

Study Title:

Principal Investigator:

**EXPERIMENTAL SUBJECT'S BILL OF RIGHTS**

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

***CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:***

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

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

Signature: \_\_\_\_\_

(subject)

Signature: \_\_\_\_\_

(parent or legally authorized representative, if applicable)

If signed by other than the subject, indicate relationship: \_\_\_\_\_

Short Form - English (4/26/04)

*(This form should be accompanied by the Experimental Subjects' Bill of Rights and the IRB approved consent document)*

**Consent to Participate in a Research Study**

Subject's Name: \_\_\_\_\_ IRB Study #: \_\_\_\_\_

Medical Record/Subject ID #: \_\_\_\_\_

You or your child is being asked to participate in a research study. A research study is how scientists (doctors, nurses and other professionals) try to understand how things work and gain new knowledge. A research study can be about how the body works, what causes disease, how to treat diseases, or what people think and feel about certain things.

Before you decide whether you or your child will participate in this research study, the investigator must tell you about (i) the purposes of the research study, the activities that will take place - these are called procedures, and how long the research will last; (ii) any procedures that are experimental (being tested); (iii) any likely risks, discomforts, and benefits of the research; (iv) any other potentially helpful procedures or treatment; and (v) how your privacy will be maintained.

Where applicable, the investigator must also tell you about (i) any available payment or medical treatment if injury or harm occurs; (ii) the possibility of unknown risks; (iii) situations when the investigator may stop your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings that may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a copy of the approved consent form for this study written in English.

You may contact \_\_\_\_\_ at \_\_\_\_\_ any time you have questions about the research or about what to do if you are injured. You may contact the Institutional Review Board, at 323-223-2340 if you have any questions about your rights as a research subject.

Your participation in this research is voluntary (your own choice), and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name/Signature of the Witness

\_\_\_\_\_  
Date

Routing of signed copies of the consent form: 1) Give to family; 2) Medical Record; 3) Investigator's file.