Consent Template--PHI from UVM (Luse)

**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 for assistance with determining what needs to be included in each section.**

**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
* Reports about drug and alcohol treatment
* 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
* 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
* The University of Vermont
* 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, 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?**

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.

**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 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.