

## CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

I. STUDY TITLE: [Exactly as appears on study title page]

II. PROTOCOL NUMBER & PROTOCOL DATE:

III. PRINCIPAL INVESTIGATOR AND COLLABORATORS:

To include names and phone numbers of all investigators and collaborators at Lancaster General Hospital (if “Cooperative Agreement” study, please include Lancaster Regional Medical Center investigators and collaborators, as well).

IV. Include the following statement verbatim prior to the “Introduction” paragraph:

Anyone who is asked to participate in a research trial of a new drug, device or medical treatment must give his or her consent prior to participating. In order to decide if you want to take part in this study, you need to understand the risks and benefits that are involved. The consent form you are about to read gives detailed information about this study. Once you understand the study, you will be asked to sign this consent form if you wish to participate. A signed copy of this consent form will be given to you for your records.

V. INTRODUCTION:

√ To include statement that the study involves research or experimental procedures.

VI. STATEMENT OF PURPOSE:

Research objectives drafted in lay person’s terms using fourth-grade vocabulary.

VII. NUMBER OF SUBJECTS INVOLVED:

State the total number of subjects expected to be enrolled in the entire study and the number at LGH.

VIII. PROCEDURE, DURATION OF PARTICIPATION, AND REQUIRED FOLLOWUP:

Describe in lay person’s terms the protocol to be followed in the conduct of the research study, being certain to include a lay person’s description of the protocol, the length of the study, the tests involved and visits to the doctor, and anything else involving the patient in terms of the study and follow-up.

IX. BENEFITS:

Describe benefits to the subject and/or to others, which may be reasonably expected.

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X. RISKS, DISCOMFORTS, AND INCONVENIENCES:

- ✓ Side effects
- ✓ Material risks
- ✓ Expected physical discomforts
- ✓ Unexpected or unforeseeable risks/discomforts
- ✓ Inconveniences to the subject

XI. ALTERNATIVE THERAPIES:

State alternative procedures and/or treatments, which may be available.

XII. COSTS:

A statement regarding the cost of the protocol to the patient, including any costs that might not be expected to be covered by the patient's insurance plan need to be detailed. Any coverage for these costs not covered by the patient's insurance plan should be explained.

XIII. COMPENSATION FOR INJURY OR COMPLICATION:

Include verbatim:

In the event of a physical injury or illness resulting from the research procedure, there will be no monetary compensation made to you. However, any emergency medical treatment which may be necessary will be made immediately available to you [at no cost] [at your expense].

Any statement regarding any possible compensation plan that the sponsor has should be included here and then the following paragraph must be included verbatim.

Neither the Lancaster General Hospital\*, nor [principal investigator's name/collaborators] has a compensation program for defraying medical or hospital expenses resulting from your participation in this research activity, regardless of the outcome, possible complications, or physical injury. The only compensation or defraying of expenses would be that which might be available to you through your personal health or other insurance plans.

The investigator's name and names of collaborators should be included in the above disclaimer in the appropriate spot within the parentheses.

\* If this is a "Cooperative Agreement" study with Lancaster Regional Medical Center, the statement shall be included as follows:

Neither the Lancaster General Hospital nor Lancaster Regional Medical Center nor [principal investigator's name/collaborators] has a compensation program for defraying medical or hospital expenses resulting from your participation in this research activity, regardless of the outcome, possible complications, or physical injury. The only compensation or defraying of expenses would be that which might be available to you through your personal health or other insurance plans.

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If applicable: [Name of Sponsor] will pay for any immediate care and/or treatment needed for a research-caused condition.

XIV. PREGNANCY / BREASTFEEDING WAIVER:

If female subjects of reproductive age are included in the study, a separate statement of risk to the fetus or breast-fed child is required along with a statement that if pregnant or nursing, study participation is excluded. If maternal risk is expected, a commitment to avoid pregnancy by standard effective means and acceptance of a pregnancy test prior to enrollment in the study must be obtained.

The following statement should be included in cases where maternal risk is expected:

A pregnancy test will be done before entry into the study. You will be required to use an acceptable method of contraception for the duration of the study. Nursing mothers are excluded from participation in the study.

XV. QUESTIONS / FURTHER INFORMATION:

Include verbatim:

If you have any questions about this research or if you believe you have been injured as a result of participating in this research study, you can contact Dr. [principal investigator's or collaborator's full name] at [phone number]. (See Section III for complete list of investigators and collaborators.)

XVI. SUBJECT'S RIGHTS OR QUESTIONS:

Include verbatim:

If you have any questions about your rights as a participant in this research study, you may contact the Chairman of the Institutional Review Board at Lancaster General Hospital, at 717-544-5091.

XVII. VOLUNTARY PARTICIPATION:

Include verbatim:

You understand that your participation in this study is voluntary. You may refuse to participate in or withdraw from this study at any time without fear of penalty or loss of benefits to which you are otherwise entitled. Your participation or withdrawal will in no way jeopardize any of your medical care by your physician. If significant new information is found during the course of this study which may affect your decision to participate, this information will be provided as soon as possible to you and your physician for review and discussion.

XVIII. TERMINATION OF PARTICIPATION / RIGHT TO WITHDRAWAL:

Describe in lay person's terms the procedure for the orderly termination of participation by the subject in the research study.

date

page x of y

Patient Initials \_\_\_\_\_

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XIX. CONFIDENTIALITY:

Describe the extent to which records identifying the patient will be maintained and who will have access to these records. The FDA or OPRR may review original research records, so a statement of this possibility is appropriate.

XX. STATEMENT OF CONSENT:

The following statements must be included verbatim:

I have read the above information, or have had it read to me, and I understand the purpose of the study, as well as the potential benefits and risks of participation in the study. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I freely give my informed consent to be a participant in this study.

XXII. HIPAA AUTHORIZATION

The Federal law known as the Health Insurance Portability and Accountability Act ("HIPAA") includes patient privacy regulations that require your authorization to use and/or disclose your health information for purposes of this clinical research study.

- A. A description of the health information to be used or disclosed that identifies the information in a specific and meaningful fashion. You must list in the authorization all the information you plan to use or disclose. This includes standard PHI, as well as subjects' history, physical findings, and laboratory test results.
- B. Please provide the specific identity of the person(s), or class or persons, authorized to make the requested use or disclosure of the health information. In most cases, this will be the principal investigator(s) and his or her research team.
- C. Please disclose the specific individuals and/or organizations who will receive the subjects' health information, such as the clinical research organization and central laboratories, as well as oversight agencies such as the Institutional Review Board or the FDA, or, where applicable, the Federal Office for Human Research Protections (OHRP).
- D. Please provide a description of each purpose of the requested use or disclosure such as a description of the study that you may already be using on the consent form.
- E. Please provide the expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study", "none", or similar language is sufficient.
- F. Please state that the subject has the right to refuse to sign the authorization. This statement is the same as the one current research regulations require.
- G. Please provide that the subject has the right to revoke their authorization in writing to prevent the subsequent use or disclosure of their protected health information. An example of this language is as follows:

You may withdraw from the study at any time. If you withdraw, we will ask you to come back one more time for a last exam and to return your unused medicines. You must withdraw in writing in order to withdraw your permission for us to continue to use the data that we have already collected about you. Even if you withdraw our permission to use the data

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about you, we are required by the FDA to record anything that relates to the safety of these drugs.

- H. Please request the signature of the individual and date. If the authorization is signed by a personal representative of the subject, a description of such representatives authority to act for the individual/subject must also be provided.

**The consent form must be dated and each page must be numbered. (see footer)**

Spelling and grammar must be correct.

XXI. SIGNATURE LINES:

\_\_\_\_\_  
Patient Name (Printed)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of legally authorized representative  
if applicable (Printed)

\_\_\_\_\_  
Signature of legally authorized representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of person obtaining consent (printed)

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date

Revised 06/2009