

**Informed Consent for Parents with Minor Children**

**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. The Informed Consent should be written for the parent/guardian of the child participant and should be written at no higher than an 8th grade reading level. The Child Assent form should be written in 2nd person language that is comprehensive to the age of your youngest intended subjects. Multiple Child Assents can be used for different age groups, as needed. Remember to keep all consent and assent forms brief, and clear focusing on what is most important to the parent/guardian, and the child participants when deciding to engage in the research.

**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.]

Your child is 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 you allow your child to take part in this study or not. If you agree to have your child participate, and then choose to withdraw your child 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.]

Your child is 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.

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/child’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 your child if you choose to allow them 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 benefits. Do not include compensation as a benefit.] Your child will (or will not) receive compensation for participation. Instead of your child being in this research study, other 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 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 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 parents understand what is expected of their child throughout the study; 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.

Any use of student educational records (e.g., class assignments, grades, disciplinary records, etc.) regardless of whether the study is conducted by a teacher that has a valid educational interest in the records, will need to have parental permission secured and the school(s) informed. Please be precise about any FERPA-protected student records that you would like to use for research and list them in this section of the consent.

**Ex:** Allowing your child to participate in this research study will include this list of actions that we will ask you and your child to consider before engaging in the research:

1. Please read carefully the parental informed consent and child assent and be sure to contact the research team with any questions or concerns you may have.
2. If you grant permission for your child’s participation, your child will be asked to allow a research team member to take their height, weight, and blood pressure.
3. A member of the research team will ask about your child’s recent behavior and interactions with their friends, siblings, teachers.

**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 have my child [audio recorded/video recorded/photographed] during the research study.

[ ]  **I agree** that the [audio recording/video recording/photographs] can be used in publications or presentations.

[ ]  **I do not agree** that the [audio recording/video recording/photographs] can be used in publications or presentations.

[ ]  **I do not agree** to have my child [audio recorded/video recorded/photographed] 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, then in your application, 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 benefit to parents if they choose to have their child participate. Describe the benefits that have direct impact on their child’s participation 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.] If the only perceived risks are those that the subject may experience in everyday life, please 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.)Your child 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 and your child have the right to withdraw from any study procedures at any time without penalty and may do so by informing the research team.

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 [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.]

**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 (include 24-hour help resource information).

**COMPENSATION:** Specify the type and amount of compensation offered for participation, if any (including extra credit, and non-financial payments), and explain when and how subjects can expect to receive it. If compensation is affected by withdrawal from the study, specify as such.

**Ex:** If you choose not to complete all study procedures, you will still receive (compensation type/amount). 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.

**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.**

For studies compensating 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)Your child has 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 [you and] your child’s personal information private, including research study records 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 child’s participation in this study is anonymous, and the information you provide cannot be linked to their 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.

The results of this study may be published and/or presented without naming your child as a participant. The data collected about your child 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.]

**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 that will be collecting FERPA covered information on minor participants:

**I hereby agree to allow my child’s educational records indicated in the study to be used for the purpose of this research. I understand that information for the study will be secured, and all personally identifiable information will be excluded from any published research results. I am giving my consent voluntarily and can withdraw this consent at any time in writing.**

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.

**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 you have regarding your child’s rights as a research subject, 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 the above.
* You confirm that you have been told the possible benefits, risks, and/or discomforts of the study.
* You understand that your child does not have to take part in this study, and your refusal to allow participation, or your decision to withdraw will involve no penalty or loss of rights or benefits.
* You understand your child’s rights as a research participant, and you voluntarily consent to allow your child to participate in this study; you also understand that the study personnel may choose to stop your child’s participation at any time.
* By signing, you are not waiving any of [you and] your child’s legal rights.
* By signing, you are authorizing the research team to have access to and use your child’s education records for the purposes of this study.

Please sign below if you are at least 18 years of age and voluntarily agree for your child to participate in this study.

**SIGNATURE OF PARTICIPANT OR GUARDIAN 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



**Child Assent Form**

**(to be paired with Informed Consent for Parents with Minor Children)**

Please add one “assent” section for the child participants. Please use the version that fits the age range of your subjects. Please allow the child time to ask any questions.

**REMIINDER:** Text in RED is used as guidance text and should be deleted before submitting your IRB protocol. Text in black should not be edited. The Child Assent form should be written in 2nd person language that is comprehensive to the age of your youngest intended subjects. Multiple Child Assents can be used for different age groups, as needed. Remember to keep all consent and assent forms brief, and clear focusing on what is most important to the child participants when deciding to engage in the research.

**Age Range 13-17:**

**Assent for Child Participation – Ages 13-17**

Children in this age range can assent by reading through the consent form provided to their parent:

By agreeing to participate in this research study, you confirm that you have read or have had read to you the entire informed consent document. You understand that you can ask questions or decide to withdraw your participation at any time without any penalty to you.

Describe how you will obtain child assent. You can either obtain the child’s signature for assent, you accept their verbal or electronic agreement for participation.

Ex: You indicate your participation is voluntary by completing and returning this form.
Ex: You indicate your participation is voluntary by beginning this phone interview.
Ex: Clicking on the button provided below indicates that you voluntarily agree to participate in this research study.

Age Range 12 and Under:

It is recommended that you create a simplified version of the parental consent. Allow the child to read it on their own, and verbally explain certain sections to make certain the child understands – this is highly recommended for children 7 years and younger.

ASSENT FOR CHILD PARTICIPATION – Ages 12 and under

My name is [identify yourself to the child by name.]

I am doing a research study and would like to ask you to be a part of my study. Research studies help us to learn and test new ideas. I am going to give you a paper to read that will tell you all about our research study. You can ask us questions at any time.

We want to include you in this research study because we are trying to learn more about [outline the study in language that is applicable to your subject’s maturity and reading level.] You can decide if you want to be part of this research study. I will tell you more to help you to decide.

If you say yes to be included in this study [give more details on the experience of completing the research procedures, and data collection from the child’s point of view.]

[Describe any risks to the child that may result from participation in the research, including any discomfort or distress]

[Describe any benefits to the child that may result from their participation in the research.]

Please talk with your [parent(s), guardian] about your decision. We will also check with them to see if it is okay for you to be included in this study. Even if your parent(s) [or guardian] say yes, you can still at any time decide not to be included.

If you decide not to be in this study, you do not have to. Being in this study is up to you and no one will be mad or upset even if you choose later not to continue and stop before you are finished. That is okay.

You can ask me questions that you have about the study now. If you have a question later that you did not ask now, you or your parents can call or email me, or you can ask me when I see you next time.

Describe how you will obtain assent. You may obtain assent through their verbal response, a signature, or their agreement to proceed. If you choose verbal response, please make sure that is documented somewhere in the data collection.

Ex: Verbally ask the child: Would you like to be in this research study? If you say “yes” then you agree to be in this study.

For very young children, or infants with limited capability that cannot reasonably be consulted, an assent process may not be appropriate. In this case, the child assent process can be waived, and permission would be obtained solely from the parent(s).

If you would like to be part of this study, please sign your name below.

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Printed Name of Child

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Child Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Parent/Guardian Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Investigator Date