

Parental Permission to Participate in Research

You are being asked to allow your child to participate in a research study. Before you agree, you must be provided with a summary of the research study. This summary must contain the key information to help you understand the reasons why you might or might not want your child to join the study.

Before you agree, the investigator must tell you about:

- (i) the purposes, procedures, and duration of the research;
- (ii) any procedures which are experimental;
- (iii) any reasonably foreseeable risks, discomforts, and benefits of the research;
- (iv) any potentially beneficial alternative procedures or treatments; and
- (v) how confidentiality will be maintained; and
- (vi) who to contact with questions, complaints, and injuries.

Where applicable, the investigator must also tell you about:

- (i) any available compensation or medical treatment if injury occurs;
- (ii) the possibility of unforeseeable risks;
- (iii) circumstances when the investigator may halt your child's participation;
- (iv) any added costs to you or your child;
- (v) what happens if you decide to stop your child's participation;
- (vi) when you will be told about new findings which may affect your willingness to allow your child to participate;
- (vii) how many people will be in the study; and
- (viii) how you need to authorize use of your child's medical information for the study.

You child's participation in this research is voluntary, and your child will not be penalized or lose benefits if you refuse to allow your child to participate or decide to stop. Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to allow your child to participate. If you agree to allow your child to participate, you must be given a signed copy of this document and a written summary of the research in English.

Questions?

If you have questions, complaints, injuries, or concerns about this study, you can contact the investigator using the phone numbers in the written study summary. If you have questions regarding your child's rights as a research participant, or if you have questions, complaints or concerns which you do not feel you can discuss with the investigator, please contact the University of Utah Institutional Review Board Office by using the phone number or email address in the written study summary.

Child's Name

Name of Parent/Guardian

Signature of Parent/Guardian

Date

Relationship to Child for Parent/Guardian

I confirm that I was present as an interpreter for the duration of the consent process for this research study. I confirm that I am qualified and have the necessary skills to provide interpretation between the parent/guardian's language and English. By signing this form, I confirm that I provided a full and complete interpretation of the exchange between the researcher obtaining consent and the participant's parent/guardian, to the best of my ability.

Name of Interpreter

Signature of Interpreter

Date

IMPORTANT: The following signature block for the 2nd parent should not be included unless requested by the IRB.

Name of 2nd Parent/Guardian

Signature of 2nd Parent/Guardian

Date

Relationship to Child for 2nd Parent/Guardian

Permission cannot be obtained from the second parent/guardian because (please check which one applies to the situation, 45 CFR 46.408):

- The parent/guardian is deceased.
- The parent/guardian is unknown.

Must be used with an English version of the full consent document approved by the IRB

- The parent/guardian is incompetent.
- The parent/guardian is not reasonably available.
- Only one parent has legal responsibility for the care and custody of the child