**INSTRUCTIONS TO INVESTIGATORS**

This template is for use with Expedited or Full Board Review research projects that involve **minors as subjects** **requiring documentation of parental permission.**

Delete the **RED** text before submitting this form to the IRB.

**Guidelines for completing this consent template:**

* Student researchers must include their Faculty Sponsor contact information.
* Use simplified language that is understandable to your subjects and avoid technical terminology, acronyms, scientific jargon, and abbreviations.
* Avoid using first person language from the perspective of the participant (e.g., “I understand . . . “or “I agree to . . . “).
* Delete all instructions in **RED** text in the template and made the font and color of text the same throughout before submitting for review.
* Proofread your consent document for grammar and spelling errors prior to attaching it to your IRBNet package.
* Enter the version date of the consent & page numbers in the header before submitting for review.
* Be sure to include the generic DU logo in the heading or your specific department logo.

**Parent or Guardian Permission Form**

**for Child’s Participation in Research**

**Title of Research Study:** Title*. [if the official title is technical and difficult to understand, a simplified non-technical title should be used in addition to the official title]*

*If a study has more than one consent form, label each form or title them appropriately, and use the same reference within the IRB Application to avoid confusion*.

**Principal Investigator:** *name and credentials*

**Faculty Sponsor:** *if student investigator, insert faculty sponsor’s name and credentials*

**Study Site:** *Location where study will take place [i.e., DU department or lab, school district, community center, etc.]*

**Sponsor/Funding Source:** *delete if not applicable*

**Your child is being asked to participate in a research study.** Participation in this research is voluntary and they do not have to participate. Your child may decline to participate or to withdraw from participation at any time. Withdrawal or refusing to participate will not affect their relationship with the University of Denver in anyway. You can agree to allow your child to be in the study now and change your mind later without any penalty. This document contains important information about this study and what to expect if your child participates.

The purpose of this form is to provide you (as the parent or guardian of a prospective research study participant) information that may affect your decision as to whether or not to let your child participate in this research study. The person performing the research will describe the study to you and answer all of your questions. Read the information below and ask any questions you might have before deciding whether or not to give your permission for your child to take part. If you decide to let your child be involved in this study, this form will be used to record your permission.

NOTE: If research is part of a classroom activity, state:

This research study will take place during regular classroom activities; however, if do not want your child to participate, an alternate activity will be available. [*Describe the alternate activity]. If the study involves a classroom setting, state that the child’s grades will not be affected by the study. If the study is in a clinical setting, state that the study will not affect the child’s care.]*

**What if my child does not want to participate?**

In addition to your permission, your child must agree to participate in the study. If your child does not want to participate they will not be included in the study and there will be no penalty. If your child initially agrees to be in the study they can change their mind later without any penalty.

**Purpose of the Study**

If you agree, your child will be asked to participate in a research study about *[insert general statement about study].*The purpose of this study is*[explain the research questions and purpose in lay language].*

**What is my child going to be asked to do?**

If you allow your child to participate in this study, they will be asked to [*Use bullet points to explain tasks and procedures including details about completing surveys, interviews, tests, and/or focus groups as applicable].* This study will take *[insert length of time for participation, frequency of procedures or any other applicable information]* and there will be *[insert number of study participants]* of other people in this study.

***If you will make recordings (e.g., audio/visual) of subjects****, indicate if you will keep the records indefinitely, will share them with other researchers, or use them in presentations or publications, and explain whether the parent/guardian will be given an opportunity to review the recordings or delete any portions. If the study involves the child’s class or instructional time, inform the parent/guardian whether the child will miss any instructional time and what the child will do if they don’t participate in the study]*.

**NOTE: If audio/video recordings will be made include the following statements:**

If you choose to participate in this study, your child *[will be/may choose to be] [audio and/or video]* recorded. Any *[audio and/or video]* recordings will be stored securely and [*insert who will have access*] will have access to the recordings. Recordings will be kept for *[insert length of time]* and then erased.

**If educational records will be accessed:**

* Specify the records that may be disclosed;
* State the purpose of the disclosure; and
* Identify the party or class of parties to whom the disclosure may be made.

***NOTE: If the study involves identifying a health concern and/or an intervention to address a health concern, include the following statement:***

This is a research study and, therefore, not intended to provide a medical or therapeutic diagnosis or treatment. The intervention provided in the course of this study is not necessarily equivalent to the standard method of prevention, diagnosis, or treatment of a health condition.

**For studies that involve invasive procedures using aseptic techniques, include the following statement**:

Aseptic technique includes sterile and/or or disposable equipment (e.g., blood collection apparatus) and adherence to standard medical precautions.

**What you will you be asked to do in the study?**

If you agree to let your child(ren) participate in this research study, you will be asked to [*details about the procedures that the parent, guardian, or legally authorized representative participant will be asked to do if he/she is also a participant in the study or if he/she may have to dedicate time to the study, such as transportation of the child to and from the study site.]*

**What are the risks involved in this study?**

**NOTE: If risks are minimal include the statement:**

There are no expected risks to participating in this study. *Do not state that there are no risks or that risk “should be” minimal.*

**If risks are greater than minimal include the statement:**

This *[treatment, procedure, intervention or describe other]* may involve risks that are currently unforeseeable. Possible risks associated with this study are *[explain risk, including the likelihood of the risk occurring].*

**What are the possible benefits of this study?**

**Note:** *If the study has direct benefits (monetary compensation cannot be categorized as a benefit) include this statement:*

The possible benefits of participation are [*insert benefits that may be reasonably expected*].

*If the study does not have direct benefits to the research participant, include this statement:*

Your child will receive no direct benefit from participating in this study; however, [*explain benefits to society].*

**Source of Funding**

The [*investigator/study team member or the University of Denver*] is receiving *[financial support, OR describe other type of support from [insert sponsor’s name].*

**Financial Interest**

*This section is required when any investigator has a Financial Conflict of Interest.*  *If no one has a Financial Conflict of Interest, this section should be omitted.*

[*Investigator name*] has a financial or other relationship with *[company or sponsor’s name].*

**Incentives to participate**

You and/or your child will receive *[describe any compensation, reimbursement, or incentives being offered for participation]* for participating in this research project.

**Note: Incentives include cash payments, extra credit for class, gift cards, or other goods (i.e., iPads, T-shirts, toys, etc.) provided for participation. Include specific method of payment, schedule of payment, information regarding any prorated payment if study includes multiple sessions or if withdrawing excludes participant from payment. Note that participants are entitled to payment for time invested in the project, even if they withdraw early.**

**Study Costs (if applicable)**

You will be expected to pay for [*description of any costs that might be incurred by participants during the study (e.g., your own transportation, parking, child care, etc.)*. *If this does not apply, delete this section.]*

The University of Denver has not provided for any payment to you for treatment if you or your child are harmed or injured as a result of taking part in this study. *[Note: Include if the study is physical in nature or includes reasonably foreseeable risks of injury. If externally funded, describe any arrangement provided by the sponsor for medical care for research-related injury. If the sponsor will not pay for research-related injury, you may add the sponsor’s name after University of Denver in the statement above (e.g, “The University of Denver and NIH have not provided...”]*

**Alternatives (if applicable)**

*Describe appropriate alternative procedures or courses of treatment that might be advantageous to the research participant. If this does not apply, delete this section.*

**How will your child’s privacy and confidentiality be protected if s/he participates in this research study?**

Your child’s privacy and the confidentiality of his/her data will be protected by *[Describe how participant privacy and confidentiality of participant data will be accomplished and maintained.]. [If the study will collect anonymous data describe how participant anonymity will be accomplished and maintained]*.

**Describe the way you will maintain the confidentiality of records that identify the subject. Use words to the following effect, if appropriate:**

Your child’s name will not be used in any report. Identifiable research data will be encrypted and password protected.

**If you will be coding the data:**

Your child’s responses will be assigned a code number. The list connecting their name to this code will be kept in an encrypted and password protected file. Only the research team will have access to the file. When the study is completed and the data have been analyzed, the list will be destroyed.

**If the study will be anonymous, use words to the following effect:**

The information that you give in the study will be anonymous. Your child’s name will not be collected or linked to your answers.

**If it is possible to deduce the participant’s identity through their responses, state the following:**

Because of the nature of the data, it may be possible to deduce your child’s identity; however, there will be no attempt to do so and your child’s data will be reported in a way that will not identify them.

**If the information will be shared:**

Information that may identify your child may be used for future research or shared with another researcher for future research studies without additional consent. [*Explain]*

**OR**

Information that identifies you will only be used for future research or shared with another researcher after obtaining your consent. [*Explain]*

**OR**

Information collected about your child will not be used or shared for future research studies.

The information that you provide in the study will be handled confidentially. However, there may be circumstances where this information must be released or shared as required by law. Representatives from the University of Denver may also review the research records for monitoring purposes.

An interpreter will be used in this study. *[Describe how you will guarantee that the bilingual interpreter will maintain confidentiality of subjects, who the interpreter works for, and how the interpreter was recruited for your study.]*

**Use of your child’s information for future research**

*One of the following statements is required if any identifiable private information or biospecimens/samples are collected*:

Your child’s information collected for this project will NOT be used or shared for future research, even if we remove the identifiable information like your child’s name or date of birth.

OR

All identifiable information (e.g., your child’s name, date of birth) will be removed from the information or samples collected in this project. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

**Data Sharing**

*(We strongly recommend that you include this section in your consent, to inform participants that you may share de-identified data you collect from them. Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals in a variety of disciplines. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.)*

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information (e.g., your child’s name, date of birth) that could identify your child before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify your child from the information or samples we share. Despite these measures, we cannot guarantee anonymity of your child’s personal data.

**Whom to contact with questions about the study?**

Prior, during or after your participation you can contact the researcher **[INSERT NAME HERE]** at **[PHONE NUMBER]** or send an email to **[EMAIL ADDRESS]** for any questions or if you feel that you have been harmed.This study has been reviewed and approved by The University of Denver’s Institutional Review Board and the study number is **[STUDY NUMBER].**

The Faculty Sponsor overseeing this project is **[Name]** and may be reached at **[phone number and/or email address]**.

**Whom to contact with questions concerning your rights as a research participant?**

For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, the University of Denver (DU) Institutional Review Board by phone at (303) 871-2121 or email at IRBAdmin@du.edu.

**Consent for Accessing Education Records**

Education records used by this research project are education records as defined and protected by Family Educational Rights and Privacy Act (FERPA). FERPA is a federal law that protects the privacy of student education records. Your consent gives the researcher permission to access your child’s records identified above for research purposes. *[If this does not apply, delete this section.]*

\_\_\_\_ **YES**, I give permission to the researcher to access my child’s education records for this research project.

\_\_\_\_ **NO**, I do not give permission to the researcher to access my child’s education records for this research project.

**Consent to video / audio recording / photography solely for purposes of this research**

This study involves video/audio recording, and/or photography. If you do not agree to be recorded, you (CAN STILL/CANNOT) take part in the study*. [If this does not apply, delete this section.]*

\_\_\_\_\_ YES, I agree to allow my child to be video/audio recorded/photographed.

\_\_\_\_\_ NO, I do not agree to allow my child to be video/audio recorded/photographed.

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| --- |
| You are making a decision about allowing your child to participate in this study. Your signature below indicates that you have read the information provided above and have decided to allow them to participate in the study. If you later decide that you wish to withdraw your permission for your child to participate in the study you may discontinue his or her participation at any time. You will be given a copy of this document.**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Printed Name of Child****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_****Signature of Parent/Guardian Date** |

***For Researcher Only: Instructions on parent/guardian signatures.***

**Number of Parent Signatures Required**

*In general, permission should be obtained from both parents before a child is enrolled in research. However, the DU Institutional Review Board (IRB) may find that the permission of one parent is sufficient for research to be conducted under the federal regulations* [*46.404*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.404) *or* [*46.405*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.405) *(research that involves minimal risk to child participants). When research is to be conducted under* [*46.406*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.406) *and* [*46.407*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.407) *(more than minimal risk) permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. If both parents’ signatures are a requirement for IRB approval, adequate documentation must be maintained by the researchers for any case in which both parent signatures are not obtained (e.g., if one parent is deceased).*