## Title of research study: ***[Insert title of research study here with protocol number, if applicable.]***

## Investigator: ***[insert name of principal investigator]***

## What should I know about a research study?

1. This form will explain this research study to you.
2. Whether or not you allow your child to take part is up to you.
3. You can choose not to allow your child to take part.
4. You can agree to allow your child to take part and later change your mind.
5. Your decision will not be held against you or your child.
6. You and your child can ask all the questions you want before you decide.

**Why is this research being done?**

[Tell the parent the purpose of the research. Explain the background of the research problem. Explain any potential benefits of the knowledge gained.]

## Why is my child being invited to take part in a research study?

We invite your child to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects eligible for the research. This should be consistent with inclusion/exclusion criteria outlined in your protocol.]

## What happens if I say yes, I want my child to be in this research?

[Tell the parent what to expect using lay language and simple terms. The procedures described here should be consistent with the procedures in your research protocol. Use bullet points or simple step-by-step language to describe procedures in the order in which they will occur.]

## How long will my child’s part in the research last?

We expect that your child will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event].

## How many children will be studied?

We expect about \_\_\_\_\_ children here will be in this research study.

## What happens if I do not want my child to be in this research? Or, what happens if I say yes, but I change my mind later?

You can decline to take part or remove your child from the research at any time and it will not be held against you or your child. [When applicable, provide specific examples of how refusal to participate or withdrawal will involve no penalty or loss of benefits to which the individual is otherwise entitled. For example, for students recruited in a classroom setting: “Your consent, refusal to consent, or withdrawal of your child from the study will have no impact on your child’s grades or your child’s relationship with his/her teacher.”

[Include if there are alternatives other than participating. Otherwise delete.] Instead of allowing your child to be in this research study, your choices may include: [List alternatives procedures. For students in classroom settings describe what will occur if the child does not take part in research activities, when applicable.]

## Is there any way being in this study could be bad for my child?

[Describe risk to subjects and ensure that risks are consistent with those identified in your protocol. If known, describe the probability and magnitude of the risk. Explain any steps the researchers are taking to minimize these risks.]

[If there are no risks or discomforts anticipated, this should be simply stated.]

## Will being in this study help my child any way?

[If there are no benefits anticipated, this should be simply stated.]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you, your child, or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Then describe the potential benefits of participation. First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Compensation or payment for participation is not a benefit.]

## What happens to the information collected for the research?

***[Clearly outline how the data is managed during collection and analysis (e.g., coding, de-identification, etc.). Inform subjects how their data may be presented in the results or findings (e.g., by name, use of pseudonyms, etc.). Describe the final disposition of the data - that is, what you will do with the data when the study is completed. If identifiable data will be kept indefinitely, this needs to be explicitly stated. If the researchers are collecting audio or video data, explain how the data may be transcribed, if identifiable information will be included in the transcription process, and if/when the audio or video files will be destroyed. The IRB requests that study records (e.g. consent forms, etc.) be kept for a period of 3 years following the completion of the study.]***

***[If data will be retained after the study for future research, explain where the data will be stored, who will have access to the data or specimens, and how long the date will be retained.]***

***[For focus groups, the researchers should clearly explain the limits of their ability to keep information confidential. A statement should be included to instruct participants not to disclose responses and/or the identities of other participants during or after the study.]***

Efforts will be made to limit the use and disclosure of your child’s personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Your child’s information may be reviewed by MSU Denver’s Institutional Review Board (IRB) that oversees human research or by other authorized representatives of MSU Denver. [Add to this list other organizations that may have access to the subject’s records such as the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

## What else do I need to know?

[Describe any plans to gain assent from child subjects in addition to parental consent.]

[Include for sponsored research. Otherwise delete.] This research is being funded by [Insert name of sponsor].

 [Include if subjects will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount] for your time and effort. [Explain the timing and circumstances of payment. Indicate if the amount is pro-rated for research visit completion.]

[Include if subjects may incur any costs for participation. Otherwise delete.] If you agree to take part in this research study, there may be some cost to you. This includes \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [If subjects are provided a referral for a service, such as follow-up counseling, please inform them of who would be responsible for payments.]

You will be provided a copy of this form to keep. [For studies that do not document consent, modify this to “You may keep this consent form.” For consent language provided online, “Please print a copy of this consent form for your records.”

## Who can I talk to about this research?

We will answer any questions you or your child may have about this study. If you have questions, concerns, or complaints, or think the research has harmed your child, talk to the research team at [Insert contact information for the research team. At a minimum, the name and contact information of the Principal Investigator should be included. Student researchers are advised to limit contact details to official University email addresses.]

This research has been reviewed and approved by an Institutional Review Board (IRB). If you would like to talk with someone other than the researcher(s), have questions about your child’s rights as a study participant, or have questions or complaints that are not being answered by the researchers, please contact MSU Denver’s Human Subjects Protection Program at 303-352-7330 or by email at hspp@msudenver.edu.

**Signature Block for Children**

 [Omit the signature block if there is no written documentation of consent.]

[In some studies specific permissions may need to be obtained and documented in addition to the general consent to participate – such as, optional procedures, permission to identify subjects in results, permission to be re-contacted for future studies, etc. Add these to the signature block when needed. For data collection involving audio, video, or photographs, a separate release form may be used or permissions can be built in to the signature block.]

|  |
| --- |
| The IRB has determined that the permission of one parent is sufficient.Your signature documents your permission for the named child to take part in this research.  |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent |  | Date |
|  |  |
| Printed name of parent |

 ***[Add the following block if you will document assent of children]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

 ***[Add the following block to all consents]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

***[Add the following block if a witness will observe the consent process. The use of a witness must be fully described in your protocol. A witness is required when using a short form of consent documentation or when enrolling blind or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject’s parent, and that consent was freely given by the subject’s parent. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

***[For studies that propose to gain consent from an individual other than the parent (e.g. a legal guardian), use the more detailed language related to documentation below in place of the “parent” signature block above.]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  | * Parent
* Individual legally authorized to consent to the child’s general medical care (See note below)
 |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. |
| ***[For studies that require permission of both parents when reasonably available, add the checkboxes below to document cases when this cannot occur.]*****If signature of second parent not obtained, indicate why: (select one)** |
| * Second parent is deceased
* Second parent is unknown
* Only one parent has legal responsibility for the care and custody of the child
 | * Second parent is incompetent
* Second parent is not reasonably available
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