**The University of North Carolina at Chapel Hill**

**HIPAA Authorization for Use and Disclosure of Health Information**

**for Research Purposes**

**INSTRUCTION PAGE**

**This page is informational and instructional only and not to disclose to research participants. Delete this page and all other instructions highlighted in yellow before submitting.**

**Purpose:**

This HIPAA Authorization grants permission for the participant to have their PHI obtained and used for research purposes as outlined in the HIPAA Authorization.

**Instructions:**

* The text in yellow-highlighted brackets provides instructions and indicates information that must be inserted.
* Do not alter any of the following text, except as indicated.
* The form must be written in 2nd person (e.g., You are being asked to take part in a research study about…)
* Be sure to use plain language.
* When you have finished providing all the requested information and/or information, delete this page and the instructions that are highlighted yellow in the brackets, and delete the brackets.

**For questions about the HIPAA Authorization, please contact the Institutional Privacy Office at** **privacy@unc.edu****.**

**-------------Delete the information above this line before submitting--------------**

**The University of North Carolina at Chapel Hill**

**HIPAA Authorization for Use and Disclosure of Health Information**

**for Research Purposes**

**IRB Study #** [IRB NO.]

**Title of Study:** [TITLE]

**Principal Investigator:** [PI NAME]

**Mailing Address for UNC-Chapel Hill Department:** [DEPT ADDRESS]

Participation in research may involve some loss of privacy. However, to the extent possible the University of North Carolina at Chapel Hill (“University”) is committed to respecting your privacy and keeping health information that identifies you safe. The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), a federal law, provides additional protections of your medical records and related health information. One of those protections requires your written authorization for your health information to be used in this research study. This form (“HIPAA Authorization”) is intended to inform you about how your health information will be used or disclosed by approved study doctors and staff in this study. If you agree to take part in this study and sign this HIPAA Authorization, you are providing that authorization. Your health information will only be used in accordance with this HIPAA Authorization and the informed consent form and as required or allowed by law. Please read this HIPAA Authorization carefully before signing it.

**What is the purpose of this research study and the use or disclosure of my health information?**

[Provide a description of the study, such as its purpose, and describe how the individual’s health information will generally be used in the study, including any publication.]

**How will my health information be obtained?**

If you sign this HIPAA Authorization, you give permission to the study team to request health information about you from the following parties:

Any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, clinics, hospitals, home health agencies, diagnostics centers, laboratories, treatment or surgical centers, including but not limited to the UNC Health Care System and its members and affiliates (collectively, “UNC Health”), health insurance plans, and government health agencies.

[Delete any entities that do not apply to your study. Add any specific covered entities from which you will seek PHI for this study.]

**What health information will be used or shared for this study?**

Any information in your medical records relevant to your participation in this research. These records might include information about mental health, drug or alcohol use, HIV/AIDS or other communicable diseases, or genetic testing. Other information includes:

[Describe the information to be used or disclosed for the research study, including the timeframe. This may include medical records, physical exam results, medical history, lab tests, or specific health information. Ensure the information is limited to the minimum necessary and consistent with the IRB-approved study protocol.]

**Who will receive or be able to see or use my health information?**

The health information in your research study or medical records may be shared with, used by or seen by:

* Research and support personnel at the University;
* Collaborating researchers;
* Institutional Review Board;
* The sponsor of the research study, its representatives, agents, or outside reviewers for audit or other regulatory purposes;
* Third-parties retained by the researchers or sponsor to provide services in facilitation of the research study; and
* Government agencies and public health authorities, such as the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA).

The HIPAA protections that apply to your medical records generally do not apply to your information when it is in the research study records. There is also the potential for health information disclosed pursuant to this HIPAA Authorization to be subject to redisclosure by the recipient and, if so, the health information may no longer be protected by HIPAA.

[Include only if study participants are provided an incentive, such as a payment or a gift, for their participation] You may receive a payment or gift for your participation in this study. Any payment provided for your participation may be subject to applicable tax withholdings. Payments may be paid through third-party processors, such as external financial institutions or their vendors. To process payments, the study team may share certain identifiable information about you, such as name, contact information, and Social Security number, with third-parties, such as external financial institutions or their vendors, to process payments or tax reporting purposes.

**Will I be able to see information about the research study in my medical record?**

[For UNC-Health patients only] As part of this research study, you may be asked to have certain tests and/or procedures performed that may be done as part of your regular care. If so, the study doctor may use the results of these tests both for your clinical treatment and to complete this research. The result of tests and/or procedures done solely for this research study and not part of your regular care [will or will not] be included in your legal medical record.

[For participants who are not UNC-Health patients] All tests and/or procedures completed for this research study are done solely based on your participation in this research study. The study results [will or will not] be provided to you [or sent to your personal healthcare provider].

[For all studies] If this research study creates health information about you that will go into your medical record, you may not be able to see the health information in your medical record until the entire research study is over.

**Do I have to sign this HIPAA Authorization?**

If you do not sign this HIPAA Authorization, you cannot participate in this research study. However, your right to treatment, payment, enrollment or eligibility for medical services outside of this research study will not change if you refuse to sign this HIPAA Authorization.

**When will the HIPAA Authorization expire?**

[Choose one option] This HIPAA Authorization will not expire unless you stop it in writing. OR

This HIPAA Authorization will expire [insert date or event such as “at the end of the research study”].

**How do I stop this HIPAA Authorization?**

You may stop this HIPAA Authorization at any time. Revoking this HIPAA Authorization will not stop information sharing that has already happened. Any health information obtained prior to revoking this HIPAA Authorization may still be used or disclosed as necessary to maintain the integrity or reliability of the research study. To revoke this HIPAA Authorization, you must write to:

[Researcher’s name with mailing and/or email address.]

If you withdraw from the research study, no new data about you will be collected for study purposes unless the data concerns an adverse event related to the study. In the event an adverse event occurs, even if you have revoked this HIPAA Authorization, the study team may still need to review your medical record or share your information with the relevant parties described above.

**Will I get a copy of this HIPAA Authorization?**

The study team will provide you with a copy of this signed HIPAA Authorization.

**To be Filled out by Participant:**

Signature of Participant

Printed Name of Participant

Date

**Personal Representative of the Participant:**

[If authorization is to be obtained from a personal representative, signature line(s) for representative(s) must be included on the HIPAA Authorization, as well as a description of their authority to act for the participant. Remove if not applicable.]

Signature of Personal Representative

Printed Name of Personal Representative

Description of Authority to Act for the Participant

Date