Louisiana State University Health Sciences Center - New Orleans

**And**

**Children’s Hospital**

**Consent Form**

**1. Study Title:**

 Insert study title here.

**2. Performance Site:**

Children's Hospital, 200 Henry Clay Ave., New Orleans, LA 70118

**3. Names and Telephone Number of Investigators:**

Principal Investigator Address and Phone:

24-Hour Phone: 504- xxx-xxxx

Co-Investigators Address and Phone Number:

 In case of a research related injury contact:

 Phone:

**4. Purpose of the Study:**

**The drugs used in this study are/are not FDA approved.**

**5. Description of the Study:**

The will be XX patients enrolled in this research study nationally and xx locally.

*[Include the following if this is an applicable clinical trial of a drug, device or biologic or other product regulated by the FDA. [US Public Law 110-85 Title VIII Section 801 and as published in the Federal Register January 4, 2011 vol. 76, no. 2 Final Rule 21CFR Part 50]*

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.

The National Clinical Trials number for this study is NCT\_\_\_\_\_\_\_\_\_\_\_\_\_.

**6. Benefit to Subject:**

**7. Risk to Subject:**

*[All possible risks should be stated, including risks for blood draws, and the risk of death, if applicable.]*

**8. Alternatives to Participation**:

 *[Include statement:]* The alternative is not to participate.

**9. Subject Removal from the Study:**

***[****The phrase “you or your child may also be used in this section]*

The researcher may stop you from taking part in this study if at any time it is believed to be in your best interest; if you do not follow the study procedures; if the study is stopped. You could be taken off the study if your health worsens; if another treatment option appears to be appropriate; or for any other cause which prevents your continuing in the study.

**10. Subject’s Right to Refuse to Participate or Withdraw:**

 **[***The phrase “you or your child may also be used in this section]*

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may refuse to participate or withdraw from the study at any time without jeopardizing, in any way, your medical treatment at this institution in the present or future. Information already collected about you and sent to the sponsor will still be used [*This sentence may be deleted if it is not applicable to the study]*. Tell the researcher if you are thinking about withdrawing from the study so that you may do so safely. If you decide not to continue participation in the study you should seek medical advice for alternatives. Stopping treatment could result in the continuation of the disease.

Should significant new findings take place during the course of the research that may relate to your willingness to continue participation, that information will be provided to you.

**11. Subject’s Right to Privacy:**

The results of the study may be released to the funding agency. *[Provide the name of the funding agency.]* If the results of the study are published the privacy of subjects will be protected and they will not be identified in any way. Your personal information may be disclosed if required by law.

**12. Release of Information:**

Organizations that may look at and/or copy your medical records for research, quality assurance and data analysis include: the sponsor (name of sponsor), the LSUHSC Institutional Review Board, the Children’s Hospital Institutional Review Board, and the doctors on page 1 and their staff. While every effort will be made to maintain your privacy, absolute confidentiality cannot be guaranteed. Records will be kept private to the extent allowed by law.

**13. Financial Information:**

*[The subject must be informed as to who is responsible for all costs. These could include drugs, visits, procedures, and complications, both related and unrelated, to participation in the study. If the sponsor is responsible for providing study drugs and will pay for office visits and procedures, this should be clearly stated. As applicable to your study]*

The costs of all drugs, visits, procedures and study-related and unforeseen complications {(will be covered by the sponsor) / (must be met by the subject. The treatments required are felt to be a part of good medical care and are for the most part covered by most insurance companies.)} *[If additional costs are to be incurred by participation in the study, the subject must be informed. If not, state the following.]* Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar conditions.

Administration of the drugs will be charged in the usual way. The research requires that the subject get certain commonly used medical tests and examinations. These commonly used tests and examinations will be charged in the usual way.

[*If a sponsor study, the information listed in this section related to research related injury must coincide with the CTA]*

The principal investigator will arrange for medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. This will be provided on a fee-for-service basis. There {are/ are not} funds available to pay for any disability that results or for damages such as lost wages, etc.

You {will/will not} be paid for your participation as reimbursement for your time and travel. *[If subjects are to be paid for their participation or reimbursed for expenses, the amount and conditions for payment must be stated. Payments must be made in equal amounts at each visit throughout the course of the study. Payment must be based on a prorated system. Since subjects can withdraw from a study at any time they cannot be required to complete the study to receive payment. Payment must not constitute an undue inducement to participate.]*

**14. Signature:**

The study has been discussed with me and all my questions have been answered. Additional questions regarding the study should be directed to the investigators listed on page 1 of this consent form. If I have questions about subject’s rights, or want to discuss problems, concerns, or questions, or obtain information or offer input, I can contact the Chancellor of the LSU Health Sciences Center at (504) 568-4801 and the Chairperson of the Children’s Hospital Institutional Review Board, at (504) 899-9511. I agree with the terms above and acknowledge I have been given a copy of the consent form. I have not waived any of my legal rights by signing this consent form and that I am entitled to receive a signed copy of this form.

Signature of Subject Date

Parent/Legal Guardian Signature Date

Signature of Person Obtaining Consent Date

Consent Administered by Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name

The subject has indicated to me that he/she is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Reader Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name

The subject is a child and I certify that I am his/her legal guardian.

Mother’s Name Mother’s Signature Date

Father’s Name Father’s Signature Date

Legal Guardian Name Legal Guardian Signature Date

Child’s Name Child’s Age

Child’s Signature Date

Reason for not obtaining child assent: