**INSTRUCTIONS TO INVESTIGATORS**

This template is for use when obtaining written documentation for research projects **that involve minors over the age of 13** as research subjects.

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

**For older child participants, taking into consideration the age, maturity and psychological state of the child involved and the complexity of the study, it may be best to utilize the Minors Over the Age of 13 assent template if the child can read the form on his/her/their own. The Adult consent template may be modified and used depending on the maturity level of the minor.**

**Be sure to adequately describe the consenting process in the study submission materials and delete the RED text before submitting this form to the IRB.**

**Guidelines for completing this assent 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 make 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.

**Assent Form for Participation in Research**

**Minors Over the Age 13**

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

**IRBNet #:**

**Researcher:** *Name and credentials*

**Faculty Sponsor:** *If student investigator, insert Faculty Sponsor’s name & credentials*

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

**What is a research study?**

A research study is a way to find out new information about something. We would like to learn more about to *[details regarding the study aim or goals of the investigation in simple terms].*

**Do you have to be in the study?**

You do not have to be in this study. It is up to you. You can say okay now to be in the study and change your mind later. All you have to do is tell us when you want to stop. No one will be upset if you don’t want to be in the study or if you change your mind later. You can take time to think about being in the study before you decide.

**Why are you being asked to be part of this research study?**

You are being asked to join the research study because *[insert name of condition or other reason(s) for inclusion]*. About *[approximate number]*other children will be in this study.

**If you join the research study, what will you be asked to do?**

If you agree to join this study, you will be asked to *[describe the procedures (e.g., answer questions, complete activities, give samples, etc.) in words a child would know and understand. Also include number of visits and time frame understood by a child. If there are multiple phases or visits, bullet points may be best to simplify the description.].*

* You will be asked to come see the researcher during the study times at *[location]*, and you will need to stay *[duration (e.g., overnight, for about # hours)].*
* You will have a *[equal chance, one in #]* of getting either *[the treatment, medication, service]*or *[dummy pill, service as usual, no treatment]*, and you will be asked *to [take it, participate, complete it]*for *[duration]*.
* You will be in the study for *[duration of overall participation. Break down into phases or visits if needed.].*
* We will ask you to *[describe procedures (e.g., give blood, answer questionnaires, complete an activity, attend instructional workshops, etc.)].*
* During your first visit, you will be asked to *[describe procedures (e.g., give blood, answer questionnaires, complete an activity, attend instructional workshops, etc.)].*
* During your second visit, you will be asked to *[describe procedures (e.g., give blood, answer questionnaires, complete an activity, attend instructional workshops, etc.)].*
* **If applicable.** We will want to *[audio and/or video]*record you during the study as you *[answer questions or complete the activities].* If you do not want to be recorded, that is okay too. Just tell us if it makes you uncomfortable.

Your parent or guardian will be expected to pay for *[description of any costs that might be incurred by participants during the study (e.g., your transportation, parking, etc.).]*if needed. *[if this does not apply, delete this section]*

There are other ways to help your *[condition or illness]*if you don’t want to be in this study. Examples include…*[Describe appropriate alternative procedures or courses of treatment that might be advantageous to the research participant].*

The University of Denver has not provided for any payment to you or your parent/guardian for your treatment if you 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...”]*

**Will any part of the study hurt or be uncomfortable?**

**Use any of the following statements as appropriate to describe the possible risks or discomforts of the study. Take into account child fears.**

We do not think that you will be hurt or upset during the study.

We think that *[procedure or activity (e.g., blood draws, physical activities, answering questions)]* may *[hurt a little, be uncomfortable, or hard to do].*

**Will the study help you or others?**

**Use any of the following statements as appropriate to describe the benefits of the study.**

We do not know if being in this study may help you.

We think the study will help you by *[describe how in simple terms.].*

We may learn something that will help other children with *[insert name of condition or topic under study]*someday.

**Do your parents or guardians know about the study?**

This study has been explained to your parent or guardian, and they said that we could ask you if you want to be in the study. You can talk this over with your parent or guardian before deciding if you want. You do not have to be in this study even if your parent or guardian thinks it is a good idea. It is up to you.

**Will anyone else know that you are in this study?**

We will not tell anyone else that you are in this study. You do not have to tell anyone about the study or *[the activities, your answers to the questions, etc.]*

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.

*[Note: If the project involves situations that may reasonably elicit a response indicating the existence of child abuse/neglect, suicide ideation, or threatened violence against another specific person, that information must be reported.]*

**Who will see the information collected about you?**

**Use any of the following statements as appropriate to describe the confidentiality of the study.**

The researcher will *[details to protect privacy/confidentiality of subjects*] to keep your information safe throughout this study.

The information collected about you during this study will be kept safely locked up. Nobody will know it except the people doing the research.

The study information about you *[will or will not]* be given to your parents/guardians *[or teachers, principals, doctors].* The researchers will not tell your friends about the study or *[the activities, your answers to the questions, etc.].*

Your individual identity will be kept private when we write our final report. **[We strongly recommend that you include the following statements 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.]** *Other researchers may want to use the information we collect during this study for their research to help other children. We may allow them to use your information without talking with you again.*

**What do you get for being in the study?**

You and/or your parent or guardian will receive *[enter item, goods, or amount for cash or gift card, or details of a lottery opportunity]* for *[each visit, phase, treatment, or entire study].*

**What if you have questions?**

You can ask any questions that you have about the study at any time. Just tell the researcher or your parent/guardian that you have a question. You or your parent/guardian can contact the researcher,*[Researcher Name]*, any time during the study by calling *[phone number]* or emailing *[email address].*

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| ***If your study will include optional parts to which participants can agree or disagree, include a section for participants to indicate their choices in that regard.***  **Options for Participation**  Consent to video / audio recording / photograph soles 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.]*  Please initial your choice for the options below:  \_\_\_ **YES**, I agree to be video/audio recorded/photographed.  \_\_\_ **NO**, I do not agree to be video/audio recorded/photographed. |

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| *Use this section if signed documentation of consent will be obtained.*  Please take all the time you need to read through this document and decide whether you would like to participate in this research study.  If you agree to participate in this research study, please sign below. You will be given a copy of this form.  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**  **Participant Signature Date** |

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| ***Use this section below only if signed consent will not be obtained and waiver of written documentation of assent will be requested through the submission of Appendix A. Be sure to remove the written signature section above.***  **Please take all the time you need to read through this document and decide whether you would like to participate in this research study.**  If you decide to participate, your completion of the [research procedures] indicates your consent. |