You are being asked to take part in a research study.

Before you agree to take part, someone will explain to you:

- Why you are being invited to take part in a research study
- What you should know about the research study
- Why this research is being done
- How long the research will last and what you will need to do
- Any ways being in this study could be bad for you
- Any ways being in this study could help you
- What happens if you do not want to be in this research
- Who you can talk to
- How many people will be studied
- What happens if you say yes, you want to be in this research
- What your responsibilities are if you take part in this research
- What happens if you say yes, but you change your mind later
- What happens to the information collected for the research
- Whether you can be removed from the research without your OK
- Anything else your need to know

Who can I talk to?

- If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team at (555) 555-1213 or researchteam@organization.org.
- This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (555) 555-1212 or irboffice@organization.org if:
    - Your questions, concerns, or complaints are not being answered by the research team
    - You cannot reach the research team
    - You want to talk to someone besides the research team
    - You have questions about your rights as a research subject
    - You want to get information or provide input about this research

When applicable, someone will explain to you:

- Whether you will get treated or paid if injured
- The possibility of unknown risks
- When you may be taken off the research without your agreement
- Added costs from taking part
- What will happen if you stop taking part
- Steps to safely stop taking part
- When new information will be told to you
- The number of people expected to take part
- That the Food and Drug Administration may inspect the records
- What happens to collected data if you stop taking part
- An explanation of www.ClinicalTrials.gov

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject	
Signature of legally authorized representative	Date
Printed name of legally authorized representative	
Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Signature Block for Children

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

Printed name of child

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.

Signature of parent

Date

Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

- ❑ The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

Signature of witness to consent process

Date

Printed name of person witnessing consent process