All Required Documents for IRB Submission

Category	Required For	Details
IRB Application Form (*also called "IRB Protocol"*)	All studies	- All new UTA Human Subjects Research studies are required to include the appropriate version of the IRB Application Form. There are two versions: 1. Initial IRB Application for Primary Research Studies 2. Initial IRB Application for Secondary Research ONLY - Complete only **one** version of the IRB Application & upload in electronic system
Informed Consent Document(s)	All studies where it is possible for researchers to obtain consent from adult subjects	- Consent Templates are available on IRB Forms & Templates Page - Keep all consents clear, concise, & as close as possible to an **8th grade reading level** - 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 - If needed, create multiple consent versions for different groups of participants for clarity - Submit both English and translated versions of consents for non-English fluent subjects
Informed Assent Document(s)	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	- Template for Parental Consent & Child Assent is available on Forms & Templates Page - If a child is under age 3 or 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 - 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)
Request for Waiver or Alteration of Consent	Studies that involve deception or incomplete disclosure; federally funded studies where a signed consent will not be obtained	- Complete & upload Form 3, Request for Waiver or Alteration of Consent
Recruitment Materials	All studies where the research team will request participation in the study from potential subjects	- Often includes multiple methods, such as posted flyers, emails, and visiting classrooms to read a verbal script; describe all methods in IRB application form - Upload copies of all recruitment flyers, emails, online postings, ads, verbal scripts, etc. - We do not provide templates; however, for guidance on how to create IRB approvedrecruitment materials, please visit this link from Northwestern University
Data Collection & Screening Instruments	All studies	- Upload instruments, questionnaires, or tools for screening subjects - 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.

All Required Documents for IRB Submission

Vulnerable Population Forms	As Applicable	- Mentally Incapacitated - Pregnant Women - Prisoners - Children
Site Permission Letters	As Applicable	- Documented approval from a site to use their facility for research purposes, if the facility is privately owned (school, private business, clinic, church) - 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 high school)
Medical Devices	All studies which will use a device to collect data or perform an intervention on human subjects	- Form 4 for Medical Devices - Device Manual or specs - FDA IDE if applicable - 510(k) clearance letter from FDA or other documentation of FDA status - Lab-related SOPs for using the device
Drugs/Chemicals	As Applicable	- Safety information, manufacturer, drug label/package insert, Investigator's Brochure if available - FDA IND if applicable - Lab-related SOPs for using the drug(s)
Grant Application or Contract	Funded Projects	- Copy of the grant application or contract - Documentation of any requested changes to the human subjects research plan from the study sponsor
Formal Agreements	Collaborations, Data Transfer Projects, etc.	- MOUs - Data Use Agreements (DUA) - Collaborating site IRB documents
Data Safety Monitoring Plan	Funded Projects, if required by sponsor; FDA-Regulated Research & Clinical Trials	Plan templates and guidance found at these links: - Pages 2-3 here - "Implementation" section, including checklist here - Examples available here
Supplemental Information	As Needed for IRB review	- SOPs that relate to subject interaction or safety (lab instructions for blood draws, safety/emergency response plans, etc.) - References/literature that pertain to your study topic or provide evidence of safety for human subjects in previous studies - CVs or resumes of research personnel for documentation of qualifications/expertise