**External IRB Consent-HIPAA Checklist**

If you have decided to rely on an external IRB as the IRB of Record, the study sponsor or lead site will most likely provide you with a template consent form. You will need to revise this template consent form so that it complies with the policies and requirements of UVM/UVMMC’s Human Research Protections Program. The UVM/UVMMC does not require or even recommend that you thoroughly re-format the consent template to align with the UVM/UVMMC’s Template Consent Form. Many central IRBs and local sites will not approve your revised consent if you alter the formatting and organizational structure of the consent form.

This document provides the required local consent language. Only include sections where applicable to the protocol. Consent should be on UVM/UVMMC/Departmental letterhead.

**Always insert UVM/UVMMC site names**

University of Vermont Medical Center, (if applicable) Central Vermont Hospital **(Health Network is not participating in any NIH multisite protocols at this time, please do not list)**

**HIV testing**

An HIV test will be performed for this research study. You should be aware that state law may require that both HIV and AIDS cases be reported to state health agencies. Disclosure of a positive test may result in discrimination by friends, family, employers, insurance companies and others. If any test for HIV is positive, you will be informed of these results.

**Subject compensation include**

You may be requested to provide your name, social security number, and address. This information will be disclosed one time to either the University of Vermont’s Procurement Services Department or UVM Medical Center Accounts Payable Department for purposes of reimbursing you for participation in this study. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork for payment.

**Greater than minimal risk include**

**UVM Medical Center Policy**

If you are injured or become ill as a result of being in this research, The UVM Medical Center, the hospital partner of the University of Vermont, will provide reasonable and usual medical care for that injury or illness. There will be no cost to you if the conditions listed below apply to your injury or illness. These conditions are:

1. The investigator, in consultation with the study sponsor, determines that your injury or illness results from the research and not from your underlying condition or its usual treatment.
2. You let the investigator know about the injury or illness when you first notice it; and
3. You follow medical advice about proper treatment options for the injury or illness.

The UVM Medical Center may claim payments for your medical treatment directly from the study sponsor or your insurance company when these payments are allowed.

For an injury or illness that results from being in this study, the University of Vermont and The UVM Medical Center will not offer you any other payments, such as lost wages or expenses, except for your medical care. Even though you may receive medical care at no cost to you under certain conditions if you are in this study, the UVM Medical Center and the University of Vermont do not admit to any responsibility for an injury or illness that results from being in the study.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

**Include only if Central Vermont is participating**

**Central Vermont Medical Center Policy**

It is not the policy of Central Vermont Medical Center to provide payment or free medical treatment for injury resulting from research. You may contact the Clinical Research Coordinator at Central Vermont Medical Center at (802) 225-5419 for more information regarding this research study.

**Health Information (HIPAA) language**

**What health information will be used and disclosed for this study?**

The health information we plan to collect for this study is listed below.

*[This list should be edited and revised to be accurate and study specific.]*

* Medical history and examinations.
* Information that identifies you, such as your name, address, age, and sex.
* Reports from hospital and clinic visits
* Laboratory and other test results
* X-ray and other images and reports
* Lists of medications you are taking
* Responses to health surveys and questionnaires
* Reports from mental health services and testing *[if applicable]*
* Reports about drug and alcohol treatment *[if applicable]*
* Health related video and audio recordings, and photographs *[if applicable]*
* Reports of testing for infectious diseases, including HIV [*if applicable]*
* Genetic testing results *[if applicable]*

**Who is disclosing your health information for this research study?**

* The University of Vermont Medical Center
* Other doctors’ offices and hospitals where you may receive medical care while this study is active.

*[List other health care providers specifically by name if known]*

**Who will use your health information in this study?**

Our research team will use your health information. We may also share it with those who assist with the conduct of the research or oversight of the activities for this study. The representatives from the institutions, organizations, and agencies are listed below.

* The University of Vermont and its Committees on Human Research
* The University of Vermont Medical Center
* The University of Vermont Cancer Center
* Sponsor of this study: *[Insert the name of the oncology group and other sponsoring organization, if applicable.]*
* The U.S. Food and Drug Administration (FDA) *[Delete if FDA regulations do not apply to the study.]*

 *[This list should be edited and revised to be accurate and study specific. The list should include, as applicable, a clinical research organization, an independent data and safety monitoring committee, a coordinating center, collaborators and their home institutions, and foreign regulatory agencies.]*

Federal law usually protects the confidentiality of your health information. Once your health information is disclosed in this study, these laws may no longer apply. As a result, your health information could be further disclosed for other purposes. In the absence of a Certificate of Confidentiality, it is also possible for a court or other government official to order the release of study data. Refer to the study consent for further information regarding confidentiality. The confidentiality of your health information cannot be guaranteed if you agree it may be used in this study.

**How long will your health information be used for research?**

Your permission to use your health information will not end until the study is completed. During this study, you will not have access to study data. You may ask for your data once study activities are complete. You have a right to receive a copy of the information in your medical record at any time.

**What if you decide not to give permission for research use of your health information?**

If you decide not to allow the use and disclosure of your health information, you may not take part in this study. Your decision will have no effect on your current or future medical care.

If you later choose to stop taking part in this study in the future, you may cancel permission for the use of your health information. You should let the research team know that you are cancelling your permission. A member of the research team will assist you in making your decision effective. The study will continue to use the health information already collected for the study before you cancelled your permission.

**Who can answer your questions about the use and disclosure of your health information?**

If you have questions or concerns about the use and disclosure of your health information, you should ask a member of the study team at \_\_\_\_\_\_\_ or the Privacy Officer at The University of Vermont Medical Center, Inc. Michael Hawkins, at (802) 847-3532.

**Clinical Trials Registration**

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 results. You can search this website at any time.

**Always include Contact Information**

You may contact Dr. insert investigator’s name, the Investigator in charge of this study, at insert phone number for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been injured as a result of your participation in this study you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

**Financial Conflict of Interest**

You should also know that [investigator] has a significant financial interest (e.g. a separate relationship with the sponsor or a related company involving ownership or stock, payment for services or other significant financial payments) that could potentially compromise or influence the investigator’s professional judgment or actions in the performance of the study (e.g. the design, conduct, oversight, evaluation or reporting of the results of the study). The investigator has disclosed that personal financial interest to one of the institutions. The applicable institution(s) has reviewed the [investigator’s] financial interest and determined that any potential conflicts are being appropriately managed. However, negative impacts on subjects participating in this study, are always possible, and therefore the potential conflict is being disclosed to you. Please discuss with the Investigator any questions you may have about this.

**I have read the information in this form and my questions about it have been answered. By signing this form, I agree to allow the use and disclosure of my health information for the research described above. I expect that a copy of this form will be given to me for my records.**

Subject’s Name [print] [Signature] Date