University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants: Phase I

United States Environmental Protection Agency

Medical IRB Study # 95-0518 (95-EPA-66)

Consent Form Version Date: September 8, 2020

Title of Study: Recruitment and Screening of Potential Subjects for EPA Studies
Phase I-Screening Questionnaire

Principal Investigator: Dr. Ann Chelminski

Principal Investigator Department: Aux Services Affiliates: EPA

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Funding Source and/or Sponsor: United States Environmental Protection Agency (US EPA)

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What are some general things you should know about research studies?

You are being asked to take part in a screening process for potential participation in research studies sponsored by the U.S. EPA. The investigators listed above oversee this study. Other professional persons may help or act for them. Joining this study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, at any time, without penalty.

Research studies are designed to obtain new knowledge. This new information may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study to receive health care.

Details about this screening process are discussed below. It is important that you understand this information so that you can make an informed choice about whether you want to participate. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this screening process is to gather information from you (to be described later) that will help the U.S. EPA's recruitment and medical staff determine your eligibility to participate in research studies. Your signature on this form **DOES NOT GRANT YOU PERMISSION TO PARTICIPATE IN ANY RESEARCH PROTOCOLS**. If you are found to be eligible, you may be asked later for your consent to participate in a specific research study.

Are there any reasons you should not be in this study?

You should not continue here today if any of the following apply to you:

- You are pregnant or think you may be pregnant.
- You are less than 18 years of age.
- You do not speak, understand, and read English well

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 500 to 700 persons screened per year for potential participation in studies sponsored by the U.S. EPA.

How long will your part in this study last?

It will take you approximately 1 hour to complete the forms provided in the recruitment package. You may opt to complete this screening process at home or at the U.S. EPA Human Studies Facility. If you are found to be eligible you may be asked to return for the second phase of the screening process called Phase II Physical Exam. Participation in an actual study may extend over a period of several weeks to several months.

What will happen if you take part in the study?

During this screening phase, you will complete the following forms provided in the recruitment package:

- Phase I Consent Form
- HIPPA Authorization
- Locator/Demographic Form
- Medical History Questionnaire
- Physical Activity Questionnaire
- Reimbursement Form
- Payment Disclosure Form
- Social Security Collection Payment Reporting Form

If you have elected to complete this packet at home, follow the instructions provided for returning the completed forms. A postage marked envelope will be included in the packet. Based on the information you provided in your medical history questionnaire, you will either be scheduled for Phase II Physical Exam or be told that you are not a candidate for further study.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved with being in this study?

There are no risks and discomforts in this stage of the screening process.

What if we learn about new findings or information during the study?

You will be given any new information gained during the study that might affect your willingness to continue your participation. Please note that the U.S. Environmental Protection Agency is not financially responsible should you decide to pursue with your physician any abnormal findings identified during screening.

How will your privacy be protected?

No research subject's personal identity will be in any report or publication of this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill and the U.S. Environmental Protection Agency will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University or government agencies for purposes such as quality control or safety.

Information gathered from you may be stored in two ways: (1) a computerized recruitment data base for which access is password-protected and is 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.

What will happen if you are injured by this research?

All forms of human health research involve a chance that something bad might happen to you. This may include the risk of injury or illness. Despite our high level of precaution, you may develop an injury or illness due to participating in this study. If you develop an injury or illness determined by an appointed U.S. EPA physician to be due to your participation in this research, the U.S. EPA will reimburse your medical expenses to treat the injury or illness up to $5000.

If you believe your injury or illness was due to a lack of reasonable care or other negligent action, you have the right to pursue legal remedy. The Federal Tort Claims Act, 28 U.S.C. 2671 et. seq., provides for money damages against the United Sates when personal injury or property loss results from the negligent or wrongful act or omission of any employee of the U.S. EPA while acting within the scope of his or her employment. Signing this consent form does not waive any of your legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence.

If a research related injury or illness occurs, you should contact the Director of the U.S. EPA National Health Environmental Effects Research Laboratory (NHEERL) Human Research Protocol Office at 919.966.6217.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you do not meet the inclusion criteria, have had an unexpected problem, have failed to follow instructions, or because the entire study has stopped.

Will you receive anything for being in this study?

You will receive $15.00 for completing Phase I of the screening process. You will receive payment for Phase I following the completion of Phase II physical examination. If you choose to withdraw prior to Phase II screening, a $15.00 check will be mailed to you for completing Phase I. If you are withdrawn from participation by study staff or if your appointment is cancelled by EPA staff within 24 hours of your scheduled appointment, you will be paid $15.00. We must notify the Internal Revenue Service when we pay a volunteer $600 or more in a year.

Will it cost you anything to be in this study?

It will not cost you anything to participate in this study. The costs of this research will be paid for by the U.S. Environmental Protection Agency.

Who is sponsoring this study?

This study is being sponsored by the U.S. Environmental Protection Agency.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have further questions about your visit today, you may contact the researchers listed on the first page on this form or call the U.S. EPA Medical Station at (919) 966-6232. Collect calls are accepted.

What if you have questions about your rights as a subject?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu. and/or the Director of the EPA NHEERL Human Research Protocol Office at (919) 966-6217.

Study Title: Recruitment and Screening of Potential Subjects for U.S.EPA Studies

Phase I-Screening Questionnaire

Medical IRB Study # 95-0518 (95-EPA-66)
Principal Investigator: Dr. Ann Chelminski

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent