University of North Carolina-Chapel Hill
HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

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IRB Study #09-0605
Title of Study: UNC Health Registry

Principal Investigator: H. Shelton Earp MD
Mailing Address for UNC-Chapel Hill Department: CB#7295

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 (described in #2 below) about you:

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, health insurance plans, and government health agencies.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to researchers to use in this 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: name, age, telephone number, address (number, street, city, and zip code), date of birth, medical records including but not limited to height, weight, medical diagnoses, laboratory test results, medical treatments, and dates of clinic appointments, hospitalizations, and visits to the emergency room.

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 or government agencies if needed to oversee the research study. HIPAA rules do not usually apply to those persons 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.

All research staff are trained to maintain strict confidence of patient data. All information collected about you for this registry will be kept confidential. Some of the information in your medical records may include identifying information (for example, your name or address). This data from medical records will be linked together with your biologic specimens. It may also be matched with existing records in other datasets. A unique research ID will be used for this linkage and only authorized research staff will have access to your identifying information. All electronic data will be

stored on a password-protected, restricted-access database. All paper forms will be stored in locked cabinets. The link between your identifying and research information will be kept secure. You will not be identified in any report or publication about this research.

All information obtained for research is stored and released under conditions designed to protect the privacy of participants. Your research specimens and data may be shared with researchers at this or other institutions and will only be given to people who are approved by the UNC's Lineberger Comprehensive Cancer Center Data and Specimen Sharing Committee and the IRB. Your personal identifying information will not be sent to other researchers.

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 #1 on this form to give access to the information about you that is listed in #2 on this form. 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.

7. You have the right to stop this HIPAA authorization at any time. HIPAA rules are that if you want to stop this HIPAA authorization, 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.

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_____ _____
Signature of Research Subject Date

_____
Print Name of Research Subject

For Personal Representative of the Research Participant (<u>if applicable</u>)

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