 *The University of Vermont*

Committees on Human Research

 Serving the University of Vermont and

 University of Vermont Medical Center

**Single IRB Consent-HIPAA Language Requirement Checklist – 11/15/19**

If you are relying 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 to include the required local language for both the consent and HIPAA authorization as applicable. We do not require or even recommend that you thoroughly re-format the consent template to align with the UVM/UVMMC’s Template 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.

**Introduction Section**

*Always include this statement to indicate the relationship between UVM and UVMMC.*

This research is being conducted by the University of Vermont at The University of Vermont Medical Center.

**Risks and Discomfort Section**

*If HIV testing is being done as part of research, include*

An HIV test will be performed for this research study. You should be aware that state law requires that both HIV and AIDS cases be reported to the state health agency. 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.

**Risk and Discomfort Section**

*If subjects are being compensated by UVM, include*

You will be required to provide your name and address each time you receive a payment. You will also be requested to provide your social security number if the amount of the payment is $100 or if the total payments from UVM are equal to or greater than $600. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork including your immigration status for payment. This information will be strictly confidential and will be used for tax withholding and reporting purposes only and will allow the University to determine your US residency for federal income tax purposes.

*Or, If subjects are being compensated by University of Vermont Medical Center, include*

You will be required to provide your name, social security number, and address to receive any amount of payment. This information will be disclosed one time to UVM Medical Center Accounts Payable Department for purposes of reimbursing you for participation in this study and to meet tax reporting obligations. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork for payment.

**Confidentiality of Health Information Section**

*If using protected health information from UVMMC, include*

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

Your health information is being used for your participation in this research protocol. We need to know your past medical history to ensure that it is safe for you to participate and we need to collect ongoing health information once you have begun the research study to ensure your continued safety and to determine what effect the research project has had on your diagnosis.

*Note: Substance Use Disorder Treatment Program information*

*42 CFR Part 2 protects the confidentiality of records relating to the identity, diagnosis, prognosis, or treatment of any patient records that are maintained in connection with the performance of any “Part 2 program”. If you are conducting research relating to a Part 2 Program (such as DayOne), please note that there are additional restrictions on the use and disclosure of this information. Please see 42 CFR Part 2, Section 2.52.*

**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
* Reports about drug and alcohol treatment, including records relating to treatment at a substance use treatment program
* Health related video and audio recordings, and photographs
* Reports of testing for infectious diseases, including HIV
* Genetic testing results

**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.

**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
* Officials from agencies and organizations that provide accreditation and oversight of research
* The University of Vermont Medical Center
* Other researchers and centers that are part of this study, including individuals who oversee research at those sites
* The sponsor of this study *insert the name of the sponsor*, or others who fund the research, including the government
* Companies that provide drugs or devices for the 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, (insert appropriate hospital(s)) 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 unless you withdraw your permission. 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?**

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

*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.*

***OR,*** *this section when there is* ***no protected health information (HIPAA)***

**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.

**What Happens if You Are Injured? Section**

*If project is greater than minimal risk include the injury language below*

If you are injured or become ill as a result of being in this research, The University of Vermont Health Network Affiliate hospital where you are enrolled in this research, 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 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.

If the above conditions are not met, The University of Vermont Health Network affiliate hospital where you are seeking care may claim payments for your medical treatment from the study sponsor or your insurance company when these payments are allowed. If we bill your insurance for this care, you will be responsible for any associated co-payments or deductibles.

For an injury or illness that results from being in this study, The University of Vermont Health Network affiliate hospital where you are receiving care 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 University of Vermont Health Network affiliate hospital 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.

**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.

**Financial Conflict of Interest section**

*Include only if a conflict has been identified.*

You should also know that *investigator 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 name* 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 section**

*Always include this statement to provide local contact information for our participants*

You may contact Dr. *insert PI 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.

We would like to store your specimens and data obtained as part of this research study for future research related to *describe here the types of research that may be conducted with these data to the extent that a reasonable person would understand and consent to storage.*

Please initial below whether you consent to storage of your specimens and data.

\_\_\_\_\_ Yes, I agree to have my specimens and data stored for future research.

\_\_\_\_\_ No, I do not agree to have my specimens and data stored for future research.