

**REMOVE THIS FIRST PAGE PRIOR TO GIVING CONSENT  
TO THE POTENTIAL SUBJECT.  
IT IS FOR INVESTIGATOR INFORMATION ONLY.**

**SHORT FORM CONSENT  
Consent to Participate in Research – Short Form**

1. The UTCOMC/EHS preferred consent policy is that an investigator use an IRB-approved translated full consent form in the language of the subject. You should only be using this short form in the event that there is an unanticipated need for consent in this subject's language.
2. If you obtained this short form from the IRB website, the translation is approved. If there is not an IRB-approved short form on the website in the language the investigator needs for this subject, the investigator will need to have a short form translated by a certified interpreter and then approved by the IRB.
3. **The PI or the protocol-approved designee is a certified translator and explains the consent in the subject's language.**
  - The PI or designee signs both English and translated short form and the consent form.
  - The subject signs the short form in his/her native language.
  - The subject is given signed copies of the short form and the English consent.
  - The witness to the process signs the document in the language the witness understands.
4. **The PI or the protocol-approved designee requires a certified interpreter to explain the protocol in the appropriate language.**
  - The PI or designee signs the English version.
  - The translator signs the English version and the translated short form.
  - The subject signs the short form in his/her native language.
  - The subject is given signed copies of the short form and the English consent.
  - IF the translator is in the room, he/she may serve as the witness. If a phone interpreter is used, there needs to be a separate witness to the process in the room.

**THIS DOCUMENT MUST BE WRITTEN IN YOUR LANGUAGE**

**SHORT FORM CONSENT  
Consent to Participate in Research – Short Form**

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Title of Study/IRB number

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Principal Investigator

Phone number

Printed Name of Subject \_\_\_\_\_

**Introduction**

At the UT College of Medicine Chattanooga and Erlanger Hospital there are a number of research studies being done. The goal of research, in general, is to gain new knowledge. The University and Erlanger engage in research activities to foster new knowledge and to improve health care.

You are being asked to take part or allow your child to take part in a research study. Taking part in research is **voluntary**. We encourage you to take time to talk about the research study with family and friends. When this consent refers to “you,” it can be assumed it implies “you or your child.”

Whether or not you take part, you will continue to receive the best of care at this hospital. Your decision will not affect the care you receive.

Before you decide if you want to take part in a research study, the researchers will give you information. The information will help you decide if you want to be included in this research.

**What do you need to know before you make a decision about taking part in research?**

• **WHY the research study is being done**

Before you make a decision the researchers will tell you why the research study is being done. They will explain what the researchers hope to learn from this study.

• **WHAT will happen in the research**

The researchers will tell you:

- How long the study will last.
- What will happen if you take part.

- If any of the procedures or medications or tests are experimental.
- How the research study differs from the usual care you would receive.

- **What are your OPTIONS**

Some research studies, but not all, provide care and treatment. The researchers must tell you about all of your treatment and care options. You need to know what your care choices are before you agree to be in a research study.

**What are the RISKS of the research study**

The researchers will tell you:

- What are the risks to you if you take part.
- How the risks of the research compare to the risks of standard care.
- Whether there may be risks that are not known at this time.
- What will happen if there is a research related injury and who will pay for treating the injury.

- **What are the BENEFITS of the research study**

The researchers will explain if the research offers benefits to you. They will tell you if the research might benefit future patients or society.

- **You need to know about CONFIDENTIALITY**

The information researchers learn about you is confidential. The researchers will tell you who will receive information about you and others taking part. This information is called research data.

When a research study is testing experimental drugs or devices, two groups will receive the research data. One group is the U.S. Food and Drug Administration (FDA). The FDA is responsible for the safety of drugs and medical devices used in the U.S. The other group is the company making the experimental drug or device. The FDA and the company may review your medical records to check the research data. All information about you sent to the company or FDA is confidential.

- **You need to know about COSTS**

You will be told if there are additional costs to you from taking part in the research.

**What if you don't want to take part? What if you want to stop?**

**Taking part in research is voluntary.** It is OK to say no. If you start, you can stop taking part at any time. There is no penalty or loss of benefits for saying no or for stopping early.

Also, the researchers can take you off the study. They will do so if it is in your best interest. If they stop the study, they will explain to you the reasons why.

**What if you want to take part?**

If you want to learn about the research study you will meet with a researcher. This researcher, with the help of a certified interpreter, will tell you about the study. You are encouraged to ask questions! If you want to take part, you will be asked to sign this form. You will be given a copy of the signed form to keep. You will also be given a copy of the English consent form that describes this study. The researcher will sign the English form.

For questions about the research study, call the researchers at the telephone numbers on the first page of this form. Leave your name and telephone number and the researcher will return your call with an interpreter.

**If you/your child have an emergency related to being in the research study, call 911.**

Persons taking part in research have rights. (The last page of this form tells you about the rights of persons taking part in research). If you have questions about these rights, you may call the IRB at 423-778-3818. The IRB is the committee that reviews and approves research and is responsible for protecting the rights of people taking part in research. Leave your name and telephone number and a member of the IRB will return your call with an interpreter.

Participant/Parent/Legal Guardian's Statement

I have been given an oral presentation of the research study. An interpreter fluent in my language has been present during the oral presentation. I have had the chance to ask questions. I understand that the persons listed on the first page of this form will answer any future questions I have about the study or about research participants' rights. I know the number to call if there is an emergency. I voluntarily agree to take part or allow my child to take part in this research study.

PLEASE NOTE: If the participant to be involved in this research study is a foster child or a ward of the state please notify the researcher or their staff who is obtaining your consent.

\_\_\_\_\_  
Printed Name of Research Participant

\_\_\_\_\_  
Signature of Research Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Printed Name of Parent or Legal Guardian (if subject is younger than 18 years old)

\_\_\_\_\_  
Signature of Parent or Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

Interpreter Information (if interpreter is not part of the research team as approved by the IRB)

\_\_\_\_\_  
Name of Interpreter  
(If interpreter is used during initial presentation of the study)

\_\_\_\_\_  
Signature of Interpreter  
(If interpreter is used during initial presentation of the study)

\_\_\_\_\_  
Date Time

Witness Statement

I have been present during the oral presentation of this research study. (The interpreter may serve as witness if he/she was present in the room; a phone interpreter may not serve as witness.)

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date Time

Investigator/Designee Signatures

I have carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the person who is signing this consent form understands clearly the nature, demands, benefits, and risks involved in his/her participation and his/her signature is legally valid. A medical problem or language or educational barrier has not precluded this understanding.

\_\_\_\_\_  
Date/Time Printed Name of Staff Explaining Signature of Staff Explaining Consent

I certify that the Informed Consent was obtained correctly.

\_\_\_\_\_  
Date/Time Printed Name of Investigator Signature of Principal Investigator

**(This form must be included in all consent forms)**  
**CONSENT TO RELEASE INFORMATION**

Patient's Name: \_\_\_\_\_

Patient's Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Telephone No.: \_\_\_\_\_

SS#: \_\_\_\_\_

Release of Information to \_\_\_\_\_,

I authorize the release of medical information from:

\_\_\_\_\_  
Name of Physician, Institution, etc.

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State, Zip

Please send information requested below to: *(Insert Physicians Address, Phone and Fax Number)*

Reason for Disclosure: *Treatment information, long-term follow-up & survival status.*

\_\_\_\_\_ Research Study

I have read, or have had read to me, the above statements, and understand them as they apply to me. I further understand that I may revoke this consent at any time, except to the extent that action has already been taken in accord with this consent.

\_\_\_\_\_  
Signature of Patient or Authorized Agent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Relationship to Patient

## Research Participant's Rights\*

**Every person who is asked to be in a research study has rights.** As a research participant, you (or your child) have the following rights:

1. To be told what the study is trying to learn,
2. To be told what will happen to you or your child during the study. To be told whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3. To be told about the frequent and important risks, side effects, or discomforts of the things that will happen to you or your child during the research study,
4. To be told if you or your child can expect any benefit from participating, and, if so, what the benefit might be,
5. To be told of the other choices for care you or your child have and how they may be better or worse than being in the study,
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7. To be told what sort of medical treatment is available if any complications arise,
8. To refuse to participate at all or to change your mind about participation or your child's participation after the study is started. This decision will not affect your or your child's right to receive the care you or your child would receive if not in the study,
9. To receive a copy of the signed and dated consent form,
10. To be free of pressure when considering whether you wish to agree to be in the study or agree for your child to be in the study.

\*Adapted from the State of California Experimental Subject's Bill of Rights