All Required Documents for IRB Submission

Category	Required For	Details
IRB Application Form (*also called "IRB Protocol")*	All studies	- IRB Protocol Applications are available on IRB Forms & Templates Page - 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 to Mentis
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 thestudy before they make a decision about whether or not to participate - If needed, create multiple consent versions for different groups of participants forclarity - 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 IRB 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'sbehavior and cues indicating that they do not wish to participate - For adults that cannot provide consent for themselves, an assent should be provided inappropriate 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. This form can be found on our IRB Forms & Templates Page.
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.

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Approval for Use of Platforms/Apps not Pre-Approved by UTA	As Applicable	- All electronic data must be maintained on UTA-sanctioned storage tools and data collection via surveys should utilize QuestionPro (UTA's preferred vendor). Utilizing a product outside of the UTA-sanctioned storage tools and QuestionPro would require exceptions by the Office of Information Security (OIT) and Information Security Office (ISO). - Technology Acquisition Helper: https://webapp.uta.edu/tap - TAPREQ Form – https://go.uta.edu/tapreqform - ISO Risk Assessment Form: https://go.uta.edu/isoappassessment
Vulnerable Population Forms	As Applicable	- Mentally Incapacitated - Pregnant Women - Prisoners - Children - All versions of the forms can be found on our IRB Forms & Templates Page
Site Permission Letters	As Applicable	- Documented approval from a site to use their facility for research purposes, if thefacility 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 from our IRB Forms & Templates Page - 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	- Form 5 for Drugs, Food, Dietary Supplements from our IRB Forms & Templates Page - Safety information, manufacturer, drug label/package insert, Investigator's Brochure ifavailable - 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 thestudy sponsor
Formal Agreements	Collaborations, Data Transfer Projects, etc.	- MOUs - Data Use Agreements (DUA) - Collaborating site IRB documents (IRB Approval Letter from IRB of Record and IRB Protocol Application. Additional Documentation may be requested).
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

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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 safetyfor human subjects in previous studies - CVs or resumes of research personnel for documentation of qualifications/expertise