UTA Faculty, staff, or students who propose to engage in any research, research development, testing or evaluation with human subjects must have review and approval from the UTA IRB prior to initiation. Some activities involving humans are not considered human subject research requiring IRB review (i.e., class projects, program evaluation, oral histories, quality improvement). Refer to the [**Research Project Chart**](https://resources.uta.edu/research/_documents/rs_documents/UltimateChart%20v%200321.pdf) for more information.

**\*\***Utilize the [**Required IRB Documents Chart**](https://resources.uta.edu/research/_documents/rs_documents/IRB%20Forms%20and%20Templates/All%20Required%20Documents%20Chart.pdf)to guide you through the full IRB application process. **All study personnel must have completed** [**Human Subjects Protection (HSP) Training**](https://ra.uta.edu/ra/real/) **prior to study approval. HSP Training expires and must be retaken every 3 years.\*\***

If you require assistance to complete this form or need additional information, please contact Regulatory Services at 817-272-3723 or regulatoryservices@uta.edu.

**This version of the IRB Application Form should be used for ALL studies that will involve “primary research” with human subjects, defined as: the collection of new information or biospecimens from human subjects for research purposes by way of: 1)** **interaction with the individual, which includes any form of communication or interpersonal contact between the investigator(s) and the subject; and/or 2) intervention with the individual, which includes both physical procedures by which information or biological samples are gathered (like blood draws) and manipulations of the subject or the subject’s environment for the research.**

**IMPORTANT: Studies that will involve only secondary research use of private identifiable information or identifiable biospecimens that have been (or will be) collected or generated for purposes other than the present research study should instead complete the** [**UTA IRB Application for Secondary Research**](https://resources.uta.edu/research/regulatory-services/human-subjects/irb-forms-and-templates.php)**.**

SECTION A: GENERAL INFORMATION

1. **Non-UTA Personnel:** *Enter all individuals that are* ***NOT affiliated with UTA*** *who will interact or intervene with human subjects for the research study OR who will access identifiable subject data.* ***UTA-affiliated*** *personnel should be listed on the electronic portion of the protocol (#3) in the electronic submission system.*

***\*Note:*** *In the electronic submission system, upload a completed* [*Non-UTA Collaborator Form*](https://resources.uta.edu/research/regulatory-services/human-subjects/irb-forms-and-templates.php) *and Human Subject Protection training for each listed Non-UTA individual.*

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| **Name:** | **Organization:** |
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1. **Expected Start Date and Completion Date:**      *(You are not authorized to start any research on human subjects including subject recruitment until the IRB has approved the research protocol.)*
2. **Funding:** *Indicate existing, potential, or pending sources of funding below (you may select more than one).*

**\*Note: If you do (or may) receive funding from NSF, NIH, CMMS, DOD, DOJ, DOE, DOEd, DOT, or any other federal agency, you MUST disclose this funding source below to ensure that your study is reviewed in accordance with the appropriate federal regulations for that specific federal funding source.**

 **External:****[ ]  Federal (Sponsor:**     **) [ ]  State (Sponsor:**     **)** **[ ]  Industry (Specify Sponsor:**      **)

Grants & Contracts Bluesheet Number from** [**Mentis**](https://mentis.uta.edu/public/#grantmanagement/index/index)**:**       **Other:

[ ]  UTA Department Account [ ]  Personal Funds [ ]  Other:**       **[ ]  None (*No funding*)**

SECTION B: RESEARCH CLASSIFICATION, RATIONALE, PROCEDURES, SITES, QUALIFICATIONS, OVERSIGHT

1. **Research Classification:** *Indicate if this study is categorized as* ***Minimal Risk (MR)*** *or* ***Greater than Minimal Risk (GMR).*** *“Minimal Risk (MR)” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the subjects’ daily life or during the performance of routine physical or psychological examinations or tests. “Greater than Minimal Risk (GMR)” refers to research activities that do not meet the definition of “Minimal Risk.” Throughout this application form, there are additional questions or information requested for studies categorized as GMR; these instructions will be presented in purple.*

**[ ]  Minimal Risk (MR) [ ]  Greater than Minimal Risk (GMR)**

 ***\*Note:*** *Studies that are federally funded and/or FDA regulated will be further classified into exempt, expedited, or full board in accordance with the* [*Common Rule 45 CFR 46*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) *and/or* [*21 CFR parts 50*](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50)*and*[*56*](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56?toc=1)*. See*[***Flowchart***](https://resources.uta.edu/research/_documents/rs_documents/IRB%20Flex%20Flowchart%20August%202020.pdf)***.***

1. **Rationale:** *List the primary research questions, hypotheses, and / or objectives guiding this study.*

1. **Procedures:** *Describe the procedures step-by-step, including details on all methods that will be used to collect human subject data from the beginning to the end of the study. Describe what data will be collected (and if it will be individually identifiable); when and where the data will be collected; and how it will be collected (instruments or other measures). Use clear, concise layman’s language that can be easily understood by persons outside your field and provide definitions for any technical terms. Add pictures if needed. If applicable, description and source of secondary research use of information and/or specimens.* ***\*Note: Refer to the*** [***Types of Research guidance page***](https://resources.uta.edu/research/regulatory-services/human-subjects/guidance-for-researchers/types-of-research.php) ***for a list of specific information required for different types of research.*** *For GMR research, it is also helpful to provide references or pilot data to support the proposed procedures.*

1. **Duration:** *Indicate how many participation sessions, interactions, or follow ups are expected for each subject participant, including the amount of time required for each visit and how long their total participation is expected to take (weeks, months, years, etc.) over the entire duration of the study. Please ensure that the duration described here is consistent with procedures and time-frames described elsewhere in the protocol application.*

1. **Alternatives to Participation:** *Describe subjects’ available options if they choose not to participate in the research study and clarify whether individuals that decline participation will still be subjected to the intervention (even if their data will not be utilized for research purposes). If research involves students, describe their alternatives to obtain course / extra credit if applicable. If research involves a health intervention, clarify whether individuals that decline will continue to receive standard care.*

1. **Location(s) and Site(s):** *Specify all locations where research procedures are expected to take place and which study procedures will take place at each site. Studies that take place online should specify the websites where data will be collected. Describe if any of the research will take place internationally. For multi-site research studies, review the web page for* [*Collaborative Research*](https://resources.uta.edu/research/regulatory-services/human-subjects/guidance-for-researchers/multi-site-research.php)*. If any part of this study will be conducted in an institution or location administratively separate from UTA, indicate the institution(s) and upload a site permission letter.*

1. Personnel Qualifications: *List each member of the research team/personnel in the table below and describe 1) their role in the study, and 2) their relevant qualifications, special training, and experience as it pertains to the specific procedures or population of the study. If personnel will receive special training for conducting this study, please describe.  If one or more personnel do not have any relevant qualifications or experience, please state that; the IRB will consider the risk level of the study and evaluate if additional oversight or input is necessary.*

|  |  |  |
| --- | --- | --- |
| Name of Research Personnel | Role in the study | Relevant qualifications, special training, and experience |
|  |  |  |
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1. Study Oversight: *The Principal Investigator has ultimate responsibility for the conduct of this research, protection of subjects, and supervision of all protocol personnel. Describe your plan for oversight and communication to ensure that the entire research team: conducts the research ethically and in accordance with the approved protocol, creates/maintains appropriate study documentation and research records, and protects confidentiality of data. Your plan should address how the* [*PI responsibilities*](https://resources.uta.edu/research/regulatory-services/human-subjects/principal-investigator-responsibilities.php) *are met. If a Faculty Advisor is overseeing student PI human subject research, the plan should address how the* [*Faculty Advisor responsibilities*](https://resources.uta.edu/research/regulatory-services/human-subjects/faculty-advisor-responsibilities%20.php) *are met.*

SECTION C: POPULATION & ENROLLMENT

1. **Population(s):** *Describe the target population(s) of the study, for example: UTA students, competent or healthy adults, children, prisoners, non-English speaking, pregnant women, individuals with impaired decision-making capacity, other vulnerable populations.*

***\*Note: Additional forms may be required for your population. Obtain these from the*** [***Forms & Templates Page***](https://resources.uta.edu/research/regulatory-services/human-subjects/irb-forms-and-templates.php)***.****For Individuals with Impaired Decision-Making Capacity: Upload Form 2A.
For Pregnant Women, Fetuses, Women Undergoing In-Vitro Fertilization, or newborns: Upload Form 2B.*

*For Prisoners (Individuals involuntarily detained): Upload Form 2C.*

*For Children (Under 18 or the local legal adult age): Upload Form 2D.*

1. **Inclusion Criteria:** *List all criteria for including subjects and explain the methods you will use to determine whether a subject is eligible based on your criteria (i.e., pre-screen, medical chart review). If your study is/will be funded, ensure that the inclusion criteria listed here match the details in your proposal.*

1. **Exclusion Criteria:** *Explain any specific factors or contraindications that would make a subject
ineligible to participate in this study, even if they would otherwise meet the inclusion criteria listed above. Describe how the exclusion criteria will be verified. If your study is/will be funded, ensure that the exclusion criteria listed here match the details in your proposal.*

1. **Number of Subjects:** *Provide the number of subjects (or subject records/data sets) you intend to enroll over the course of the study. This information will be utilized by the IRB to understand the scope and logistics of the study; you may provide a projected range. For secondary research, please describe the number of records to be accessed.*

***\*Note:*** *For MR research, after the protocol is approved, enrollment can exceed the number provided here without submitting a modification to the protocol.*

*For GMR research, the proposed number of subjects must be supported by statistical justification and/or references; please provide that information here. Enrollment for GMR research is capped (IRB will approve a specific range or maximum number of participants and enrollment must not exceed that approved number unless the IRB approves a modification request).*

1. **Recruitment Strategies:** *The first contact with a research participant is considered the beginning of research procedures, therefore describe how you will identify and contact potential participants, and how you will obtain their contact information. List who will provide access to contact information. Upload permission letters/emails as needed from individuals or organizations providing access to private contact information. Describe all your recruitment sources and methods.*

**16.a. Recruitment language and/or materials:** *Provide the planned wording or language used in recruitment materials or scripts. Alternatively*,*upload a copy of all planned recruitment materials in the protocol submission. Examples include: letters/emails; website/social media posts; printed flyers; telephone scripts; subject pool posts (SONA, Mechanical Turk, Research Match); scripts for recruitment in-person.*

 **SECTION D: INFORMED CONSENT**

***\*Note:*** *The ethical foundation of human subject research is informed consent. It is important to ensure that subjects are provided with sufficient information to understand the requirements of their participation and the use/purpose of their data. You also cannot obtain information about a person through another individual (such as a family member) unless that person has undergone the informed consent process themselves. Use the Office of Human Research Protection (OHRP) informed consent checklist (*[*http://www.hhs.gov/ohrp/policy/consentckls.html*](http://www.hhs.gov/ohrp/policy/consentckls.html)*) and the IRB’s* [*Templates*](https://resources.uta.edu/research/regulatory-services/human-subjects/irb-forms-and-templates.php) *as guidance.*

1. **Informed Consent, Broad Consent, & Assent:** *Describe the informed consent process, including when, where, and how subjects will be consented. If children or mentally disabled or incapacitated persons will be subjects, explain the assent process. If broad consent (consent to use data for future studies) will be requested, describe the scope and the process for tracking subjects’ accept/decline responses. Upload finalized copies of all consent, assent, and / or verbal consent script documents in the electronic system. If applicable, please address informed consent for any secondary research.* ***There are several consent form templates available for your use on the*** [***Forms & Templates Page***](https://resources.uta.edu/research/regulatory-services/human-subjects/irb-forms-and-templates.php)***.***

**17a. Requesting a Waiver of Consent or Waiver of Written Documentation:** *If you wish to waive some or all of the requirements of informed consent, or the requirement for written/signed informed consent, please describe (if your study is federally funded or FDA-regulated, also upload Form 3 from the* [*Forms Page*](https://resources.uta.edu/research/regulatory-services/human-subjects/irb-forms-and-templates.php)*).*

1. **Incomplete Disclosure / Deception:** *Describe if your study will withhold information (incomplete disclosure) from subjects or involve deception regarding the purpose of the research or the nature of the intervention, interaction, or procedures. Provide scientific justification for utilizing incomplete disclosure or deception (if your study is federally funded, also upload* [*Form 3*](https://resources.uta.edu/research/regulatory-services/human-subjects/irb-forms-and-templates.php)*.*

***\*Note:*** *“Incomplete disclosure” occurs when an investigator withholds information about the specific purpose, nature, or other aspect of the research.* “*Deception” occurs when an investigator gives false information to subjects or intentionally misleads them about some key aspect of the research.*

**SECTION E: COMPENSATION AND COSTS**

***\*Note:*** *You are responsible for maintaining accurate and confidential records regarding payment of your subjects. Per* [*Accounting Services procedures*](https://policy.uta.edu/doctract/documentportal/08D8956399B2E58738F673ABE2C9EC6B)*, compensation must be documented for tax purposes using a W-9 form unless an exception is granted by the Accounting department. Obtaining an exception should be considered for cases of sensitive research or when disclosure of a subject’s identity would expose them to high risk. Exception requests are submitted through the* [*Business Affairs Exceptions Tracker (BAET)*](https://mavsuta.sharepoint.com/sites/forms/baet/SitePages/Home.aspx) *in SharePoint. Contact Business Technology Services at 817-272-2155.*

1. **Compensation:** *Describe any compensation to subjects for participation, including monetary payments, gift cards, course/extra credit, raffle prizes, goods or services, donations to charity, etc. Describe how and when you will provide the payment to the subjects, and how confidentiality will be maintained (for example, use of coding in payment logbooks/receipts). The IRB must understand how, when, and in what form you will be providing compensation. If compensation is pro-rated, please describe the pro-rate time points. If it’s possible that a participant may be timed out, describe how this impacts compensation, if any. If you intend to hold a raffle, explain when you expect that the raffle will be drawn, and how participants will be contacted if they win the drawing. For course / extra credit, alternative non-research assignments must be offered for an equal amount of credit.*

1. **Costs:** *Describe any costs or expenses (monetary or non-monetary) subjects will incur as a result of participation.*

SECTION F: RISKS & BENEFITS

1. **Risks to Subjects:** *Explain any potential risks to subjects that could result from the research intervention/procedures, including* ***physical risks*** *(i.e. fainting, falls, infections, muscle soreness, pain, broken bones, physical fatigue, headache, burns, medication side effects);* ***psychological risks*** *(i.e. depression, anger, stress, guilt, embarrassment, damage to self-esteem);* ***social risks*** *(i.e. potential damage to financial standing, reputation, or employability);* ***risks to privacy or confidentiality*** *(i.e. exposing someone as a research subject, release or breach of sensitive data); and/or* ***risk of perceived coercion/undue influence*** *(i.e. if investigator could have influence by nature of their relationship or status, such as a teacher & student, manager & employee, doctor & patient).*
2. **Strategies to Minimize Risks:** *Explain the strategies that the research team will use to minimize each potential risk listed above.*

1. **Health & Safety Considerations:** *Specify whether the study involves any hazardous materials, locations, or equipment that is relevant to the health and safety of either the subjects or the protocol personnel (i.e. handling of human blood/body fluid/tissue, chemical or biological hazards, radiation/X-rays, lasers, or carcinogens). List any related authorizations/approvals from the Environmental Health & Safety Office.*

1. **Benefits:** *List potential benefits that may accrue directly to the study subjects as a result of their participation, if any (other than compensation). Also describe the expected or potential benefits of this study to the field or society at large.*

SECTION G: PRIVACY & CONFIDENTIALITY

1. **Privacy:** *How will the privacy of subjects be protected during the course of the study (privacy refers to controlling the environment and circumstances of interactions with subjects to prevent situations where they might be embarrassed, exposed, or stigmatized)?*

1. **Confidentiality & Data Security**

**26a. Confidentiality:** E*xplain if the data collected (including biospecimens) will be anonymous, identifiable/coded, or de-identified****\*****. Explain the precautions that will be taken to protect confidentiality of subject data and information, and how these precautions will be communicated to subjects (during informed consent or another process).* ***NIH Studies****:*[Certificates of Confidentiality (CoCs)](https://grants.nih.gov/policy/humansubjects/coc/NIH-funded-Research.htm) *are automatically deemed to be issued for research that collects or uses* [identifiable, sensitive information](https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=42-USC-441187688-1662214233&term_occur=999&term_src=title:42:chapter:6A:subchapter:II:part:A:section:241)*. The informed consent template contains wording to inform research participants of this protection. If your study is subject to the* [*NIH Data Management and Sharing (DMS) Policy*](https://resources.uta.edu/research/regulatory-services/human-subjects/guidance-for-researchers/index.php)*, please be sure that the data types and controls defined in the approved plan are listed here.*

***\*Note:*** *“Anonymous” means that the data is unidentifiable (personally identifiable information will not be collected or accessed). “Identifiable” means that data obtained will be recorded in such a manner that subjects’ identity can be readily ascertained, either directly or indirectly through identifiers linked to the subjects (research involving a coding mechanism that links to identifiable data is considered identifiable, but it is a helpful measure to protect confidentiality). “De-identified” means that all direct personal identifiers are permanently removed, no code or key exists to link the data to its original source, and the remaining information cannot reasonably be used by anyone to identify the source.*

***26b. Data Security:*** *Security should be considered for each phase of data’s life cycle, including collection, transmission, accessing, collaboration, storage, analysis, reporting, and disposition. Consider the tools and resources that will be utilized for data collection, how access to identifiable data will be limited only to authorized research personnel, and who will be responsible for storage and disposition.****Recordkeeping:*** *UTA and the IRB must be able to access research records and consent forms at any time; therefore,* ***all paper documents in their original form must be stored on the UTA campus*** *unless the IRB grants an exception.* ***All electronic data must be maintained on UTA servers utilizing*** [***sanctioned storage tools***](https://www.uta.edu/security/policies/procedure.php) *unless the Office of Information Security grants an exception through the* [*Technology Approval Process (TAP*](https://www.uta.edu/accessibility/eir/resources/faculty-staff/tapreq)*). Technology resources include software (both on your desktop and online), Software as a Service (SaaS) resources, apps, and related vendor services. Examples include project management software, simulation software, online criminal background check services, social media account management services, ticket sales services, mass email services, and online/electronic marketing services.* ***Record Retention Period:*** *All records (paper or electronic) must be maintained and kept secure for at least 3 years after the closure of the protocol or in accordance with funding agency requirements (whichever is longer). Student PIs should address long-term storage arrangements if planning to leave UTA prior to the end of the retention period.*

**Visit the** [**UTA IRB’s Web Page on Human Subjects Data Security**](https://resources.uta.edu/research/regulatory-services/human-subjects/human-subjects-data-security.php) **for allowable data storage options and more helpful information about DO’s and DON’Ts with human subject data!**

**26c. Legal Limits to Confidentiality:** *If any part of this study could result in the potential identification of child abuse, elderly abuse, communicable diseases, or criminal activities that would / could not have been otherwise identified, explain this possibility and estimate the likelihood of disclosure. Describe the plan of action that you will take if this occurs. In rare circumstances when research reveals these issues, confidentiality should be maintained to the extent that the law allows.*

1. **Data Sharing:** *If you intend to share, release, or present any identifiable subject data from this study, explain where, when, and to whom the identifiable information will be shared, presented or released, and how this will be communicated to the subjects beforehand.* ***NIH Studies****: If your study is subject to the* [*NIH Data Management and Sharing (DMS) Policy,*](https://resources.uta.edu/research/regulatory-services/human-subjects/guidance-for-researchers/index.php) *please be sure that the controls defined in the approved plan are listed here if the plan includes the sharing of identifiable data or de-identified data with controlled access.*

**SECTION H: CONFLICT OF INTEREST**

1. **Conflicts of Interest (COI):** *Does the principal investigator or any protocol personnel (internal and external) have an affiliation, arrangement, or financial interest that could be perceived as a conflict of interest*? *If yes, please describe. If the principal investigator or any protocol personnel (internal and external) have an active research conflict of interest management plan, please describe if the COI may be perceived as related to the research and provide a copy of the management plan.*

***\*Note****: “****Financial Interest”*** *is defined as anything of monetary value (existing or potential), whether or not the value is readily ascertainable. “****Conflict of Interest”*** *is defined as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.*

***\*Note:*** *All Covered Individuals in GMR research are required to have a current COI disclosure on file in* [*Mentis*](https://mentis.uta.edu/public/#coi/disclosure/my) *(this must be complete prior to approval of the protocol). Covered Individuals are those with responsibilities for the conduct, design, or reporting of this research study.*

**SECTION I: REQUIRED ADDITIONAL ATTACHMENTS**

1. **Upload finalized versions of the following documents as applicable to your study in the electronic submission system***:*
* Survey instruments / questionnaires (and any versions translated into other languages)
* Demographics surveys
* Interview questions / prompts
* Focus group instructions / questions / prompts
* Observation data collection sheets
* Psychological & educational tests
* Educational materials
* All recruitment materials including flyers, ads, scripts, emails, social media posts, etc.
* Informed Consent Documents / cover letters and translated versions (See [Forms Page](https://resources.uta.edu/research/regulatory-services/human-subjects/irb-forms-and-templates.php) for Templates)
* Permission letters from non-UTA study sites / collaborating organizations
* Signed Non-UTA Collaborator Forms & HSP Training ([Collaborative Research Page](https://resources.uta.edu/research/regulatory-services/human-subjects/guidance-for-researchers/multi-site-research.php)).
* Technology Approval Process Request Approval(s)