

**Informed Consent and HIPAA Authorization - Adults**

**INSTRUCTIONS:** Text in RED is used as guidance text and should be deleted before submitting your IRB protocol. Text in BLACK should not be edited.

**TITLE OF RESEARCH STUDY:** [insert the title of research study here (must match protocol title)]

**RESEARCH TEAM:** [Type name, department, office phone and e-mail address for the principal investigator (PI). If the PI is a student, indicate that project is part of thesis or dissertation being conducted under the supervision of (faculty supervisor’s name). List any other members (i.e. Key Personnel) of the research team that the subjects will interact with.]

You are being asked to participate in a research study. Taking part in this study is voluntary. The investigators will explain the study to you and will any answer any questions you might have. It is your choice whether or not you take part in this study. If you agree to participate and then choose to withdraw from the study, that is your right, and your decision will not be held against you.

[The new Common Rule regulations require that informed consents begin with Key Information - a concise and focused summary of the study information at the beginning to assist a prospective subject or legally authorized representative in understanding the reasons why a participant may or may not wish to take part in the study. The following information should be clear and concise.]

You are being asked to take part in a research study about [explain the purposes of the research in simple, non-technical language.]

This research is being funded by [Insert name of sponsor.] Delete this section if your study is unfunded.

Your participation in this research study involves [provide a general, concise summary of the procedures that will be done and include the duration of the subject’s participation.] More details will be provided in the next section.

**Ex:** “You will be given a questionnaire to complete about teachers’ conceptions of mathematics instruction.” Or “We are conducting this study to evaluate endurance of athletes. You will also be asked to provide blood samples.”]

You might want to participate in this study if you [Provide reasons why a subject might want to participation, such as “If you want to share your views on conceptions of mathematics instruction.” However, you might not want to participate in this study if you [Provide reasons why a subject might not want to participate, such as “You might not want to participate if you do not have the time to participate in three focus group sessions.”]

You may choose to participate in this research study if you are [provide the inclusion and exclusion eligibility here.]

The reasonable foreseeable risks or discomforts to you if you choose to take part is [List the most important behavioral, biomedical, legal, economic, and/or privacy/confidentiality risks, which you can compare to the possible benefit of [list the possible personal benefits, if applicable, if not, indicate that that there are no personal benefit or include possible benefit to . Do not include compensation as a benefit.] You will (or will not) receive compensation for participation. Instead of being in this research study, your choices may include [List appropriate alternatives which may be advantageous or delete the statement if the only alternative is not participating].

[The information above should be clear and concise to adhere to the new requirements regarding “key information” and “organized and presented in a way that facilitates comprehension.” The following information should provide more details about the study, in addition to the information listed above.]

**DETAILED INFORMATION ABOUT THIS RESEARCH STUDY:** The following is more detailed information about this study, in addition to the information listed above.

**PURPOSE OF THE STUDY:** [Describe the purpose of the study in non-technical language. It should be written in in language understandable to the population being recruited; for studies recruiting the general population, consents should be written at no higher than an 8th grade reading level.]

**TIME COMMITMENT:** [Explain to subjects the total duration of the research study, including any interactions or follow up visits expected from them. Ensure you include the total participation time (days, weeks, months, years, etc.).

**Ex:** Participation in this study is expected to last approximately one hour.]

**STUDY PROCEDURES:** [Provide a detailed description of all procedures to help subjects understand what to expect throughout the study written in second person; if multiple activities are required, please use a bulleted or numerical list of activities that the participant will be asked to perform as part of the research. Include as much information as necessary to provide the subjects with a complete understanding of the procedures. Whenever appropriate include the following items:

1. List research procedures/research interventions/ research activities and explicitly identify them as such
2. A description of what the study procedures/Activities will entail. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures, activities and/or tests for research that require more than 1 or 2 steps/visits
3. The length and duration of study visits, study activities, and study procedures
4. With whom the participant will interact
5. Where the research will be done (Physical location)
6. When the research will be done
7. How often study activities and procedures will be performed
8. If the study involves any type of clinical care, (e.g. mental health care) what is being performed as part of standard care and what procedures are part of regular medical care that will be done even if the participant does not take part in the research.
9. When applicable indicate that the participants will be asked for permission to be contacted for future research.
10. Make certain to indicate if sensitive subject matter is involved, and give examples of such questions.
11. Include a clause or indicate whether subjects may skip questions that may make them uncomfortable.]

**AUDIO/VIDEO/PHOTOGRAPHY:** Include this section if audio/video/photography that will be included as part of the research study, otherwise delete this section.

[ ]  **I agree** to be [choose audio recorded/video recorded/photographed as appropriate] during the research study.

[ ]  **I agree** that the [choose audio recorded/video recorded/photographed as appropriate] can be used in publications or presentations.

[ ]  **I do not agree** that the [choose audio recorded/video recorded/photographed as appropriate] can be used in publications or presentations.

[ ]  **I do not agree** to be [choose audio recorded/video recorded/photographed as appropriate] during the research study.

[Include a statement here to indicate if the subject may still participate if they do not agree to be audio recorded/video recorded/photographed.]

**Ex:** “You may participate in the study if you do not agree to be audio recorded/video recorded/photographed.”

Also, add one of the following clauses, if applicable: [The recording will be immediately destroyed after transcription.] Or [The recordings will be kept with other electronic data in a secure UNT OneDrive account for the duration of the study.]

[If using a third party transcription service in your research, please provide the UNT IRB with the name of the third party transcription service along with a signed non-disclosure agreement, and a link to the third party privacy policy for review.]

**POSSIBLE BENEFITS:** [Explain the possible benefits to subjects if they choose to participate. Describe the benefits that have direct impact on the subject and then describe any benefits to others. If after the study has ended the benefits do not continue, state this. Do not over-promise benefits in studies that include experimental interventions; use tentative language, e.g., “may benefit” versus “will benefit”. Also, as a reminder – monetary reimbursement for participation is not a benefit.]

**POSSIBLE RISKS/DISCOMFORTS:** [Explain any foreseeable risks or discomforts, which the subject may experience as a result of participating in this research study. Explain any safeguards that are in place to minimize these potential risks or discomforts. Describe any potential physical, psychological, privacy, legal, social, or economic risks and provide the possible ramifications of the risks. If the possible risks or discomforts to participating in the research study are equivalent to those that participants would experience in their everyday lives, state that.

**Ex:** For studies that are conducted online:” Participation in this online survey involves risks to confidentiality similar to a person’s everyday use of the internet and that there is always a risk of breach of confidentiality.

**Ex:** (Use this example if there are risks.)You might experience [list foreseeable risks/discomforts] during this research study. [Provide an explanation of the safeguards in place to minimize the potential risks/discomforts, and include 24 hour help resource information. Please select the most appropriate resource based on your participant population and your study. If the population studied are not all UNT staff and students, please provide a resource outside the UNT Campus resources. Examples may include, but are not limited to: Denton County MHMR crisis hotline at 1-800-762-0157; UNT Mental Health Emergency line at 940-565-2741; Family Violence Shelter of Denton County Crisis Line at 940-382-7273; National Suicide Prevention Hotline at 1-800-273-8255; UNT Survivor Advocate for students effected by Violence or Sexual Assault at 940-565-2648]. Remember that you have the right to withdraw any study procedures at any time without penalty, and may do so by informing the research team.

**Ex:** (Use this example if there are no known risks.)This research study is not expected to pose any additional risks beyond what you would normally experience in your regular everyday life. However, if you do experience any discomfort, please inform the research team [Please include 24 hour help resource information. Please select the most appropriate resource based on your participant population and your study. If the population studied are not all UNT staff and students, please provide a resource outside the UNT Campus resources. Examples may include, but are not limited to: Denton County MHMR crisis hotline at 1-800-762-0157; UNT Mental Health Emergency line at 940-565-2741; Family Violence Shelter of Denton County Crisis Line at 940-382-7273; National Suicide Prevention Hotline at 1-800-273-8255; UNT Survivor Advocate for students effected by Violence or Sexual Assault at 940-565-2648]. Participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured by the research team. As with any use of electronic means to store data, there is a risk of breach of data security.

**EX**: (Add this language if you are performing in-person research activities) Participating in this research study may involve increased risk of exposure to COVID-19 due to in-person interactions with the research team. The study team will follow local regulations and institutional policies, including using personal protective equipment (masks) and social distancing guidelines while those regulations and policies are in effect. If you have any questions or concerns, please discuss them with your research team.

If you experience excessive discomfort when completing the research activity, you may choose to stop participating at any time without penalty. The researchers will try to prevent any problem that could happen, but the study may involve risks to the participant, which are currently unforeseeable. UNT does not provide medical services, or financial assistance for emotional distress or injuries that might happen from participating in this research. If you need to discuss your discomfort further, please contact a mental health provider, or you may contact the researcher who will refer you to appropriate services. If your need is urgent, helpful resources include [Please provide relevant 24 hour resource information and campus or community resources. Please select the most appropriate resource based on your participant population and your study. If the population studied are not all UNT staff and students, please provide a resource outside the UNT Campus resources. Examples may include, but are not limited to: Denton County MHMR crisis hotline at 1-800-762-0157; UNT Mental Health Emergency line at 940-565-2741; Family Violence Shelter of Denton County Crisis Line at 940-382-7273; National Suicide Prevention Hotline at 1-800-273-8255; UNT Survivor Advocate for students effected by Violence or Sexual Assault at 940-565-2648].

**COMPENSATION:**

Specify the type and amount of compensation offered for participation, if any (including non-monetary goods or items such as food, gifts/promotional items, course credit, extra credit, etc.), explain when and how subjects can expect to receive it, and the approximate costs of the items if you are offering non-monetary goods or items. If no compensation will be offered for participation in this study, state this. If offering extra credit, include the amount of extra credit being offered, AND include a non-research alternative will be available that is equal to the time and effort of the study for those students that do not wish to participate in the research study.

EX. For studies compensating research participants with checks, cash, gift cards, or gift certificates and paid on a grant or other local funds, you must follow the procedures outlined in UNT’s Procurement Guide found here: <https://www.untsystem.edu/hr-it-business-services/procurement/procurement-guide>. Please note on IRS requirements for documenting payments and what the PI must submit to UNT System Tax after each event or disbarment date to serve as supporting payment documentation for expensing the funds (found on page 67 of the Procurement Guide). Also, you must add in this clause within your consent: Internal Revenue Service (IRS) considers all payments made to research subjects to be taxable income. Your personal information, including your name, address, and social security number may be acquired from you and provided to UNT System Tax Office for the purpose of payment. If you are an employee, we will be collecting your employee ID. If your total payments for the year exceed $600.00, UNT will report this information to the IRS as income and you will receive a Form 1099 at the end of the year. If you receive less than $600.00 total payments in a year, you are personally responsible for reporting the payments to the IRS.

**Ex: (**For studies where compensation is affected by withdrawal or partial completion of the study) If you choose not to complete all study procedures, you will still receive (compensation type/amount).

Explain any alternative procedures or courses of action that will be offered or that the subject might find beneficial or advantageous. If there are no alternative procedures offered for this study, state this.

**Ex:** (for studies that will offer alternative procedures)You have the option to participate in other research studies, or complete alternative class assignments in order to fulfill your course research requirements.

**Ex:** (for studies that will not offer alternative procedures)There are no alternative activities offered for this study.

**CONFIDENTIALITY:** Efforts will be made by the research team to keep your personal information private, including research study and medical records, and disclosure will be limited to people who have a need to review this information. All paper and electronic data collected from this study will be stored in a secure location on the UNT campus and/or a secure UNT server for at least three (3) years past the end of this research [describe location, such as a locked file cabinet, password protected computer in PI’s campus office, etc.] Research records will be labeled with a code [or “pseudonym”] and the master key linking names with codes will be maintained in a separate and secure location.

**Ex:** (for studies that are completely anonymous where no identifiers will be collected – including codes – or matched to the subject for the duration of the study) Your participation in this study is anonymous, and the information you provide cannot be linked to your identity.

**Ex:** (for studies that are HIPAA-regulated) This research uses or discloses Protected Health Information as defined by the Health Insurance Portability and Accountability Act (HIPAA), and you will be asked to sign a form to authorize use of this information.

**Ex:** (For focus groups) Please be advised that although the researchers will take these steps to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.

**Ex:** For studies that are conducted online: Participation in this online survey involves the potential for the loss of confidentiality similar to a person’s everyday use of the internet.

Ex: (for ALL studies that collect sensitive information from participants regarding sexual assault/sexual violence/stalking, regardless if the data collected is identifiable)

Due to Senate Bill 212, all University of North Texas employees are required to report all events of sexual harassment, sexual assault, dating violence, or stalking that involve a current student or employee.  These reports are made to the University’s Title IX Coordinator. You should understand that some of the information you provide during this study will be disclosed by the researchers to the appropriate authorities, if required by the law.

The results of this study may be published and/or presented without naming you as a participant. The data collected about you for this study [choose one: may, will] be used for future research studies that are not described in this consent form. If that occurs, an IRB would first evaluate the use of any information that is identifiable to you, and confidentiality protection would be maintained. [If you know that you intend to share identifiable data with individuals outside of the UNT research team, or use identifiable data for future studies, you must explain how it will be used or with whom the data will be shared.]

While absolute confidentiality cannot be guaranteed, the research team will make every effort to protect the confidentiality of your records, as described here and to the extent permitted by law. In addition to the research team, the following entities may have access to your records, but only on a need-to-know basis: the U.S. Department of Health and Human Services, the FDA (federal regulating agencies), the reviewing IRB, and sponsors of the study.

**Ex:** (for studies using any third-party software) This research uses a third party software called [Insert software name] and is subject to the privacy policies of this software noted here: [Copy and paste link to software privacy policies]

**Ex:** For studies using Amazon Mechanical Turk:

This research examines [purpose]. You will be asked [a series of questions about these issues.] The survey should take [#] minutes to complete. After completing the survey, you will be paid [amount] for your participation. We do not ask for your name or any other information that might identify you. You may withdraw at any time any you may choose not to answer any question but you must proceed to the final screen of the study in order to receive your completion code, which you must submit in order to be paid. In accordance with Mechanical Turk policies, we may reject your work if the HIT was not completed correctly or the instructions were not followed. If you have any questions about the research please contact me at [email address] if you have questions about your rights as a research subject, contact UNT’s Institutional Review Board at untirb@unt.edu or 940-565-4643.

USE AND DISCLOSURE OF HEALTH INFORMATION: If you sign this document, you give permission to [name or other identification of specific health care provider(s) or description of classes of persons, (e.g., all doctors, all health care providers) at [name of covered entity or entities] to use or disclose ]release] your health information that identifies you for the research study described in this document.]

HEALTH INFORMATION TO BE USED OR DISCLOSED: The health information that we may use or disclose (release) for this research includes (complete as appropriate):

[Provide a description of information to be used, or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.]

WHO MAY RECEIVE THE INFORMATION: [name of covered entity] is required by law to protect your health information. By signing this document, you authorize [name of covered entity] to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

EXPIRATION OF THE AUTHORIZATION: This Authorization does not have an expiration date [or as appropriate, insert expiration date or event, such as “end of the research study.”]

RIGHT TO REVOKE AUTHORIZATION: Please note that you may change your mind and revoke (take back) this Authorization at any time, except to the extent that [name of covered entity has already acted based on this Authorization. To revoke this Authorization, you must write to: (name of the covered entity and contact information.)]

**CONTACT INFORMATION FOR QUESTIONS ABOUT THE STUDY:** If you have any questions about the study you may contact [insert research team names and contact information.] Any questions you have regarding your rights as a research subject, or complaints about the research may be directed to the Office of Research Integrity and Compliance at 940-565-4643, or by email at untirb@unt.edu.

**CONSENT:** Your signature below indicates that you have read, or have had read to you all of the above.

* You confirm that you have been told the possible benefits, risks, and/or discomforts of the study;
* You understand that you do not have to take part in this study and your refusal to participate or your decision to withdraw will involve no penalty or loss of rights or benefits;
* You understand your rights as a research participant and you voluntarily consent to participate in this study; you also understand that the study personnel may choose to stop your participation at any time.
* By signing, you are not waiving any of your legal rights. Please sign below if you are at least 18 years of age and voluntarily agree to participate in this study.

**SIGNATURE OF PARTICIPANT DATE**

**\*If you agree to participate, please provide a signed copy of this form to the researcher team. They will provide you with a copy to keep for your records.**

Include the following for studies with more than minimal risk, or studies that go to the full board:

**For the Principal Investigator or Designee:**

I certify that I have reviewed the contents of this form with the subject signing above. I have explained the possible benefits and the potential risks and/or discomforts of the study. It is my opinion that the participant understood the explanation.

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Signature of Principal Investigator or Designee Date