

**RESEARCH SUBJECT  
INFORMATION FORM**

**Protocol Title:** (In English) Full Title of Protocol

**Principal Investigator:** (In English) Name and phone number

**Emergency Contact:** (In English) Name and contact phone, cell phone or pager number

You are being invited to participate in a research study.

Before you agree, the investigator must explain a number of things to you. These things include:

- The purpose of the study
- How many people will be enrolled in the study and how long the study will last
- The tests, procedures or treatments that will be done
- Which tests, procedures or treatments are experimental
- Any risks from the study. There may be risks from a study drug or device, or from a study test or procedure
- If the study will benefit you in any way
- How you will be told if there is new information about the study that could affect your decision to continue with the study
- Other options you have rather than participating in the study
- What to do if you are injured or hurt during the study
- Whether there are any costs to you for participating
- Whether you will be paid anything for participating
- Reasons the investigator may halt your participation in the study
- Who can see or use information about you from the study
- How your information and privacy will be protected

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your participation in this research study is voluntary. If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care. If you have questions about your participation in this research study or about your rights as a research subject, make sure to discuss them with the study investigator or members of the study team. You may also call the IRB Office at The Children's Hospital of Philadelphia at (215) 590-2830 to talk about your rights as a research subject.

You will be asked to sign this form to show that

- the research study and the information above have been discussed with you
- you agree to participate in the study

You will receive a copy of this signed form and the summary of the study that will be discussed with you.

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Subject's Name **[print]**

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Subject's Signature (18 years or older)

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Date

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Parent/Guardian Name **[print]**

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Parent/Guardian Signature (children < 18 years)

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Date

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**Witness/Interpreter**

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

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Witness/Interpreter Name **[print]**

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Witness'/Interpreter's Signature

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Date