

Cayuse IRB Initial Submission Guide*

Tips to get you started:

- Plan in advanced to allow enough time for submission, review and approval of your study.
- If you are a new user, please complete the [Cayuse Access Request](#).
- Reference the UNT IRB [website](#) for Cayuse user guidance.
- To begin submission, [Log in to Cayuse IRB](#).
- Mozilla Firefox Brower is the preferred browser for Cayuse users.
- Email CayuseAccess@unt.edu for any questions regarding Cayuse access.
- Email untirb@unt.edu with any questions regarding protocol submission.

Directions: Below, is a listing of all the questions in the initial IRB Cayuse application. Please follow the question directions as they appear in Cayuse (shown in the left column of this document). On the right column, you will find tips and tricks to walk you through the application process.

* This is a general guidance document that pertains to a majority of research activity. However, each study will require unique items, some of which may not be included in the guidance below. If you have questions, please reach out via untirb@unt.edu and we are happy to discuss the specifics of your study with you.

Core Info- Funding, Review Category

<p>In what general discipline(s) is your proposed research with human subjects?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biological or clinical science (biomedical), e.g., nutrition and kinesiology. <input type="checkbox"/> Socialscience, behavioral science, or education (SBER), e.g., consumer preference and psychology. <input type="checkbox"/> Other 	
<p>What kind of funding or support do you have for this study with human subjects? <i>For any internal or external funding, please submit the statement of work or a project summary and provide the Proposal Number or Project ID Number for any external funding or the account number for any internal funding for this project.</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Federal such as NSF, NIH, DoD, DoE, DoEd, etc. <input type="checkbox"/> UNT program such as _____, Trio, Office of Research and Innovation, etc. <input type="checkbox"/> Other type, such as private sources. <input type="checkbox"/> None 	<p>Some funding agencies require additional training. View training requirements here: https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/training-and-education</p>
<p>Are you collaborating with another group such as a school, community association, government agency, etc.?</p> <p>Is IRB approval necessary, or being obtained elsewhere (domestically or internationally?)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Yes 	<p>If yes, please attach an approval letter from the collaborating group.</p>

<input type="checkbox"/> No	
<p>Under which IRB review category would you consider that your study will fall?</p> <input type="checkbox"/> Exempt	<p>*The IRB will make the final determination</p> <p><u>Exempt:</u></p> <ul style="list-style-type: none"> • Research using existing data or samples • Observation of public behavior • Research involving surveys or questionnaires where no personally identifying information is gathered or retained • Eligibility for exemption must be determined by the IRB, not the investigator <p><u>Expedited:</u></p> <ul style="list-style-type: none"> • Poses no more than minimal risk to the subject, i.e., no more than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" • Approvable by review of one member of the Board • Doesn't necessarily mean quick or fast review <p><u>Full board</u></p> <ul style="list-style-type: none"> • More than minimal risk studies • Research that involves vulnerable populations • Research that is neither exempt nor expedited must receive review by the full committee • Means a convened meeting of the IRB for face-to-face discussion
<input type="checkbox"/> Expedited or Full Board (Category will be determined by the IRB)	

Personnel-Pis, Status, Training, Facilitator

<p>Identify your status as it applies to this IRB protocol. <i>In order to serve as Principal (Lead) Investigator, you must be a full-time UNT faculty member or a full-time staff employee whose job responsibilities include conducting human subjects research. The IRB application must be submitted by the lead PI/supervising investigator (in the case of student projects).</i></p> <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Unaffiliated Researcher	<p>Full-time faculty can serve as lead PI of your study for the IRB purposes. Adjuncts or lecturers must either submit a letter from the Department Chair acknowledging their approval for the research submission. a</p> <p>Unaffiliated Researcher: Any researcher who is not (1) a student, (2) a faculty member, or (3) a staff member at University of North Texas. Individuals may collaborate with members of the UNT faculty and staff to conduct investigations of mutual interest.</p>
<p><u>Principal Investigator (PI):</u> Unless there is someone designated for this purpose within your research group, enter yourself with the <i>FIND PEOPLE</i> button.</p>	<p>Must be full-time faculty member who is PI eligible. If not, an individual can request approval from their department chair to serve as a PI. Approval from department chair/leadership should be shown by a letter of support attached to this section of the application.</p> <p>Students cannot serve as Principal Investigator.</p> <p>Individuals will only show up in the "FIND PEOPLE" search if they have a Cayuse IRB account created in their name.</p>

<p>Please list any <u>Co-Principal Investigator(s)</u>:</p>	<p>Co-PIs must be full time faculty or staff member(s) who are PI eligible.</p>
<p>Please list any <u>Student Investigator</u>:</p>	<p>The primary student investigator (ie. Dissertation project) will be listed here. Additionally, any other students should be listed here.</p>
<p>Please list <u>Key Personnel</u>: Please list all key personnel (including anyone unaffiliated with UNT)</p>	<p>Any unaffiliated researcher(s) will be listed here. Additionally, any other key personnel including other collaborating students, faculty, or staff at UNT that you cannot find under the “find me” buttons should be listed here.</p>
<p>Please choose the Primary Contact for this study. This may be the same as the PI or Co-PI.</p> <p>Name: Organization: Address: Phone: Email:</p>	<p>Primary contact should be anyone listed on the study personnel list who would also like to be contacted, in addition to the PI, for IRB communications. Must be UNT affiliated.</p> <p>Note: Only the PI and Key Personnel will receive Cayuse email notifications regarding the study.</p>
<p>Have all investigators and key personnel completed the required IRB human subjects online training? *Please attach a copy of all training certifications</p>	<p>Must answer ‘yes’ and provide training for each person listed in the Personnel section.</p> <p>Please read more about required trainings by following this link: https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/training-and-education</p> <p>Training must be completed in the last three years.</p> <p>Everyone on study must have training completed, even outside affiliates.</p>

Section 1- Research Focus & Concepts

Research, for IRB purposes, is defined as a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.? <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

<p>Describe the purpose of the study. In no more than a half a page, briefly state the purpose of your study in <u>lay language</u>, including the research question(s) you intend to answer. A brief summary of what you write here should be included in the informed consent form.</p>	<p>Explain the rationale and impetus for your research project. Provide enough detail such that: a) the IRB member(s) reviewing your protocol will understand your research plan and b) it supports a judgment of the risks and benefits in order to approve the use of the research participants.</p>
<p>Previous Research In no more than half a page, summarize previous research leading to the formulation of this study, including any past or current research conducted by the Investigator that leads directly to the formulation of this study (including citations and references.)</p>	<p>What literature is related to your research? On what are you basing your own work, pertaining to the use of human subjects? What are you doing that builds on existing research findings/best practices? What work has come before and what have you learned from it to inform your own methods and questions? Provide citations if available (APA or MLA reference styles are good).</p>

Section 2- Methods

It is important that the procedures to be applied-some might call these treatments - to the human subjects are thoroughly explained and outlined. Those who will review and approve your study must fully understand what will take place during its conduct. Once approved, it is necessary that the procedures be carried out in the way they are officially described in this protocol.

<p>Summarize the overall <u>design</u> of your proposed study.</p>	<p>What kind of quantitative, qualitative, or mixed design are you using, for example, experimental randomized treatment, correlation, quasi-experimental, case study, etc.? What are the independent variables, interventions, treatments, etc.?</p>
<p>Will you be testing a food product on participants or providing a nutritional supplement to participants as part of the study?</p> <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> • <i>Please provide detailed information on the food product and/or the nutritional supplement. e.g. brand, administering schedule, dosage, contact person for adverse effects, possible adverse effects, etc.</i> <p><input type="checkbox"/> No</p>	
<p>Provide a step-by step outline of the activities included in this study.</p> <p>What events will occur and in what order? How will the information about the study be presented to the participants?</p>	<p>Describe research activities so that the IRB reviewer will understand your research plan.</p> <p>We prefer this to be written in a bulleted or numbered list of events in the order as they occur.</p>

Section 3- Subjects & Recruitment

The terms subjects and participants are often interchangeable. A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. (Dept. of Health and Human Services, 45CFR46)

Recruitment of Participants	
<p>Describe the projected number of subjects.</p>	<p>Please provide a hard, total maximum number of subjects that will be consented (no estimates).</p> <p>Note: The number provided in this section will be the maximum number of participants that can be recruited. If you are only reviewing data records, this would be the total number of data records to be reviewed.</p>
<p>Describe the population from which subjects will be recruited (including gender, racial/ethnic composition, and age range.)</p>	<p>Must comment on gender, racial/ethnic composition and age range.</p>
<p>Describe how you will recruit subjects (face-to-face, e-mail, flyer, classroom announcement, etc.)</p>	
<p>Describe where recruitment of subjects will take place. If you are recruiting from a business, office, or school, please attach a consent letter from all locations on</p>	<p>If recruitment will take place at a private entity (business, school, social media group), an approval letter must be attached in this section.</p>

<p>their company letterhead.</p>	<p>If researchers plan to post in a social media group (ex: Facebook group), a letter of approval from the group's administrator must be uploaded.</p> <p>Any email distribution lists need permission from the person who is responsible for the distribution list.</p> <p>If you want to send a blanket email to all students on campus, you need permission from the registrar's office.</p>
<p>Have you attached a copy of all recruitment materials such as flyers, e-mails, and scripts for classroom announcements, e-mails, and social media posts?</p> <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> • Please attach all supporting documentation and recruitment materials. <p><input type="checkbox"/> No</p> <ul style="list-style-type: none"> • Please explain if you are not submitting any recruitment material. 	<p>See an example of a recruitment flyer here: https://research.unt.edu/sites/default/files/recruitment_flyer.pdf</p> <p>Recruitment materials must include:</p> <ul style="list-style-type: none"> • University of North Texas • Name of dept. • The word "Research" • Title of study or research condition • Location of research • Inclusion criteria • Purpose of research • Study procedures • Time requirements • Compensation (Do not provide a dollar amount for compensation, just state "you may/will/will not be compensated for participation.") • PI name and contact information.
<p>Vulnerable Populations</p>	
<p><i>Vulnerable populations will require an Expedited or Full Board review application.</i></p> <p><i>When a subject has limitations, is coerced or manipulated, there is a loss of capability to volunteer, and the subject may be vulnerable. According to regulations, vulnerable subjects include prisoners, pregnant women, minors and fetuses. The IRB considers other kinds of vulnerability, for example, the possibility that bosses can coerce at the workplace and teachers can manipulate in the classroom. Research conducted with regulated vulnerable subjects requires demonstration of your training and experience with that specific population.</i></p>	
<p>Vulnerable Populations</p> <p><input type="checkbox"/> Children</p> <ul style="list-style-type: none"> • Children in most circumstances are those less than 18 years of age. Research with children involving no greater than minimal risk requires the permission of one parent and the assent of the child (45 CFR 46.404). Please note: Research involving minors is typically subject to full IRB review. <p><input type="checkbox"/> Prisoners</p> <ul style="list-style-type: none"> • Please note: Research involving prisoners is typically subject to full IRB review. <p><input type="checkbox"/> Mentally Impaired</p> <ul style="list-style-type: none"> • Please note: Research involving mentally impaired is typically subject to full IRB review. <p><input type="checkbox"/> There are no vulnerable populations in this protocol.</p>	<p>If any vulnerable populations are checked, describe any special precautions to be taken in your study due to the inclusion of these populations. Please note, selections in this section may require additional safeguards in other areas of the application.</p>
<p>Location of the Study</p>	<p>If studies are taking place at a private location, please</p>

<p>Identify all locations where the study will be conducted. If you are conducting your research study at a business, office, or school, please attach a consent letter from all locations on their company letterhead.</p> <p><i>*Please attach consent letters from locations.</i></p>	<p>upload a letter of approval/support from the external site.</p> <p>If research activities are completely conducted online, please specify in this box.</p>
<p>Foreign Languages</p> <p>Will your study involve the use of any language other than English for informed consent forms, data collection instruments, or recruitment materials?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	<p>If yes, please provide:</p> <ul style="list-style-type: none"> • An interpreter fluent in both English and the participants' spoken language to aid in consent process. This person should be identified in the personnel section of the application. • A written consent document in the participants' primary language (upload in section 8). • Translated Consent form must be submitted to the IRB for approval along with a Certificate of Translation (upload in section 8). If a Certificate of Translation is not available, we will accept a copy of the translator's CV showing the education/training that makes this individual qualified to perform the translation.

Section 4- Data Collection

Data collection methodologies include, but are not limited to: surveys, interviews, focus groups, observational research in public schools, physiological sensors, weight scales, and extracting information from existing data sets.

Data includes: the information (responses) on survey sheets and questionnaires, biological samples, audio and video tapes, interview questions. If performing audio recordings, please mention who will be responsible for transcribing the audio data. If you intend on using a third-party transcription company, please provide a copy of that company's non-disclosure agreement. In addition, if audio data is not de-identified prior to transcription by a third-party company, or anyone other than the investigators or key personnel mentioned on the application, please ensure they provide a copy of their NIH training for human subjects certification. Audio recordings should be verified by the subjects before any dissemination of data occurs.

If you are using video recording, please mention how you plan to keep the subject's anonymity.

All data collected needs to be stored on the UNT campus with the Supervising Investigator for a minimum of three years past the end of the study.

<p>Please select the methods you will use to collect data</p> <p><i>Please note: If you plan to conduct a study using biologics/biological samples, you will be referred to our Institutional Biosafety Committee (IBC) to submit a protocol. You must receive IBC approval before IRB approval will be issued.</i></p> <p><input type="checkbox"/> Interviews</p> <ul style="list-style-type: none"> • <i>Please explain how this will be done, and how the interviews will be documented.</i> • <i>Please attach a list of the interview questions.</i> <p><input type="checkbox"/> Paper Survey/Questionnaire</p> <ul style="list-style-type: none"> • <i>Please attach a copy of all paper surveys and questionnaires.</i> 	<p>Describe <u>in detail</u> all procedures to be done. <u>What</u> types of test(s) will you perform on or with the subjects? <u>How</u> will you carry them out? What type of data will you collect?</p> <p><u>Interviews:</u></p> <ul style="list-style-type: none"> • Please attach a list of interview questions. If the interview is unstructured, please attach a list of the original questions that will be asked. • Please answer: How long will the interviews take place? Where will they take place? What information from the interview will be documented? <p><u>Paper Surveys/Questionnaire:</u></p> <ul style="list-style-type: none"> • Please upload the questions exactly how the participants(s) will see them.
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<ul style="list-style-type: none"> <input type="checkbox"/> Focus Group <ul style="list-style-type: none"> • <i>Please attached all materials related to the Focus Group</i> <input type="checkbox"/> Internet Surveys/ Questionnaire <ul style="list-style-type: none"> • <i>Please attached a PDF version of the first page of the online survey showing the Informed Consent Notice, along with a copy of the survey questions for IRB review.</i> <input type="checkbox"/> Review of Existing Records <ul style="list-style-type: none"> • <i>Please describe the records you plan to review. Have these records been de-identified?</i> • <i>If obtaining from an outside source, please provide approval from the outside source stating you can review these records.</i> <input type="checkbox"/> Observation <ul style="list-style-type: none"> • <i>Please describe the observations you plan to make for your study. How will the observation(s) be documented?</i> <input type="checkbox"/> Other <p><i>Please select from the list below, or add description if selection is not available</i></p> <ul style="list-style-type: none"> ○ <i>Exercise Protocol (Please describe in detail what the subjects will be doing, the time duration, and any safety precautions that will be put in place.)</i> ○ <i>DXA or Radiographic Imaging (Please ensure the required IRB guidelines have been added to your informed consent document (i.e., urine testing of women of childbearing age, side effects of radiation, etc.)</i> 	<p><u>Focus Group:</u></p> <ul style="list-style-type: none"> • Please attach all materials that will be distributed. • Include language specific to focus groups in the consent document templates (Upload in Section 8). <p><u>Internet Surveys/Questionnaires:</u></p> <ul style="list-style-type: none"> • Attach a PDF copy of the questions with the consent form as it appears in section 8 as the first page. <p><u>Review of Existing Records:</u></p> <ul style="list-style-type: none"> • Please explain how the data will be obtained. • If the data has restricted access (ex. federal data repositories) please clarify. • Please describe if the data will deidentified or identifiable. • Please provide a description of what the data set contains. <p><u>Observation:</u></p> <ul style="list-style-type: none"> • Please clarify: Will the observation will be taking place in a private or public setting? Who is being observed? What information will be collected from the observations? <p><u>Other:</u></p> <ul style="list-style-type: none"> • <u>Exercise Protocol:</u> Please note this is physical exercise (ex: running on a treadmill). • <u>DXA or Radiographic Imaging:</u> Requires radiation safety approval from risk management.
<p>Does your study collect or analyze any biological samples? (For example: blood, urine, tissue, saliva, etc.)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Yes <ul style="list-style-type: none"> • <i>Please list the biological samples that will be collected or analyzed. Please also explain the volume, frequency, and techniques of collection.</i> • <i>How will the biological samples be obtained?</i> <ul style="list-style-type: none"> <input type="checkbox"/> Collected by a member of the research team <input type="checkbox"/> Collected by the Subject <input type="checkbox"/> From an existing tissue bank <input type="checkbox"/> Other (<i>please explain</i>) • <i>Will the biological samples be processed in the lab at UNT?</i> 	<p>If yes, risk management approval, including biosafety officer approval, may be required.</p>

<ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No • Please describe the plan for storage of biological samples collected or obtained. Describe how long the samples will be stored, where they will be stored and if/how they will be disposed of • Please upload a copy of the IBC approval, if applicable <input type="checkbox"/> No	
<p>Will your study involve audio-recording or video-recording the participants?</p> <input type="checkbox"/> Yes <ul style="list-style-type: none"> • For audio: Please mention who will be transcribing audio data. For pseudonyms, please mention the criteria that will be used to ensure subject's anonymity. If third party company is doing transcription, please submit a copy of their non-disclosure agreement. • For video: Please mention how you plan to keep subject's anonymity (i.e., will subject's face be blurred?) • For all recordings, please verify that subject approval will be obtained before any dissemination of data. <ul style="list-style-type: none"> <input type="checkbox"/> Audio only <input type="checkbox"/> Video only <input type="checkbox"/> Audio & Video <input type="checkbox"/> No	<p><u>Please state how this data will be deidentified and transcribed.</u></p> <p><u>Please include who will perform the transcription. If this is being done by a third-party company, a Non-disclosure agreement may be required.</u></p> <p><u>The answers provided in this section must match that which is contained in the consent form.</u></p>
<p>International Travel</p> <p><i>For International Travel: (it is PI's responsibility to make initial contact with Risk Management)</i></p> <p>Please contact UNT Risk Management (https://www.untsystem.edu/international-travel-currently-suspended-due-covid-19-threat) for their guidance with International travel and UNT guidelines, and respond back to the IRB with either your email confirmation for traveling to a low risk location, or a Risk Assessment Report for traveling to a high risk location.</p> <p>The IRB approval, when provided, is for IRB issues only, and does not cover your requirements for International travel as a UNT employee or student.</p> <p>Will international travel take place?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No	<p>If yes, please attach a risk assessment report here.</p> <p>If research is being performed in a foreign country, please reach out to our office at untirb@unt.edu for further guidance.</p>
<p>Will you be using any third (3rd) party online websites to collect data? e.g. Facebook, Twitter, etc.</p> <input type="checkbox"/> Yes <input type="checkbox"/> No	<p>If using Qualtrics, Zoom, MTurk, social media or any other 3rd party platform, please select 'yes' and clarify what website(s) will be used.</p>
<p>Will you be gathering information from subject medical records?</p> <input type="checkbox"/> Yes	<p>If yes, HIPPA language needs to be in the consent form. HIPPA consent template can be found here: https://research.unt.edu/research-services/research-</p>

No

[integrity-and-compliance/human-subjects-irb/irb-forms-and-templates](#)

Section 5- Data Security

<p>Is the study:</p> <ul style="list-style-type: none"><input type="checkbox"/> Anonymous<ul style="list-style-type: none">• <i>Justify</i><input type="checkbox"/> Confidential<ul style="list-style-type: none">• <i>Justify</i><input type="checkbox"/> None/Neither	<p>A strictly anonymous study design is one in which it is impossible to trace data or information back to the research subject from whom it was obtained. In other words, the data cannot be identified to any particular research participant, not even by the researcher. There is total separation. No study design that involves the creation of a code linking the subject's identity to a pseudonym or a number can be termed an anonymous study, as the identity of the subject can be traced to the data. Additionally, when a written consent form is collected, this consent form must be separated from the data that the subject provides. The PI (principal investigator) needs to describe in the protocol how this will be accomplished. If IP address is being captured, this too cannot be anonymous.</p> <p>Confidential research participation means that the data from the research subject(s) can potentially be identified or linked to a particular individual. Thus, any data collected face-to-face (consumer survey, focus groups, standing in front of a classroom, etc.) is typically considered in the category of being confidential as opposed to anonymous. This is true even when the researcher assigns a coding number to the subject and this number cannot be traced back to the subject because the researcher him/herself knows who provided the data.</p>
<p>Will personally identifiable information (PII) be collected/used?</p> <ul style="list-style-type: none"><input type="checkbox"/> Yes<input type="checkbox"/> No	<p>If yes, please provide information on what identifiers are being captured (ie. Name, phone number, email address) and how identifiers will be removed or coded to protect participant's confidentiality.</p>
<p>Who will have access to the data (and/or biological samples)?</p> <p>Will any data collected from the study be made available as open access? For example, some funders and journals request that data be housed (kept, stored) at an approved site (e.g., clinicaltrials.gov), accessible to the public.</p>	<p>Please state who specifically will have access to the data. Clarify if the data will be open access or stored and protected.</p>
<p>How will the raw data be kept protected and secure?</p> <p>How will it be coded or identified?</p>	<p>Where will it be stored? Will it be coded or not? Is that data storage password protected and who will have access?</p>
<p>What will become of the data (and/or biological samples) at the end of the study?</p> <p>All collected data is required to be kept on the UNT campus in the PI's office for a period of three years past the end of the study.</p>	<p>Will the data be returned, destroyed, archived, etc.?</p> <p>Per federal regulations, all collected data is required to be kept for a period of three years past the end of the study</p>

<p>How will the data, results, and conclusions be utilized? Do you plan to use any data in a presentation, publication, or something else? Will any data be used <i>*only*</i> internally, for example within an institutional department?</p>	<p>Will the data be shared with any other researchers or funding agencies? Will these data appear in a published thesis or journal publication? This information, summarized, must be included in the consent form.</p> <p>If true, it is helpful to state that "Data will be reported in aggregate without identifiers."</p>
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Section 6- Potential Risks

Definition of risk: A potential harm, discomfort, or inconvenience associated with your research that a reasonable volunteer would be likely to consider significant in deciding whether or not to participate. Risks include legal, social, emotional, or psychological issues, physical or biological hazards, revealing an identity, damage to reputation, exposure of behavior or medical character, illness, injury, side effects of applied or consumed products, revealing or a loss of private information, etc. Risk comes at various orders of magnitude, ranging from mere inconvenience to perceptible bodily pain.

<p>What are the risks? Describe any potential harm, discomfort, or inconvenience, however minimal, as you would explain them to the subjects. If foreseeable risks involve the possibility that the subject may need counseling after the completion of the study, please include a list of 24-hour resources (including contact information) in the Foreseeable Risks section of the informed consent document.</p>	<p>It can be said that everything has a risk. Think carefully about what may potentially happen during the research activity. This information summarized must be included in the consent form. Any perceived potential risk should be included.</p> <p>For studies collecting data in a digital format the following may be helpful: "Participation in this study involves risks to confidentiality similar to a person's everyday use of the internet."</p>
<p>Describe your procedures for protecting against or minimizing the potential risks stated above.</p>	<p>For every risk stated above, there should be a procedure listed to minimize that risk.</p>
<p>Explain why these risks should be determined as reasonable in relation to the anticipated benefits, if any, while conducting research with the subjects.</p>	<p>Please provide a statement explaining the risk benefit ratio of the overall study for research benefits. For example: "The risks are considered minimal compared to potential benefits of"</p>
<p>Describe the anticipated benefits to subjects or others (including your field of study).</p>	<p>Compensation should NOT be mentioned here. Please include both benefits to the subject and to your field of study.</p>
<p>Will you utilize any of the following for the study's potential risks? Check all that apply</p> <ul style="list-style-type: none"> <input type="checkbox"/> Debriefing Statement <input type="checkbox"/> Counseling and Psychological Services <input type="checkbox"/> Adverse event protocol <input type="checkbox"/> None 	
<p>Compensation Describe any compensation subjects will receive for participating in the study. Include the timing for payment and any conditions for receipt of such compensation. If extra credit for a course is offered, an alternative non-research activity with equivalent time and effort must also be offered.</p>	<p>Please state "None" if there will be no compensation.</p> <p>Anything a subject will receive for participation is compensation (food, money, extra credit etc.).</p> <p>If the item is <u>food</u> or a <u>consumable good</u>, please provide an estimated monetary value. (EX: "Lunch is provided for subjects valued at \$15 a meal.")</p>

For cash or gift cards, IRS language needs to be added to the consent document(s) as provided in the consent templates.

Whatever is listed here, must be match the compensation section of the consent form.

Section 7- Affiliations

These questions ask about how you are related to the institution and subjects where the research project is to be conducted. As examples: you are a teacher using your students in a classroom setting as your subjects, or you work for the company where a marketing survey is to be conducted, or you have a financial interest in a product being tested. Each of these examples presents an element of risk. IRB reviewers will evaluate whether these risks are reasonable and whether they are sufficiently controlled, minimized, or eliminated by your procedures.

Do you have any kind of pre-existing relationships with the subjects (participants) or institutions involved in conducting this study?

Working at the place where the study is to be conducted may be seen as coercive to others. Consider the possibility that collection of data from either the participant or institution may be seen as a favor when asked to volunteer information. The IRB is interested in reading a statement from the PI(s) of the potential and it may be of no concern at all.

- Yes
- No

Examples: Teacher to Student, Colleague to Colleague, Boss to Subordinate etc. Any preexisting relationship to the participants should be noted here.

As an investigator involved with the project, do you or any of your family members (e.g. spouse, child) have a financial or other self interest in this study?

- Yes
- No

Though there may not be one, could there be the perception of a conflict of interest for either you, as the investigator, or for the subjects in this study?

- Yes
- No

Section 8-

The informed consent form (ICF) is the means by which you as the PI convey not only the research, but also the principles of human subjects protections to your subjects: respect, beneficence, and justice. There are examples on the [IRB website](#). Towards the top of this web page is the Word protocol document which contains the elements for the ICFs and the required header in English and Spanish: "[blank IRB protocol application](#) for training, classroom exercise, and development."

To test your ICFs for appropriate reading levels, submit your ICF to this software: <https://www.readabilityformulas.com/flesch-grade-level-readability-formula.php>

How will you obtain and document informed consent?

Please describe the interaction between the subject and researcher. *If electronic consent notice is being used, please explain here.*

Select the type of ICF you will utilize

Consent forms and templates can be found here: UNT

<p>Note that you should add the current IRB protocol number obtained when you created this protocol in Cayuse to your ICF(s) before you upload it to this site. Be sure to check the list of required ICF elements (available in the Word protocol document at the IRB website) and that the domain has been changed to UNT in email addresses and websites.</p> <ul style="list-style-type: none"> □ Informed Consent Form (paper version) <ul style="list-style-type: none"> • <i>This is the most typical means used in face-to-face explanations of study to convey the ICF elements to potential subjects/participants. This form requires signatures from both the participant and the investigator.</i> <ul style="list-style-type: none"> * Please attach ICF • <i>Describe the subject group that will be consented utilizing a paper consent form. If the answer is all study subjects, please write "all subjects".</i> □ Informed Consent Notice (electronic version) <ul style="list-style-type: none"> • <i>This version is commonly used with on-line surveys because the participants and investigators are not required to sign the document. Instead clicks/check boxes are used to indicate yes/I agree, or no/I don't agree as a means to continue to the survey or exit the survey. A copy of this document still needs to be submitted to the IRB office for approval.</i> <ul style="list-style-type: none"> * Please attach ICF • <i>Describe the subject group that will be consented utilizing a paper consent form. If the answer is all study subjects, please write "all subjects".</i> □ Waiver of Informed Consent <ul style="list-style-type: none"> * Please attach ICF • Justify the need for a waiver. <i>A justification is required and will be evaluated by the IRB member(s) doing the protocol review. "Convenience" is not a valid reason. An example is that it's impractical during medical research to obtain consent from someone unconscious. Please also list the study subjects that this waiver will apply to. If the answer is all study subjects, please state that below.</i> 	<p>IRB Forms and Templates: https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/irb-forms-and-templates</p> <p>A Waiver of Informed Consent is required if you are using the Informed Consent Notice- Electronic Consent form</p> <p>A Waiver of Consent can both waive consent requirements completely or allow an alteration to the consent process, for example when you are not obtaining a physical signature on a paper consent document. Any time you are deviating from the standard practice, a waiver is needed.</p>
<p>Will there be recruitment of subjects who cannot themselves provide informed consent?</p> <ul style="list-style-type: none"> □ Yes □ No 	<p>Vulnerable persons typically would require consent from a guardian.</p>
<p>Which study personnel will be involved in obtaining consent? Know that makes such personnel engaged with potential study subjects/participants.</p>	
<p>Describe how you will maintain and secure the consent forms received from the subjects?</p>	<p>Where (the location) will they be kept? For how long/until when? Will they be kept separate from subject data and</p>

Consent forms can be electronic or paper.	specimens?
How will you obtain and document parental/guardian consent and child/minor/ward assent? * Please attach assent form * Please attach parent/guardian consent form	Assent means a child's affirmative agreement to participate in research. (45 CFR 46.402(b)). The assent form should be age appropriate

Section 9- Study PI(s) Declaration

THE UNT IRB DECLARATION BY ALL INVESTIGATORS:

- This proposal is guided by the ethical principles regarding research involving human subjects as set forth in the [Belmont Report](#).
- I/We agree to abide by the policies and procedures of the IRB at UNT, including obtaining appropriate training in human subject research for myself and those involved in its conduct.
- I/We will not initiate any research associated with this proposal on or off campus until authorized by the IRB.
- I/We will report to the IRB about any adverse events or unanticipated problems (unexpected, possible greater risk, etc.) that occur.
- I/We will inform the IRB of a need to modify the study design requiring an amendment.
- I/We understand that approval, when granted, is valid for up to one year and will submit a renewal for its continuation if needed.

The above declaration must be followed by ALL investigators on this study. The individual who completed the protocol must type their name below. Regardless of who completed the protocol, the System will route the protocol to the lead PI to certify.

- Signature of the individual who completed this protocol:

If you are the student investigator, please work with your professor to ensure that they know you have completed your protocol in the System.

For more information visit [UNT IRB website](#).

Contact Research Integrity and Compliance

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