PATIENT CONSENT FORM

FOR RESEARCH INVOLVING HUMAN SUBJECTS

Patient's Name: ____

Attending Physician: ______________________________ Phone Number: ____________________

You are invited to participate in a research study entitled: *(study title:)*

This study is being performed by: *(investigator's name and phone number)*

Why is this study being done? *(A statement that the study involves research a summary explanation of the research including its purposes.)*

How many people will take part in this study? How will they be selected? *(Provide a statement indicating the approximate number of subjects expected to be involved in this study. Where applicable an explanation of how subjects will be selected into the arms of the study including a basic explanation of randomization the odds of a subject being selected for a specific arm of the study and in the case of drug studies whether or not the subject and/or doctor will know which experimental drug or drugs the subject will be receiving.)*

Initials ____________ Date ______________

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What is involved in this study? *(A description of the procedures to be undergone by the subject including a clear identification of which of these procedures is experimental and the amount of time required on the part of the subject. A chart laying out the procedures in a clear way may be helpful in complicated protocols.)*

What are the risks of this study? *(A description of foreseeable risks and discomforts to the subject as a result of the study including where applicable risks to unborn or nursing children.)*

What other options are there? *(A clear statement of alternative treatments to the study treatment including the risk attendant to the alternative treatments and the comparative advantages or disadvantages of each. This section should also indicate where possible which treatment or treatments are standard for the subject's medical problem and should list among the alternatives where appropriate the option of no treatment.)*

Are there benefits to taking part in this study? (*A description of the benefits to the subject or others of the study.)*

What are your rights as a participant? *(A statement specifying that the subject's participation in the study is voluntary; that the subject may choose not to participate at all may refuse to participate in certain procedures or answer certain questions; or they may discontinue the experiment at any time without penalty or loss of benefits to which the subject is otherwise entitled.)*

Will you be informed of any new information about this study? (*A statement indicating to the patient that any new information that bears on the risks and/or benefits of the study will be made available to the patient.)*

Will your confidentiality be protected? *(A statement indicating the procedures for and degree to which information about the subject will be held confidential including a statement indicating known exceptions to the promise of confidentiality. For example drug or medical device study consent forms should carry notice that the FDA study sponsor and IRRC may inspect all records including subject records. Consent forms should indicate the confidentiality could only be protected to the maximum extent allowable by law.)*

Initials ___________ Date _____________

Who do you call in case of an injury? *(A statement specifying that if an injury occurs as a direct result of the research study emergency medical care required to treat the injury will be provided by (Payee). If applicable the statement should also specify that if available reimbursement will be sought from the subject's insurance company for the emergency care and any other medical expenses incurred as a result of the injury and that no additional compensation will be provided. In the event of injury contact persons and phone numbers should be specified.)*

SUGGESTED LANGUAGE TO INCORPORATE INTO THE "TREATMENT OF INJURY" SECTION OF THE INFORMED CONSENT FORMS – <u>Select only one</u>.

1. No costs will be paid
If you are injured as a result of your participation in this research project, Sparrow Hospital will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The Hospital's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact *[insert Principal Investigator's name and phone number]* with any questions to report an injury.

2. Third party will pay
If you are injured as a result of your participation in this research project, Sparrow Hospital will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. Any costs that are not covered or in excess of what are paid by your insurance, including deductibles, shall be paid by *[name of payee]*. The Hospital's policy is not to provide financial compensation for lost wages, disability, pain or discomfort unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact *[insert Principal Investigator's name and phone number]* with any questions or to report an injury.

Option #3 (to be used if a research study is funded by Department of Defense).

3. <u>The Following Language is to be Used for Use for Contracts with the Army or Where Army Personnel are Involved</u>:
If you are hurt or get sick because of this research study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk to the principal investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221.

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Who can you contact if you have questions or concerns about this study? *(A statement indicating the name and phone number of the person(s) to contact regarding any questions or concerns that may be raised by participating in the study.)*

If you have any questions about your participation, you may contact George S. Abela, MD, IRB Chairperson, Sparrow Health System Institutional Research Review Committee. Phone: (517) 364-2150.

What are the rights of the physician to stop this study? *(A statement of the circumstances under which the investigator may terminate the study without the consent of the subject.)*

Are there any costs? *(In the case that there are likely to be additional costs to the subject investigators must incorporate a statement specifying the nature of these costs in their consent forms. A statement should be included to the effect that:*

The participation of the subject in this research project will not involve any additional costs to the subject or the subject's health care insurer.

OR

The participation of the subject in this research will necessitate additional procedures [indicate procedures, e.g., obtaining medical tests and examinations]. The costs may be covered by the subject's insurance. [Where applicable: Those costs not covered by the insurance will be provided by research funds.] The subject will remain responsible for the insurance deductibles and co-pays.

OR

The participation of the subject in the research project may involve additional costs to the subject [specifying the additional procedures, tests, etc. that occasion the costs]. The subject's health insurance will not cover all of the additional costs. As estimate of total costs is $ ________ . If actual costs exceed the estimate the subject will remain responsible for the costs.)

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SIGNATURES: Upon your authorization and consent, you may participate in the research and/or study, which will be performed by your physician and surgeon and/or other physicians or personnel participating in the investigation with your physician(s).

Your signature below indicates your voluntary decision to participate in this study:

____
Participant

____
Signature of Patient (18 years or older) or Legally Authorized Representative

____
Signature of Parent or Guardian (required permission of parent or guardian if subject has not attained age 18)

____
Witness (required for subject that is blind, does not write, or for translation of consent)

____
Date

You have received a copy of this consent form: __________ initials __________ date

ASSENT OF MINOR: *(Use only if applicable – otherwise delete)* The study has been explained to you and you agree to participate in the study.

____
Signature of Minor (required if subject is 13-17 years old)

Witness (required for subject that is blind, does not write, or for translation of consent)

____
Date

INVESTIGATOR'S STATEMENT: I acknowledge that the nature and purpose of the investigational device(s), drug(s), or procedure(s), possible alternative methods of treatment, the risks involved and the possibility of complications or unintended results were fully explained to the patient or the patient's representative by me before the patient consented.

____
Investigator

____
Date

Revised/Approved: IRRC, 5/7/01; 09/10/01; 10/08/01; 2/10/03; 4/8/03; 4/18/03; 11/14/05; 2/13/06
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