>-Minimal risk experimental interventions and non-invasive procedures</li> </ul> <p>(Note: if your experimental intervention is a behavioral intervention it may qualify for an exempt determination)</p>	<p>Examples:</p> <ul style="list-style-type: none"> <li>-All greater than minimal risk research</li> <li>-Clinical trials</li> <li>-Any research use of invasive procedures</li> </ul>	<p>Examples:</p> <ul style="list-style-type: none"> <li>-FDA regulated Investigational Product clinical trials (IND or IDE) held by local investigator</li> </ul>	<p>Use the below checklists to determine whether the use of the drug or device qualifies as Emergency Use</p>
		<ul style="list-style-type: none"> <li>• <a href="#">Checklist: Minimal Risk Study Start-up</a></li> </ul>		<ul style="list-style-type: none"> <li>• <a href="#">Checklist: Greater than Minimal Risk Study Start-up</a></li> <li>• <a href="#">Checklist: FDA IND/IDE Study Start-up</a></li> <li>• <a href="#">Checklist: Sponsored Clinical Trial (CT) Start-up</a></li> </ul>		<ul style="list-style-type: none"> <li>• <a href="#">HRP-503j – Drug Emergency Use Checklist</a></li> <li>• <a href="#">HRP-503i – Device Emergency Use Checklist</a></li> </ul>
<b>HRP-503 Protocol Templates for ERMS IRB Submission:</b>						
<ul style="list-style-type: none"> <li>• <a href="#">HRP-503a – QI Project</a></li> <li>• <a href="#">HRP-503k – Not Regulated Human Research (other than QI)</a></li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-503b – Minimal Risk - Exempt</a></li> <li>• <a href="#">HRP-503f – Minimal Risk, Chart Review</a></li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-503c – Minimal Risk Study, Non-Experimental</a></li> <li>• <a href="#">HRP-503f – Minimal Risk, Chart Review</a></li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-503d – Minimal Risk Study, Experimental</a></li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-503 – Greater than Minimal Risk Study</a></li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-503e – Investigator IND/IDE</a></li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-503h – IRB Emergency Use Notification</a></li> <li>• <a href="#">HRP-503g – Emergency Use Certification</a></li> </ul>
<b>Other Required Attachments – Select “Institutional Supplements” as the Category:</b>						
Reference the section of the protocol if applicable. <b>Do not copy and paste</b> the responses from the protocol into these forms.						
<ul style="list-style-type: none"> <li>• <a href="#">HRP-211e – Request for Not Regulated Human Research Determination</a></li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-211a – Form A</a></li> <li>• <a href="#">HRP-211b – Institutional Form</a></li> <li>• <a href="#">HRP-211d – Request for Determination of Exempt Research</a></li> <li>• <a href="#">HRP-900e – Form J – HIPAA Waiver (UT IRB)</a></li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-211a – Form A</a></li> <li>• <a href="#">HRP-211b – Institutional Form</a></li> <li>• <a href="#">HRP-211c – IRB Supplemental Form</a></li> <li>• <a href="#">HRP-900e – Form J – HIPAA Waiver (UT IRB)</a></li> <li>If applicable:                             <ul style="list-style-type: none"> <li>• <a href="#">HRP-211f – Local Repository Description</a></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-211a – Form A</a></li> <li>• <a href="#">HRP-211b – Institutional Form</a></li> <li>• <a href="#">HRP-211c – IRB Supplemental Form</a></li> <li>If applicable:                             <ul style="list-style-type: none"> <li>• <a href="#">HRP-211f – Local Repository Description</a></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-211a – Form A</a></li> <li>• <a href="#">HRP-211b – Institutional Form</a></li> <li>• <a href="#">HRP-211c – IRB Supplemental Form</a></li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">HRP-211a – Form A</a></li> <li>• <a href="#">HRP-211b – Institutional Form</a></li> <li>• <a href="#">HRP-211c – IRB Supplemental Form</a></li> </ul>	<p><b>Do not</b> submit Emergency Use in ERMS.</p> <p>Submit to <a href="mailto:IRB@uthscsa.edu">IRB@uthscsa.edu</a>.</p>

All Documents Located in the [templates tab](#).