

**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 with whom the subjects will interact.]

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 answer any questions you might have. It is your choice whether you take part in this study or not. 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 participate, 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 the participant. 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.]
12. [For online studies or studies that involve telehealth interventions] What to do in the case that technology fails during an intervention or study participation.

**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 (specific kind of account, e.g., HIPAA-compliant learning management system, Qualtrics) for the duration of the study.]

[If using a third-party transcription service in your research, please provide the UWS 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 because 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.]. Remember that you have the right to withdraw from 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.].

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)

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. UWS 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.].

**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 that is equal to the time and effort of the study for those students that do not wish to participate in the research study.

**NOTE TO RESEARCHERS: If you are planning on compensating participants in any way, review the guidance on use of compensation in the “IRB Guidance for UWS Researchers” document available on UDocs.**

**EX**. For studies that intend to compensate research participants with checks, cash, gift cards, or gift certificates and paid on a grant or other local funds, you should consult the UWS Business Office about any possible tax implications. If there are tax implications, you will need to provide a statement like this: 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 the UWS Business Office for the purpose of payment. If your total payments for the year exceed $600.00, UWS 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 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 UWS campus and/or a secure UWS 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.

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 will 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 UWS 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]

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.] If you have questions regarding your rights as a research participant, contact the University of Western States IRB at IRB-UWS@uws.edu or (971) 449-9213.

**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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator or Designee Date