



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 – 03.24.21

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 or the HN affiliate site.

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 at a VT state site, 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.

Compensation Section

If subjects are being compensated by UVM, include UVM Procurement language

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 UVMMC language

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.

If using protected health information from UVMHC or other HN affiliate site, 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 *[insert appropriate HN affiliate hospital(s)]*
- 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 [insert appropriate HN affiliate hospital(s)]
- 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 HN 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.

[to be inserted when the study is single-blinded]

Access to Your Medical Records in MyChart

By your participation in this blinded study some of your medical record may not be available to you through MyChart to ensure you remain blinded as to which study arm you are receiving.

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.

Financial Conflict of Interest section

Include only if a conflict has been identified.

You should 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). 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 local 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.