Please Note: This is a template for developing an informed consent document for use with your research study. It is meant to provide structure and guidance to the process and is not to serve as your exact informed consent document. The instructions for this template are in italics. Follow the instructions and edit as appropriate. Do not include the italicized instructions in your consent form. Delete other sections and suggested wording that do not apply.

To the fullest extent possible; keep the wording in simple, lay language. The recommended reading level is 8th grade. Use of the second person (e.g., "You will receive…") is generally preferred.

Please leave a 1 inch margin so that there is room for the IRB approval stamp.

Be sure that the footer information (version #, date, etc.) is accurate.

The Code of Federal Regulations requires certain elements and statements to be included in all informed consents. This template is a combine informed consent and HIPAA research authorization. All required elements and statements will be flagged with the word "REQUIRED" in red.

This is template version January 2012.

GREATER BALTIMORE MEDICAL CENTER (GBMC)
INFORMED CONSENT

Title of Study: *Insert title*

Principal Investigator(s): *Insert name(s)*

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS RESEARCH?

REQUIRED: It must be clearly stated that the study involves research.

Suggested text:

You are being asked to take part in this research study because *(Explain how the subject was identified. For example, you have diabetes.)*. Whether or not you take part in this study is up to you. If you choose not to participate, it will not affect the quality of medical care you receive.

This form explains the research study and your part in the study. Please read it carefully and ask questions before you make a decision. You may want to talk about this research study with your family, friends and other health care providers. Take your time. You should not sign this form until all of your questions are answered. If you do decide to participate in the study, you must sign this form to show that you want to take part.

WHY IS THIS RESEARCH STUDY BEING DONE?

REQUIRED: There must be a statement explaining the purpose of the research.

Start with an introductory sentence describing the primary purpose of the research.

Suggested text:

The purpose of this research study is to determine … *(complete the sentence)*

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

(Not required but should be included when appropriate)

Include the approximate number of participants.

Suggested text:

This study will enroll up to *(X)* people at GBMC.

HOW LONG WILL YOU BE IN THIS STUDY?

REQUIRED: There must be a statement giving the expected duration of the subject's participation.

Suggested text:

Your participation in this research study is expected to last for *(insert time frame here)*.

PARTICIPATION IN THIS STUDY IS VOLUNTARY

REQUIRED: There must be a statement that (1) explains participation is voluntary, (2) refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and (3) the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Suggested text:

Your participation in this study is voluntary. You may choose not to take part or to leave the study at any time. Your decision will not affect your relationship with your doctor or GBMC and will not result in any penalty or loss of benefits to which you are otherwise entitled.

WHAT WILL YOU DO IN THIS STUDY?

REQUIRED: There must be a description of the procedures to be followed and identification of any procedures which are experimental.

Suggested text:

If you choose to participate in this study, you will be asked to … *(complete the sentence)*

WHAT RISKS OR PROBLEMS COULD YOU HAVE BY BEING IN THIS STUDY?

REQUIRED: There must be a description of any reasonably foreseeable risks or discomforts to the subject.

Describe the possible risks and discomforts. List the physical and nonphysical (psychological, emotional, social, etc.) risks of participating in the study.

Suggested text:

You may experience risks or discomfort as a result of being in this study. Some of these may be serious. As with any research study, there may be risks that are not known at this time. The following are the risks that we are aware of:

1. Likely (chance of more than 50 percent that this will happen):
2. Frequent (chance of 25-50 percent that this will happen):
3. Common (chance of 10-25 percent that this will happen):
4. Less Likely (chance of 1-10 percent that this will happen):
5. Rare (chance of less than 1 percent that this will happen):

If there are no risks, make a statement that there are no risks.

WILL YOU BENEFIT FROM BEING IN THIS STUDY?

REQUIRED: There must be a description of any benefits to the subject or to others which may reasonably be expected from the research.

Suggested text:

You may or may not benefit from being in this study. What we learn from this research study may help other people with *(name of condition)* in the future.

Alternate suggested text, if applicable:

You will not benefit from being in this research study. What we learn from this research study may help other people with *(name of condition)* in the future.

WHAT OPTIONS OTHER THAN THIS STUDY ARE AVAILABLE TO YOU?

REQUIRED: There must be a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

Suggested text:

If you do not want to be in this study, other treatments may be available to you such as *(list alternative standard treatments and/or options for supportive care)*:

- Standard treatment options including _____.
- Taking part in another research study.
- Receiving the same treatment, but not as part of a research study.
- No treatment.

Before you decide about being in this study, you should discuss these other options with your doctor.

Suggested text if this is not a treatment study:

This is not a treatment study. Your alternative is to not take part.

WILL THERE BE ANY COSTS OR COMPENSATION TO YOU?

(Not required but should be included when appropriate—a statement as to any additional costs to the subject that may result from participation in the research)

Suggested text if participant and/or insurance provider are responsible for costs:

You or your insurance provider will be responsible for the cost of all medications, clinic visits, hospital admissions, laboratory tests, x-rays and any other tests. How much you will have to pay depends on whether or not you have insurance and what costs your insurance will cover. Insurance coverage cannot be guaranteed for all tests and treatments related to this study. You are encouraged to speak with your insurance provider prior to entering this research study to find out your individual coverage.

Suggested text if there is no cost or compensation associated with the study:

There will be no cost to you or any compensation for participating in this research study.

WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF TAKING PART IN THIS STUDY?

REQUIRED: For research involving more than minimal risk, there must be an explanation as to whether any compensation is available if injury occurs, an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.

Suggested text:

In the event that injury occurs as a result of this study, medical care at GBMC is available to you. However, GBMC is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of this study. Your medical expenses will be your responsibility or that of your insurance provider, although you are not precluded from seeking to

collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including GBMC.

HOW WILL YOUR PRIVACY BE PROTECTED?

REQUIRED: There must be a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

Suggested text and sample sentences:

GBMC will make every effort to protect your medical records and other personal information to the extent allowed by law.

As far as possible, all information obtained in this study that can be identified with your name will remain confidential. However, we cannot guarantee absolute confidentiality.

(Describe where/how data will be stored. For example: Your study file will be stored in a secure area in _____).

Only those individuals named in this consent will have access to your information.

Your name will not be revealed in any reports or publications resulting from this study without your permission.

REQUIRED: The following statement must be reproduced word-for-word in the informed consent documents of all applicable clinical trials involving FDA-regulated products (drug, device, biologic):

Required wording:

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.

INFORMATION ABOUT THE PRIVACY OF PROTECTED HEALTH INFORMATION

(This section may be left out and presented to the study subjects as a separate document--"HIPAA Research Authorization"--that is available for use from the IRB Office.)

Suggested text:

GBMC, its employees, and its affiliates are required by law to protect the privacy of information that identifies you. If you enroll in this research study, your protected health information (referred to as **PHI** in the rest of this section) may be used and shared with others as explained below.

What PHI will be used and shared with others for this research study?

REQUIRED: There must be a description of the PHI to be used or disclosed.

The following specific health information may be used and disclosed:

(Include all that apply. Delete those that do not apply. Add any applicable items not listed.)

- Complete medical records
- History and physical examinations
- Consultant reports
- X-ray/MRI/CT/diagnostic images
- Laboratory reports
- Operative reports
- Discharge summary
- Progress notes
- Photographs, videotapes, or digital or other images
- Questionnaires, interview results, focus group surveys, psychology surveys, behavioral performance tests (e.g. memory and attention)
- Tissue and/or blood specimens

Who may use and share your PHI?

REQUIRED: The names or class of persons authorized to (1) disclose and (2) receive the PHI must be identified.

- All investigators listed in this consent
- Others at GBMC who are participating in the conduct of this research study
- GBMC's Institutional Review Board

Your PHI may also be shared with federal and state agencies that have oversight of the study and may inspect your research records according to applicable laws:

- The Food and Drug Administration
- The National Institutes of Health
- The Office for Human Research Protections

Companies and organizations outside of GBMC may also use, share and receive your PHI in connection with this study:

- The study sponsor and its affiliates, agents and employees
- Other research sites involved in this study
- Other health care providers who provide services to you in connection with this study
- Laboratories and other individuals and organizations that analyze your PHI

REQUIRED: There must be a statement explaining that HIPAA protections may not apply to redisclosed information.

We will use and disclose your information only as described in this consent; however, there is a possibility that your PHI may be shared with other entities outside of GBMC. Once your

information has been released to these other entities, it may no longer be protected by federal privacy laws and regulations.

Why will your PHI be used and shared?

REQUIRED: There must be a description of the purpose for the requested use or disclosure.

(Include all that apply. Delete those that do not apply. Add any applicable items not listed.)

- To learn more about the condition/disease being studied
- To learn more about the costs of treating the condition/disease being studied
- To improve health care for persons with the condition/disease being studied
- To analyze research results
- To facilitate treatment, payment, and operations related to the study
- To complete research obligations in this study
- To comply with federal or other governmental agency regulations
- To monitor adverse events/side effects
- To determine the safety and effectiveness of the treatment(s)
- To perform quality assessments related to research at GBMC
- To teach students affiliated with GBMC
- To place in a repository or database for future research purposes

How long will your PHI be used and shared for this research study?

REQUIRED: An expiration date of the authorization must be given.

(It is strongly recommended to use the time period of "indefinitely")

Suggested text:

Since research is an ongoing process, PHI that we collect from you in this study will be kept by us indefinitely.

What if you decide that you no longer want your PHI used or shared for this research study?

REQUIRED: There must be a statement regarding (1) the individual's right to revoke the authorization in writing, and (2) the consequences of refusing to sign the authorization.

Suggested text:

You have the right to revoke this authorization and can withdraw your permission for us to use your PHI for this research by sending a written request to the principal investigator listed on page one of this consent form. If you do send a letter to the principal investigator, the use and disclosure of your PHI will stop as of the date he/she receives your request. However, the principal investigator is allowed to use information collected before the date of the letter or collected in good faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with GBMC.

GBMC INVESTIGATOR STATEMENT

Suggested text:

The sponsor of a clinical trial usually pays a fee to the institution or the investigator to cover the extra cost and effort associated with conducting a research trial. Accordingly, the investigator and/or the institution could receive compensation, monetary or otherwise, to cover the costs of administering and collecting data for this trial. If you have any questions about the relationship between the sponsoring group and your physician, you may contact (*insert GBMC study investigator's name and phone number).*

WHO DO YOU CONTACT IF YOU HAVE STUDY QUESTIONS OR CONCERNS?

REQUIRED: There must be (1) an explanation of whom to contact for answers to pertinent questions about the research subject's rights, and (2) whom to contact in the event of a research-related injury to the subject.

Suggested text:

If you need more information concerning the research, please notify (*investigator's name or the study coordinator)*, at *(insert phone number)*. In addition, you may contact **Dr. James H. Mersey, Chairman of the Institutional Review Board of GBMC, at 410-828-7417** if you need more information about your rights as a research participant or about research-related injury. You may also call Dr. Mersey to report any complaints you may have about the study and to report any injuries.

STATEMENT OF VOLUNTARY CONSENT

Suggested text:

I have read this form or have had it read to me. I have been told what to expect if I take part in this study, including possible risks and possible benefits. I have had a chance to ask questions and have had them answered to my satisfaction. I have been told that the people listed in this form will answer any questions that I have in the future. By signing below, I am volunteering to be in this research study.

Participant's Name (Print): _____

Signature: _____ Date: _____

(If Applicable) Legal Representative's Name (Print): _____

Relationship to Participant (*ex. Parent, Spouse, Legal Guardian*) (Print): _____

Signature: _____ Date: _____

(Depending on the risk category, some pediatric studies require signatures of both parents and the following three lines must be included. If this is not applicable to this study, this section can be deleted.)

Legal Representative's Name (Print): _____

Relationship to Participant (*ex. Parent, Spouse, Legal Guardian*) (Print): _____

Signature: _____ Date: _____

[Witness signatures are required whenever the participant or representative cannot read or sign the form themselves (for example, due to a medical condition or language barrier). The witness signature is used to verify that the participant was provided with and understood the information in the consent form. The witness must be impartial and cannot be a member of the research team.]

(If Required) Witness's Name (Print): _____

Signature: _____ Date: _____

Witness to: ☐ Discussion ☐ Signature

STUDY REPRESENTATIVE STATEMENT

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: _____

You will receive a copy of this form after it has been signed and dated.