

## All Required Documents for IRB Submission

Category	Required For	Details
<b>IRB Application Form</b> <i>(also called "IRB Protocol")</i>	All studies	<ul style="list-style-type: none"> <li>- All new UTA Human Subjects Research studies are required to include the appropriate version of the IRB Application Form. There are two versions: <ol style="list-style-type: none"> <li>1. <a href="#">Initial IRB Application for Primary Research Studies</a></li> <li>2. <a href="#">Initial IRB Application for Secondary Research ONLY</a></li> </ol> </li> <li>- Complete only <b>one</b> version of the IRB Application &amp; upload in <a href="#">electronic system</a></li> </ul>
<b>Informed Consent Document(s)</b>	All studies where it is possible for researchers to obtain consent from adult subjects	<ul style="list-style-type: none"> <li>- Consent Templates are available on <a href="#">IRB Forms &amp; Templates Page</a></li> <li>- Keep all consents clear, concise, &amp; as close as possible to an <b>8<sup>th</sup> grade reading level</b></li> <li>- Include all the information that a reasonable person would want to know about the study before they make a decision about whether or not to participate</li> <li>- If needed, create multiple consent versions for different groups of participants for clarity</li> <li>- When applicable, submit both English and translated versions of consents for non-English fluent</li> </ul>
<b>Informed Assent Document(s)</b>	All studies involving minors (children) where it is possible to obtain assent from the child; also applies when a legal guardian must provide consent for an adult	<ul style="list-style-type: none"> <li>- Template for <a href="#">Parental Consent &amp; Child Assent</a> is available on Forms &amp; Templates Page</li> <li>- If a child is developmentally not able to provide valid assent, explain this in the IRB Application Form and describe how the researchers will honor the child's behavior and cues indicating that they do not wish to participate</li> <li>- For adults that cannot provide consent for themselves, an assent should be provided in appropriate language for the potential subject's level of understanding; consent must also be obtained from the subject's Legally Authorized Representative (LAR)</li> </ul>
<b>Request for Waiver or Alteration of Consent</b>	Studies that involve deception or incomplete disclosure; federally funded studies where a signed consent will not be obtained	<ul style="list-style-type: none"> <li>- Complete &amp; upload <a href="#">Form 3, Request for Waiver or Alteration of Consent</a></li> </ul>
<b>Recruitment Materials</b>	All studies where the research team will request participation in the study from potential subjects	<ul style="list-style-type: none"> <li>- Often includes multiple methods, such as posted flyers, emails, and visiting classrooms to read a verbal script; describe all methods in IRB application form</li> <li>- Upload copies of all recruitment flyers, emails, online postings, ads, verbal scripts, etc</li> </ul>
<b>Data Collection &amp; Screening Instruments</b>	All studies	<ul style="list-style-type: none"> <li>- Upload instruments, questionnaires, or tools for screening subjects</li> <li>- Upload all instruments/tools utilized for collecting subject data, such as surveys, questionnaires, interview questions, focus group questions, tests, cognitive tasks, score sheets, game instructions, computerized assessments, etc.</li> </ul>

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<b>Vulnerable or Special Population Forms</b>	As Applicable	<ul style="list-style-type: none"> <li>- <a href="#">Mentally Incapacitated</a></li> <li>- <a href="#">Pregnant Women</a></li> <li>- <a href="#">Prisoners</a></li> <li>- <a href="#">Children</a></li> </ul>
<b>Site Permission Letters</b>	As Applicable	<ul style="list-style-type: none"> <li>- Documented approval from a site to use their facility for research purposes, if the facility is privately owned (school, private business, clinic, church)</li> <li>- Documented approval if permission is needed to recruit subjects (for example, approval from clinic to recruit patients or approval from ISD if conducting research procedures in a school)</li> </ul>
<b>Medical Devices</b>	All studies which will use a device to collect data or perform an intervention on human subjects	<ul style="list-style-type: none"> <li>- Form 4 for <a href="#">Medical Devices</a></li> <li>- Device Manual or specs</li> <li>- FDA IDE if applicable</li> <li>- 510(k) clearance letter from FDA or other documentation of FDA status</li> <li>- Lab-related SOPs for using the device</li> </ul>
<b>Drugs; Supplements; Food; Chemicals</b>	As Applicable	<ul style="list-style-type: none"> <li>- Safety information, manufacturer, drug label/package insert, Investigator's Brochure</li> <li>- FDA IND if applicable</li> <li>- Lab-related SOPs for using the drug(s), supplement(s), food, or chemical(s)</li> <li>- Form 5 for Drugs, Food, or Dietary Supplements</li> </ul>
<b>Grant Application or Contract</b>	Funded Projects	<ul style="list-style-type: none"> <li>- Documentation of any requested changes to the human subjects research plan from the study sponsor</li> </ul>
<b>Formal Agreements</b>	Collaborations, Data Transfer Projects, etc.	<ul style="list-style-type: none"> <li>- MOUs</li> <li>- Data Use Agreements (DUA)</li> <li>- Collaborating site IRB documents</li> </ul>
<b>Data Safety Monitoring Plan</b>	Funded Projects, if required by sponsor; FDA-Regulated Research & Clinical Trials	<ul style="list-style-type: none"> <li>Plan templates and guidance found at these links: Pages 2-3 <a href="#">here</a></li> <li>- "Implementation" section, including checklist <a href="#">here</a></li> <li>- Examples available <a href="#">here</a></li> </ul>
<b>Non-UTA Collaborator information</b>	Studies that involve Non-UTA study personnel	<ul style="list-style-type: none"> <li>- Completed Non-UTA Collaborator form</li> <li>- Human Subject Protection training documentation for Non-UTA collaborators</li> <li>- Additional Potential Training documentation, please see training information here: <a href="https://resources.uta.edu/research/regulatory-services/human-subjects/guidance-for-researchers/landing-page.php">https://resources.uta.edu/research/regulatory-services/human-subjects/guidance-for-researchers/landing-page.php</a></li> </ul>

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<b>Approval for Use of Platforms/Apps not Pre-Approved by UTA</b>	As applicable	-All electronic data must be maintained on UTA-sanctioned data collection and storage tools. Data collection via surveys should utilize QuestionPro (UTA's preferred vendor). Utilizing a product outside of the UTA-sanctioned tools would require an <a href="#">Information Security Office (ISO) Risk Assessment</a> .
<b>Supplemental Information</b>	As Needed for IRB review	<ul style="list-style-type: none"> <li>- SOPs that relate to subject interaction or safety (lab instructions for blood draws, safety/emergency response plans, etc.)</li> <li>- References/literature that pertain to your study topic or provide evidence of safety for human subjects in previous studies</li> <li>- CVs or resumes of research personnel for documentation of qualifications/expertise</li> <li>- Copy of grant application or contract</li> </ul>