For IRB Approval Stamp

# **INFORMED CONSENT**

## TITLE OF RESEARCH STUDY

Sponsor assigned number:

Industry Contracts number:

Grants number:

Sponsor(s) name & address:

IRB assigned number:

Investigator(s) Name, Degree, University Department & address:

Site(s) where study is to be conducted:

Phone number for subjects to call for questions:

### NOTE: Use the Instruction Sheet for each section as it contains required language that may not be located within this template. Delete this notation when completing the consent.

### Introduction and Background Information

You/Your child (referred to as you in the rest of this document) are invited to take part in a research study because you have been diagnosed with\_\_\_\_. The study is being conducted under the direction of \_\_\_\_\_ (list degree) at the University of Louisville**.** About \_\_\_\_ local subjects will be invited to take part in this research. The total number of subjects across all sites will be \_\_\_.

### Purpose

The purpose of this study is

### Procedures

Your participation in this study will last for \_\_\_\_\_. If you consent to participate, you will have the following procedures while you are in this study.

### Potential Risks

\*This table of risks may be included as an Appendix to the consent. Remove this notation.

The following table details the known risks related to this research and how often they may occur.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Very Common  Greater than 10% | Common  Between 1% and 10% | Uncommon But Serious  Between 0.1% and 1% | Rare But Serious  Between 0.01% and 0.1% | Very Rare But Serious  Less than 0.01% |
| Very Common  Greater than 50**%** | Common  Between 25% and 50% | Likely  Between 10% and 25% | Infrequent  Between 1% but and 10% | Rare But Serious  Less than 1 % |
| (%) | (%) | (%) | (%) | (%) |
|  |  |  |  |  |

There may also be other procedures required as part of the study. The risks associated with these procedures are

Other possible risks to you may include

Studies in animals have shown

In addition, you may suffer harms that we have not seen before.

**Possible Pregnancy Risks**

You should discuss pregnancy risks with your doctor before signing this consent form. Women who are pregnant or breast feeding may not participate in this research study. If you are pregnant or become pregnant, your unborn child may suffer harms that we have not seen before. If you (or your partner) become pregnant while in this study, the sponsor may ask to follow the outcome of the pregnancy. If you agree to allow the study doctor to follow your pregnancy, you will be asked to read and sign a separate consent form for permission to follow the outcome of your pregnancy.

If you are a man taking part in the study and your partner becomes pregnant, the study doctor may ask you to ask your partner for permission to follow her pregnancy. If she agrees, she will be asked to sign a separate consent form mentioned above.

Before starting this research study, females able to have children will have a pregnancy test. Talk to your doctor about the best method of birth control to use while you are in this study. It is important that you call your study doctorat \_\_\_\_\_ right awayif you become pregnant or father a child during the course of this study. If you or your partner becomes pregnant, a decision may have to be made whether or not to end the pregnancy.

We do not know the effects of <study drug name> on an unborn baby. There is a risk that your unborn baby could be harmed if you become pregnant during your participation in the study. (If you ask, your study doctor will discuss the possible risks to your unborn child and your options should you become pregnant while in this study.)

### Research Involving Genetic Information \*See instructions for whether or not this statement is needed in the informed consent. If not, remove the heading and paragraph.

### Benefits

### The possible benefits of this study include

### Alternatives

Instead of taking part in this study, you could choose to

**Research Related Injury**

\*Choose from the statements included in the consent form instructions and then remove this notation.

### Compensation

\*Choose from the statements included in the consent form instructions and then remove this notation.

### Costs

\*Choose from the statements included in the consent form instructions and then remove this notation.

**HIPAA Research Authorization**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for protected health information (PHI). Examples of PHI are your name, address, and birth date. PHI may also include your medical history, results of health exams and lab tests, drugs taken and results of this research study. Your PHI may not be used or shared without your agreement, unless it meets one of the HIPAA exceptions. If you agree to take part in this research you will be required to sign a "Research Authorization" form. This allows the use and sharing of your PHI by those listed in the “Research Authorization.”

**Revocation of Research Authorization**

You may cancel the permission you have given to use and share your protected health information at any time. This means you can tell us to stop using and sharing your protected health information. If you cancel your permission:

* We will stop collecting information about you.
* You may not withdraw information that we had before you told us to stop.
  + We may already have used it or shared it.
  + We may need it to complete the research.
* Staff may ask your permission to follow-up with you if there is a medical reason to do so.

To cancel your permission, you must complete a written “Revocation of Research Authorization” form. You may also obtain a copy from your study doctor, designated personnel or from the Human Subjects Protections Program Office website (<http://louisville.edu/research/humansubjects/subject-information>).

**Information Available on ClinicalTrials.gov**

\*Choose from the statements included in the consent form instructions, if applicable, and then remove this notation

**Confidentiality**

Total privacy cannot be guaranteed. We will protect your privacy to the extent permitted by law. If the results from this study are published, your name will not be made public. Once your information leaves our institution, we cannot promise that others will keep it private.

Your information may be shared with the following:

* The sponsor (name the sponsor and CRO if applicable) andothers hired by the sponsor to oversee the research
* The University of Louisville Institutional Review Board, Human Subjects Protection Program Office, Privacy Office and others involved in research administration at the University
* The local research team
* Researchers at other sites participating in the study (if applicable)
* People who are responsible for research and HIPAA oversight at the institutions where the research is conducted
* People responsible for billing, sending and receiving payments related to your participation in the study
* Government agencies, such as:
  + Office for Human Research Protections
  + Office of Civil Rights
  + Food and Drug Administration
* Data Safety Monitoring Board(s) related to the study
* Others (please specify)

### Security

### The data collected about you will be kept private and secure in

### Conflict of Interest \*See instructions for whether or not this statement is needed in the informed consent. If not, remove the heading and paragraph.

This study involves a conflict of interest because: \_\_\_\_\_\_\_\_\_\_\_ will be compensated for your participation. This compensation is used to pay for the costs of doing this study. If you want to know, please ask the investigator how:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ will benefit by your participation in the study.

### Voluntary Participation

Taking part in this study is completely voluntary. You may choose not to take part at all. If you decide not to be in this study, you won’t be penalized or lose any benefits for which you qualify. If you decide to be in this study, you may change your mind and stop taking part at any time. If you decide to stop taking part, you won’t be penalized or lose any benefits for which you qualify. You will be told about any new information learned during the study that could affect your decision to continue in the study.

### Termination

Your study doctor or the study sponsor has the right to stop this study at any point. Your study doctor may take you out of this study with or without your okay. Reasons why this may occur include:

If you stop taking part in this study, it could harm you. You will be asked to follow these steps for your own safety:

### Participation in Other Research Studies

You may/may not **(choose one or the other*)*** take part in this study if you are currently in another research study. It is important to let your doctor know if you are in another research study.

### Contact Persons

If you have any questions, concerns, or complaints about the research study, please contact:

**Research Subject’s Rights**

If you have any questions about your rights as a research subject, you may call the Human Subjects Protection Program Office at (502) 852-5188. You may discuss any questions about your rights as a research subject, in private, with a member of the Institutional Review Board (IRB). You may also call this number if you have other questions about the research, and you cannot reach the study doctor, or want to talk to someone else. The IRB is an independent committee made up of people from the University community, staff of the institutions, as well as people from the community not connected with these institutions. The IRB has approved the participation of human subjects in this research study.

**Concerns and Complaints**

If you have concerns or complaints about the research or research staff and you do not wish to give your name, you may call the toll free number 1-877-852-1167. This is a 24 hour hot line answered by people who do not work at the University of Louisville.

**Acknowledgment and Signatures**

This informed consent document is not a contract. This document tells you what will happen during the study if you choose to take part. Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in the study. You are not giving up any legal rights by signing this informed consent document. You will be given a copy of this consent form to keep for your records.

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Subject Name (Please Print) Signature of Subject Date Signed

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Printed Name of Legal Representative (if applicable) Signature of Legal Representative Date Signed

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Relationship of Legal Representative to Subject

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Printed Name of Person Explaining Consent Form Signature of Person Explaining Date Signed

Consent Form (if other than the Investigator)

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Printed Name of Investigator Signature of Investigator Date Signed

List of Investigators: Phone Numbers: