IRB Parental Consent Form for Children Aged 0 to 7 Years (Sample)

Project Information

Project Title:
Version & Date:
Sponsor Details if any:
Principal Investigator Name: **Organization:** SMBB Institute of Trauma
Other Investigators Details: **Organization:**

Introduction

This form provides you, as the parent or guardian of a potential research study participant, with information that may impact your decision about allowing your child to participate in this research study. The researcher will explain the study and answer any questions. Please read the following information carefully and ask any questions before deciding if you wish to provide permission for your child to participate. Should you agree, this form will record your consent.

Purpose of the Study

If you agree, your child will participate in a research study on [insert a brief description of the study]. The study's purpose is to [explain the research questions and objectives in plain language].

What is my child going to be asked to do?

If you allow your child to participate, they will be asked to:

- [List tasks, such as completing surveys, interviews, tests, or focus groups, as relevant to the study]

This study will last approximately [insert study duration, frequency of procedures, etc.]. The study includes approximately [insert number of participants].

Note: If the study involves a health intervention, please note that this is a research study and not intended for medical consultation, diagnosis, or treatment. You may continue seeing your child's physician as usual. For studies involving aseptic techniques or invasive procedures, please note that sterile equipment and standard precautions will be followed.

If your child will be recorded: Your child [will or may] be audio or video recorded.

What are the risks involved in this study?

If risks are minimal:
There are no foreseeable risks associated with participating in this study.

If risks exceed minimal levels:
This study involves [describe treatment, procedure, or other aspects of the study]. Possible risks include [describe risks and likelihood of occurrence].

What are the possible benefits of this study?

If there are direct benefits to participation, they include [describe any expected benefits]. If there are no direct benefits, note: Your child will not directly benefit from participating in this study; however, [describe the anticipated broader impact or benefits to society].

Does my child have to participate?

No, participation in this study is entirely voluntary. Your child may choose not to participate or may withdraw at any time without penalty. Withdrawal will not affect your child's treatment or relationship with SMBB Institute of Trauma in any way. You can agree now and change your mind later without any consequences.

If applicable:
If this study occurs during classroom activities, alternate activities are available if you prefer that your child not participate.

What if my child does not want to participate?

Your child's participation also requires their agreement. If your child does not want to participate, they will not be included, and there will be no penalty. If they agree initially, they can still withdraw later without penalty.

Will there be any compensation?

If no compensation is offered:
Neither you nor your child will receive any payment for participating in this study.

If compensation is offered:
[You/Your child] will receive [describe any payment, reimbursement, or credit provided].
Payment will be distributed according to [explain terms of payment, including any conditions for partial or full payment].

How will your child's privacy and confidentiality be protected?

Your child's privacy and data confidentiality will be safeguarded by [describe measures to maintain data security and privacy]. If data will be anonymous, explain how anonymity will be ensured. Your child's study records will not be shared without your permission unless required by law. The Ethics Review Committee may review study records, and your child's identifying information will be protected as permitted by law. Any data shared with other researchers will be anonymous, containing no information that could identify your child.

Whom to contact with questions about the study?

If you have questions before, during, or after participation, please contact the researcher, [INSERT NAME], at [PHONE NUMBER] or via email at [EMAIL ADDRESS]. This study has been reviewed and approved by the SMBB Institute of Trauma Ethics Review Committee.

Signature

You are deciding whether to allow your child to participate in this study. By signing below, you indicate that you have read the information provided and have decided to allow your child to participate. You may withdraw your permission at any time. A copy of this document will be provided to you.

- **Child's Name:**_____
- **Name of Parent(s) or Legal Guardian:** _____
- **Signature of Parent(s) or Legal Guardian:**_____
- **Date:**_____
- **Name of Person Obtaining Consent:**_____
- **Signature of Person Obtaining Consent:**_____
- **Date:**_____

For Participants Unable to Read

Witness Statement:
I confirm that I accurately read the consent form to the participant and that they had the opportunity to ask questions. The participant gave consent freely.

- **Witness Name:**_____
- **Witness Signature:**_____
- **Participant's Thumbprint:**_____
- **Date:**_____