**Consent Template – 10/12/16**

**Please use this word document as well as the Consent Template with Guidance (pdf) to develop your consent form. Both documents include all required regulatory and local elements and mandatory language as applicable.**

**Remove all sections that are not applicable (including this header and address all remaining “red” text items. Note sections of text in black, if applicable to the project, are mandatory and should not be changed. Please reference the** [**Consent Template with Guidance**](http://www.uvm.edu/irb/form/IC-template-c-guide.pdf) **for assistance with determining what needs to be included in each section.**

**Informed Consent**

# Title of Research Project:

**Principal Investigator:**

**Faculty Sponsor:** **necessary for any student led research activities**

**Sponsor:**

You are being invited to take part in this research study because[explain how/why the patient/subject qualifies or may qualify for the study]**.**This study is being conducted by the University of Vermont [if any of the research is being conducted at the hospital or any of its campuses include] at the UVM Medical Center.

We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

**Why is This Research Study Being Conducted?**

**What Is Involved In The Study?**

**What Are The Risks and Discomforts Of The Study?**

if applicable, include this section

**Incidental Findings**

if applicable, include the following section

**Genetic Information Nondiscrimination Act (GINA)**

**What Are The Benefits of Participating In The Study?**

**What Other Options Are There?**

**Are There Any Costs?**

**What Is the Compensation?**

if applicable, include this section

**Can You Withdraw or Be Withdrawn From This Study?**

include this section only when protected health information is used

**What About Confidentiality of Your Health Information?**

**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.

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.

* The University of Vermont and its Committees on Human Research
* The University of Vermont Medical Center
* Other researchers and centers that are a part of this study, including individuals who oversee research at those sites
* Officials from agencies and organizations that provide accreditation and oversight of research
* The sponsor of this study insert the name of the sponsor, or others who fund the research, including the government
* Company(ies) that provide drugs or devices for this research project
* Federal and state agencies that oversee or review research information, such as the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities
* Your health insurer, for portions of the research and related care that are considered billable

Your health information is protected by a federal law called the Health Information Portability and Accountability Act (HIPAA). Once your health information is shared outside of the University of Vermont Medical Center, we cannot guarantee that these laws will continue to 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. 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 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, and you cannot get back information that was already shared with others.

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

Include the following if UVMMC is the covered entity

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 insert phone number or the Privacy Officer at The University of Vermont Medical Center, Inc, at (802) 847-2667.

If UVM (Luse Center) is the covered entity include the following

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 insert phone number or the Chief Privacy Officer at The University of Vermont at (802) 656-2003.

One of the following two sections must be included.

Include this section when protected health information is used

**Safeguarding Your Health Information**

A record of your progress will be kept in a confidential form at the insert location. The security of your record will be maintained by the research team. The results of this study may eventually be published and information may be exchanged between medical investigators, but patient confidentiality will be maintained.

If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

If project includes videotaping, photography or voice recordings please include a special statement about disposition of materials.

[For studies that include reimbursement in any form 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.

**OR**

this section when there is **no protected health information used** (next 5 paragraphs)

**What About Confidentiality**

A record of your participation will be kept in a confidential form at the insert location. The security of your record will be maintained by the research team. The results of this study may eventually be published and information may be exchanged between investigators, but confidentiality will be maintained.

If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

If project includes video recording, photography or voice recordings please include a special statement about disposition of materials.

The sponsor insert sponsor name or their appointed designees as well as the Institutional Review Board will be granted direct access to your original research records for verification of study procedures and/or data.

[For studies that include reimbursement in any form 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.

if applicable, include this section if your protocol requires ClinicalTrials.gov registration

**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 the results. You can search this Web site at any time.

include this section only if the protocol is interventional and/or greater than minimal risk

**What Happens If You Are Injured?**

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.

if applicable, include this section

**Financial Interest**

You should also know that insert investigator’s name 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 the IRB responsible for approving this study. The IRB 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.

**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.

**Statement of Consent**

You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

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Signature of Subject Date

This form is valid only if the Committees on Human Research’s current stamp of approval is shown below.

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Minor Providing Assent Date

(applicable for children 11 years of age or older dependent upon their understanding)

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Signature of Legal Guardian or Legally Authorized Representative Date

(applicable for children and subjects unable to provide consent)

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Signature of Principal Investigator or Designee Date

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Name of Principal Investigator or Designee Printed

Name of Principal Investigator:

Address:

Telephone Number:

Name of Faculty Sponsor:

Address:

Telephone Number: