**Consent for Continued Participation in a Research Study after Age of Majority**

**Title of Research Project: This should be the same as the protocol unless the IRB approves otherwise. In some cases the titles are very complicated thus the IRB will allow simplification. No acronyms.**

**Lead Investigator: List lead PI Name**

**Sponsor: List all agencies, companies, or other Universities that are supporting this research. If internally sponsored, list the department. Do not list the sponsor here until you have obtained funding.**

You are currently taking part in a research study. Permission for you to take part in this research study was given by one of your parents or guardian. To enable your participation, the investigators had to also be given permission by your parents or guardian to have access to your private health information. Now that you have reached 18 years of age, we are asking for your consent for continued participation in this research study. You are now legally considered an adult and therefore you can decide whether you wish to continue your participation in this research study.

The original signed consent form, and if applicable an assent form that you signed as a child are attached for your review. We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

You may contact Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the Investigator in charge of this study, at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_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.

Include this section **only** when protected health information is used:

**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.

**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 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 hospital(s))
* Other researchers and centers that are a 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
* 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, (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 this 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 phone 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.

**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 continued participation in this study and you understand that you will receive a signed copy of this form.

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Signature of Subject Date

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Name of Subject Printed

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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: