TEMPLATE

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Please delete the instruction – blue text- prior to submitting the consent

I. STUDY TITLE:

II. INVESTIGATORS AND COLLABORATORS: Name, Department, Telephone Number (if student include the advisor's name, title, and telephone number)

III. Include the following statement verbatim prior to the "Overview" section:

Anyone who is asked to participate in a research study 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 can decide if you want to take part in it. If you do, you will need to sign this consent form. A signed copy of this consent form will be given to you for your records.

IV. OVERVIEW: *Invite subjects to participate and use **lay person's terms** to tell them the purposes of the study. Briefly describe the procedures to be used and the time required, providing enough detail to enable subjects to make an informed decision. Include the duration and extent of the subject's involvement.*

V. RISKS AND BENEFITS: *Describe any reasonable foreseeable physical or emotional risks, inconveniences, or discomforts associated with the study. If there are no known risks, this should be stated. Also, give a description of the likely benefits to subjects or others.*

VI. ALTERNATIVES TO PARTICIPATION: *Describe any alternatives to participation in the study that might be advantageous to the participant.*

VII. COMPENSATION FOR INJURY OR COMPLICATION (Include only for research involving more than minimal risk):

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

Example paragraph regarding sponsor compensation for injury related to research:

What if you are injured because of the study?

If you are injured because of taking part in this study, you could need medical treatment for your injuries. The sponsor has a program that may pay for medical costs of injuries that are a direct result of participation in the study. The program does not pay for lost wages, lost time or discomfort for such injuries

OR

If you are injured because of taking part in this study, you could need medical treatment for your injuries. You or your insurance company would be responsible for the costs of that treatment.

Include verbatim:

Lancaster General Hospital does not have a program to pay for medical expenses, lost wages, lost time or discomfort for such injuries.

You do not waive any legal rights to seek compensation by signing this consent form.

VIII. COMPENSATION: Provide a statement of any compensation available to subjects, along with information on how it can be obtained.

IX. CONFIDENTIALITY/HIPAA: *Specify the procedure for maintaining the confidentiality of records that identify subjects. If appropriate, specify any protected health information (PHI) that will be collected.*

Provide details as to where the research data will be stored, how it will be secured, and when will it be destroyed. If the data will be disclosed to anyone not listed as an investigator or collaborator, identify the disclosures.

Provide an 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.

State that the subject has the right to refuse to sign the authorization.

Provide a statement 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. You must withdraw in writing to the principal investigator (name and address on the first page of this consent form) in order to withdraw your permission for us to continue to use the data that we have already collected about you.

If this research represents a clinical trial that must be registered on www.Clinicaltrials.gov, you must include the following statement: A description of this clinical trial will be available on http://www.Clinicaltrials/gov as required by federal law 42 CFR Part 11. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

X. FURTHER INFORMATION/QUESTIONS:
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 II for complete list of investigators and collaborators.)

XI. SUBJECT'S RIGHTS OR QUESTIONS:

Include verbatim:

The Human Research Protection Program (HRPP) provides oversight of all research activities involving human subjects at Lancaster General Health. If you have any questions about your rights as a research participant, or if you have complaints or concerns, you may send an e-mail to the HRPP (SM-HRPP@lghealth.org). You also may call the Chair of the Institutional Review Board at Lancaster General Hospital at 717-544-5091.

XII. VOLUNTARY PARTICIPATION: *Explicitly state that subjects may refuse to participate or may withdraw for any reason without penalty. Describe the procedures for both electing to participate and for declining, along with a statement regarding the disposition of data which may have already been collected from subjects who later elect to withdraw.*

XIII. 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 possible benefits and risks of taking part in the study. I have had the chance to ask questions, and all of my questions have been answered to my satisfaction. I am 18 years or older and freely give my informed consent to take part in this study.

IVX. SIGNATURES: *Provide a space for signatures and dates of the subject and the person obtaining the informed consent.*

NOTE: The full title of the study should be included as a header on each page of the consent form. A footer should also be included with the version date of the consent form (date consent form was written) as well as page numbers, i.e., 1 of 3 (see footer).

Spelling and grammar must be correct.

01/2015; 09/29/15