## Title of Research Study: [Title of Study]

## Investigator: [Researcher Name]

## Supported By: [Sponsor name]

## What is research?

## Doctors and researchers are committed to your child’s care and safety. There are important differences between research and treatment plans:

## The goal of research is to learn new things in order to help groups of people in the future. Researchers learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

## The goal of treatment is to help you get better or to improve your quality of life. Doctors can make changes to your treatment plan as needed.

## Why am I being asked to take part in this research study?

We are asking you and your child to take part in this research study because you are the parent of a child [describe the inclusion criteria].

## What should I know about being in a research study?

* Someone will explain this research study to you.
* Whether or not your child takes part is up to you and your child.
* You can choose not to have your child take part.
* You can agree to take part and later change your mind.
* Your decision will not be held against you.
* You can ask all the questions you want before you decide.

## Who can I talk to?

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

|  |  |
| --- | --- |
| Researcher Name:Researcher Affiliation:Phone Number:Email Address: | Study Staff (if applicable):Phone Number:Email Address: |

To reach **the research team:** Please see the “Investigator Contact Information” section at the beginning of this form.

To reach someone outside of the research team: This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your or your child’s research experience, call the Research Participants’ Advocate Line at 612-625-1650 (toll free: 1-888-224-8636) or go to [z.umn.edu/participants](https://research.umn.edu/units/hrpp/research-participants/questions-concerns). You are encouraged to contact the HRPP if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You are having difficulty reaching the research team.
* You want to talk to someone besides the research team.
* You have questions about your or your child’s rights as a research participant.
* You want to get information or provide feedback about this research.

## Why is this research being done?

The purpose of this research is to learn more about:

[(1) Tell the participant the purpose of the research in terms that can be understood by people not in the medical field.

(2) Explain the background of the research problem.

(3) Explain any potential benefits to others.

(4) If the study involves an investigational drug and/or device, state this and specify that investigational means that the drug or device is not approved by the FDA or not approved for the indication under investigation.]

## How long will the research last?

We expect that your child’s participation in this research study will last [insert duration (minutes, hours, days, etc)], and your participation will last [insert duration (minutes, hours, days, etc)].

## How many children / parents will be studied?

We expect about [N#] children will be in this research study. [If the study involves the parents as participants in addition to the children, include how many parents are expected to be in this study. For multisite studies, tell how many anticipate to enroll in the whole study, and how many we expect to enroll at your site/hospital.]

## What happens if I say “Yes, I want to be in this research”?

[In terms that can be understood by people not in research or medicine, tell the parent what to expect using lay language and simple terms. Whenever appropriate include the following items:

* A timeline description of the procedures that will be performed. If practical, prepare a timeline or schedule of procedures to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits.
* The drugs or biologics that will be given to the participant.
* All devices that will be used.
* All hospitalizations, outpatient visits and telephone or written follow-up.
* The length and duration of visits and procedures.
* If blood will be drawn, indicate the amount [in English units] and frequency.
* With whom the participant will interact.
* Where the research will be done.
* When the research will be done.
* List experimental procedures and therapies and identify them as experimental.
* How often procedures will be performed.
* What is being performed as part of the research study.
* What is being performed as part of standard care.
* What procedures are part of regular medical care that will be done even if the participant does not take part in the research.
* What are the expectations of the participants/parents? (complete surveys, drug diaries, etc.)
* When applicable, indicate that the participant will be asked to be contacted for future research.
* When applicable describe if audio or video recording any research activities. Include if agreement to be recorded is required for participation or if it is optional.

[Include this statement for a clinical trial or other research that involves randomization. Otherwise delete.] The treatment your child gets will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment your child will get. You will have a(n) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal / one in three /etc.] chance of being given either treatment.

[For double-blinded research add] Neither you nor the study doctor will know which treatment your child is getting.

[For single blinded research add]You will not be told which treatment your child is getting, however your study doctor will know.

## What happens if I do not want to be in this research?

You and your child may decline to participate and it will not be held against you. [Include if there are alternatives other than participating. Otherwise delete.] Instead of being in this research study, your choices may include: [List alternatives procedures. For clinical trials, describe the options that you would normally offer a patient. If applicable, include supportive care as an option.]

## What happens if I say “Yes”, but I change my mind later?

You and your child can leave the research at any time and it will not be held against you.[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] **I**f you decide to leave the research, [Describe the adverse consequences.]

If you decide to leave the research, contact the investigator so that the investigator can [Describe the procedures for orderly termination by the participant, if any.]

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Meaning, your choice not to be in this study will not negatively affect your child’s right to any present or future medical treatment.

At any time, you or your child may decide to withdraw from the study. If you withdraw, no more information will be collected from you or your child. When you indicate that you wish to withdraw, the information already collected from you and your child will be used in the study because they will not be able to remove it from the information they have gathered. [If applicable, otherwise remove.] The investigator may ask to continue to collect information from your child’s routine medical care, such as your child’s medical records.

## What are the risks? Is there any way being in this study could be bad for me or my child?

[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk to the child. The risks of procedures may be presented in a table form.]

● Physical risks

* reproductive risks

● Psychological risks

● Privacy risks

● Legal risks

● Social risks

● Economic risks

● Group or community risks

Distinguish between the risks presented by participation in the research and the risks associated with any procedures or treatments that would occur regardless of participation in the research. Also, in general, do not include results of animal studies, unless there is no other known risk information and inclusion would aid with understanding.]

This research may hurt your child in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise delete.]In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Studies that include questionnaires or interview questions about mental health, psychological functioning, or mood, or includes participants that are at elevated risk of suicide, must include the following or similar language. Otherwise, delete.]

“As part of the research, we may ask questions about how <you feel> <your child feels> mentally and emotionally. We are providing a list of resources to you <your child> in case you <they> would like to talk to someone and get help.  If you are thinking about hurting yourself or someone else, please tell someone who can help immediately. Call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) to talk to a counselor near you.”

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

Efforts will be made to limit the use and disclosure of you and your child’s personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. The video recorded conversation is for data analysis purposes only. It will not be used in any presentations or publications.

We may publish the results of this research or share the resulting data. However, we will keep your name and other identifying information confidential.

[Describe any plans for the information collected, including general information about data storage and sharing of information outside of the study team including funding agencies or sponsors.]

We will not ask about child abuse, but if your child tells us about child abuse or neglect, we are legally obligated to report it to state authorities.

[Studies that include questionnaires or interview questions about mental health, psychological functioning, or mood, or includes participants that are at elevated risk of suicide, must include the following or similar language. Otherwise, delete.]

Anonymous Surveys (results are NOT individually identified):“We will not be able to link your responses to you <your child>, so we will not be able to provide you <your child> with personal feedback or referrals based on your <your child’s> responses to questions. If you are concerned about your <your child’s> mood, please refer to the attached resource referral information sheet. Please tell someone who can help right away. You can call also call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) to talk to a counselor near you.”

Results Individually Identifiable/In-Person:“The study team may break confidentiality in an effort to keep you <or your child> safe, which may include informing parents, local authorities, and/or health care professionals.”

“If <you tell> <your child tells> us that you <they> are thinking about hurting yourself <themself> or others, the research staff may ask more questions. Depending on how intense your <their> thoughts are or how much you <they> feel like hurting yourself <themself> or others, the research staff may give you <them> referrals for treatment, work with you <them> to contact a personal doctor, trusted family member, or therapist to discuss your <their> thoughts of harming yourself <themself>. We may need to work with you <them> on a plan that might include getting to a medical facility for safety.”

**Will anyone besides the study team be at the consent meeting?**

You may be informed by the study team that an auditor may observe the consent meeting (or a recording of the consent meeting– only applicable if consent meetings are being systematically recorded by the study team for this study). Observing the consent meeting is one way that the University of Minnesota makes sure that the rights of research participants are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not record any personal (e.g. name, date of birth) or confidential information about you or your child. The auditor will not observe the consent meeting (or a recording of the consent meeting [remove if not applicable – only applicable if consent meetings are being systematically recorded by the study team for this study]) without your being informed ahead of time.

## Will I have a chance to provide feedback after the study is over?

After the study, you might be asked to complete a survey about your child’s experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey after the study is over, but you would like to share feedback, please contact the study team or the Human Research Protection Program (HRPP). See the “Who Can I Talk To?” section of this form for study team and HRPP contact information.

## What else do I need to know?

[Revise to align with the protocol.] You or your child will be paid [amount] for their participation in this study. We will also reimburse you [amount] (if taking public transportation) or a free parking pass (if driving) to cover the costs of your transportation. All payments will be given directly to you.

If for any reason you and your child do not complete the whole study, you will still receive the full payment and travel reimbursement.

If your child becomes an adult (turns 18 years old or meets the legal definition of an adult found in Policy HRP-112) while they are still actively participating in this research, they will need to provide their consent (agreement) to continue their participation in this study by signing a consent form. (Delete if not applicable).

[Note: include this paragraph if the study is taking place in a school:

Parents please be aware that under the Protection of Pupils Right Act 20 U.S.C. Section 1232 (c)(1)(A), you have the right to review a copy of the questions asked of or materials that will be used with your students. If you would like to do so, you should contact <Name of PI> to obtain a copy of the questions or materials.]

Your signature documents your permission for you and the named child to take part in this research.

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Printed name of child participant

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Printed name of parent [ ] or guardian [ ] Date

to consent for the child to participate

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

Signature of parent [ ] or guardian [ ] Date

to consent for the child to participate

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

Signature of person obtaining consent and assent Date

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

Printed name of person obtaining consent and assent

**Witness Statement (if applicable)**
The parent/guardian was unable to read or sign this consent form because of the
following reason:
☐The parent/guardian is unable to read the information
☐The parent/guardian is visually impaired
☐The parent/guardian is non-English speaking
☐The parent/guardian is physically unable to sign the consent form. Please describe:
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☐Other (please specify):
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For the Consent of Non-English Speaking Participants when an Interpreter is
Used:
As someone who understands both English and the language spoken by the
parent/guardian, I represent that the English version of the consent form was presented
orally to the parent/guardian in the parent/guardian’s own language, and that the
parent/guardian was given the opportunity to ask questions.
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Interpreter Date
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Printed Name of Interpreter

OR:

Statement from a Non-Interpreter:
As someone who understands both English and the language spoken by the
parent/guardian, I represent that the English version of the consent form was presented
orally to the subject in the parent/guardian’s own language, and that the parent/guardian
was given the opportunity to ask questions.
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Individual Date
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Printed Name of Individual