**HIPAA Authorization Template for use when the research involves PHI – 6.21.2022**

[This template provides guidance and examples of text to be used for research involving Protected Health Information covered by HIPAA. This separate authorization form should be used when the UVM IRB is acting as the Privacy Board for studies reviewed and approved by External IRBs, instead of embedding HIPAA language in the Informed Consent Form.]

**Health Insurance Portability and Accountability Act (HIPAA) Authorization Form for University of Vermont Research**

|  |  |
| --- | --- |
| **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 |
|  |  |
| **Affiliated Hospital Investigator:** | [as applicable] If Central Vermont Medical Center (CVMC) is participating include local Investigator’s name here – no other affiliates are conducting research at this time |
|  |  |
| **Sites Where Research is Being Conducted:** | University of Vermont Medical Center[list Central Vermont Medical Center as applicable] |
|  |  |
| **Faculty Sponsor:** | If you are a student, list your faculty sponsor here. Please refer to the [UVM IRB Policies and Procedures Manual](https://www.uvm.edu/rpo/irb-policies-and-procedures) for the definition of a student. |
|  |  |
| **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. |

[For studies involving children please add here:] Throughout this document “you” refers to “you or your child”.

**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. or contact the UVMMC HIPAA Privacy Specialist.

**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 affiliate 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 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.

Statement of HIPAA Authorization

I have read the information in this form and my questions about it have been answered. Should I have any further questions about the use and disclosure of my private health information for research I will contact the person conducting the study at the address and telephone number given below. I understand that my participation is voluntary, and I may refuse to authorize the use and disclosure of my health information or withdraw this authorization at any time without prejudice to my present and/or future care. I understand that if I do not agree to the use and disclosure of my health information for research, I may not participate in this research study.

By signing this form, I agree to allow the use and disclosure of my health information for the research as described above. I expect that a copy of this form will be given to me for my records.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant Printed

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator or Designee Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Principal Investigator or Designee Printed

Name of Principal Investigator:

Address:

Telephone Number: