University of North Carolina at Chapel Hill [Or substitute with the legal name of the relevant UNCHCS affiliate conducting the research (e.g. Rex Hospital, Inc.]

HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

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DELETE THIS AND ALL OTHER INSTRUCTIONS IN ITALICS AND YELLOW HIGHLIGHTS. The form must be written in 2nd person (e.g., You are being asked to take part in a research study about…)

IRB Study # [IRBNO WILL BE INSERTED]

Title of Study: [TITLE]

Principal Investigator: [PINAME]
Mailing Address for UNC-Chapel Hill Department: [PIADDR]

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

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1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

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, "UNCHCS"), 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. Be specific if you can.]

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Any information in your medical records that relates 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:

[Add additional information as necessary so that the research subject has an accurate understanding of the nature and scope of personal health information included in the authorization and so that all information that may be needed for the research study is covered. Conversely, you should delete any items that do not apply. The sensitive items listed above must be disclosed per State law, if they will be accessed.]

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, and certain employees of the University of North Carolina at Chapel Hill or other affiliated entities conducting the research, or government agencies (like the FDA) if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

[HIPAA regulations require that we let people know that sharing the PHI with others who are not covered by HIPAA – such as pharmaceutical company sponsors – will take that PHI outside of HIPAA's coverage. For example, HIPAA generally requires authorization or waiver of authorization as well as certain accounting records for disclosures of individually identifiable information from the medical record, but these HIPAA requirements do not apply to the same individually identifiable health information in the research database. The natural concern for the research subject is whether this means that there are no confidentiality protections once the PHI has been shared outside of HIPAA coverage. The researcher should explain what confidentiality protections have been set up for the individually identifiable information in this study. In addition to the research study procedures to protect confidentiality, our standard clinical trial language requires the sponsor to protect the confidentiality of any individually identifiable data.]

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

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.
OR
This HIPAA authorization will stop (insert date or event).

[HIPAA requires that the authorization form clarify whether and when, if ever, the authorization will expire. Insert whichever of the above statements is applicable.]

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____	_____
Signature of Research Subject	Date
_____	
Print Name of Research Subject	

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: _____
Please explain your authority to act on behalf of this Research Subject:
_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Participant.

_____	_____
Signature of Personal Representative	Date