

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

IRB Study # 95-0518

Title of Study: Recruitment and Screening of Potential Participants for EPA Studies

Principal Investigator: Dr. Ann Chelminski

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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.

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, EPA Medical Station records (for subjects previously enrolled in the EPA Human Studies Division system), UNC Center for Environmental Medicine, Asthma, and Lung Biology research records, and EPA Subject Recruitment Records.

2. If you sign this HIPAA authorization 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:

- Medical records from your health care providers
- Medical history, including family and personal medical history
- Physical examination
- Pulmonary function tests
- Laboratory tests on blood, urine, sputum
- Allergy skin testing
- Electrocardiogram
- Echocardiogram
- X-Rays or other images
- Communicable Diseases

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 the sponsor of the research study, the sponsor's representatives, officials of the IRB, 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. 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. Information gathered from you may be stored in two ways: (1) a computerized recruitment data base for which access is password protected and limited to the investigators on this study and to the recruitment staff; (2) a paper medical record which is secured in a double-locked medical records room and for which access is limited to EPA medical staff and investigators on this or other studies in which you are participating. Individuals who have access to personal information are bound by a confidentiality agreement not to disclose it.

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 stop one year after the signing date.

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.

Signature of Research Subject _____ Date _____

Print Name of Research Subject _____ Date _____