



Give Blood for Medical Research

Environmental Polymorphisms Registry *Consent Form*

**Must be 18 years of age
or older to participate**

Sponsored by:

National Institute of Environmental Health Sciences
National Institutes of Health

U.S. Department of Health and Human Services
and The University of North Carolina Medical Center



**University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Subjects**

Medical IRB Study #: GCRC #2140
NIEHS IRB#04-E-N053
Consent form approved through May 4, 2007

Title of Study:

Environmental Polymorphisms Registry (EPR)

Sponsor:

National Institute of Environmental Health Sciences (NIEHS)
National Institutes of Health (NIH)
Department of Health and Human Services

Principal Investigators:

Perry J. Blackshear, M.D., D. Phil.
Office of Clinical Research
NIEHS

Paul B. Watkins, M.D.
General Clinical Research Center
UNC Medical Center

Patricia C. Chulada, Ph.D., M.H.S.
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Susan Pusek, M.P.H.
General Clinical Research Center
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You are being asked to take part in a registry and DNA bank (hereafter called "The EPR") that will be used for research studies. The investigators listed on the inside cover of this booklet are in charge of this registry; other professional persons may help them or act for them.

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

Research studies are designed to gain scientific knowledge that may help other people in the future. You may not receive any direct benefit from participating. There may also be risks associated with participating in research studies.

Your participation is voluntary. You may refuse to participate, or may withdraw your consent to participate in any study at any time, for any reason, and without jeopardizing your future care at this institution or your relationship with your doctor. If you are a patient with an illness, you do not have to participate in research in order to receive treatment.

Details about The EPR are discussed below. It is important that you understand this information so that you can decide in a free and informed manner whether you want to participate. You are urged to ask the investigators named above, or staff members who may assist them, any questions you have about The EPR at any time.

The EPR will be under the direction of Dr. Perry Blackshear at the National Institute of Environmental Health Sciences (NIEHS). Dr. Paul Watkins at the University of North Carolina Medical Center will oversee the creation of The EPR.

What is the purpose of the EPR?

This registry will allow scientists to look for certain uncommon differences in patients' genetic material or DNA. These differences are not known to be associated with any condition or

disease, but may be linked to the various ways humans respond to substances in our diets and/or environment.

How many subjects will participate in the EPR?

If you participate, you will be one of approximately 20,000 subjects in The EPR.

What will happen if you take part in the EPR?

The project is divided into two phases:

Phase 1: The creation of the registry. As a participant of the EPR, you will be asked to provide us with identification and contact information. You will be also asked to donate the blood left over in the purple top tubes of blood that were drawn from you today for laboratory tests ordered by your doctor. If you are not having a purple top tube of blood drawn but are having other blood tubes drawn today, we will ask you to give an extra tube of blood drawn into a purple top just for this study (about 1/4 of a Tablespoon). There will be no charge to you or your insurance for this. Your personal information will be entered into the registry database; DNA will be extracted from your blood, encrypted with a secret identification number, and placed in the registry's DNA bank. We only require a one-time sample, so if you donated your left-over blood to the EPR at an earlier date, please let the study interviewer know so this process isn't repeated. The UNC investigators, Paul B. Watkins, M.D. and Susan Pusek, M.P.H., will help oversee the creation of the registry which should take between 2 to 5 years. Once 20,000 patients have been recruited and the registry established, the NIEHS investigators will have sole responsibility for maintaining the registry.

Phase 2: Use and maintenance of the EPR. This registry will exist for up to 25 years. During that time, the DNA bank will be available to UNC and NIEHS researchers to look for certain differences in your DNA sequence. If one of these differences is found in your sample, a UNC or NIEHS scientist may contact you and ask you to participate in a future study of persons with the same DNA differences. They may ask for per-

mission to contact your family members as well. The NIEHS investigators, Drs. Perry Blackshear and Pat Chulada, will be responsible for phase 2 of the registry.

How long will your participation last?

Unless you withdraw from this registry, we will keep your personal information and DNA for up to 25 years. During this time, you will be contacted once a year (by mail or phone) and asked to update your contact information. Also during this time, you might be contacted and asked to participate in a future follow-up study as described above. These future studies will most likely involve filling out a questionnaire or taking a telephone survey, but may involve being interviewed or having a physical examination or laboratory evaluation including blood tests. If you are re-contacted, we will not ask you to participate in more than one study per year.

Will I have to participate in future studies?

No. Future studies are separate from the EPR. If you are asked to participate in a follow-up research study and you voluntarily agree to do so, you will be asked at that time to sign a new consent form for that study.

What are the possible risks or discomforts?

The only known risk of this study is some minimal risk associated with maintaining your confidentiality. We will make every effort to keep your participation and study results confidential. For this study, we have obtained a Certificate of Confidentiality which legally protects your personal information and study data from third parties, e.g. insurance companies, employers, and others (see privacy protection sections below).

What are the possible benefits?

You will not benefit personally by joining the EPR. However, you may be helping scientists discover differences in our genetic material that make people more sensitive to environmental factors.

Will I be given my study results?

To date, none of the DNA differences we will be looking at have been associated with a condition or disease. Therefore, you will not receive any results from the initial DNA testing. However, the objective of some of the follow-up studies might be to look for an association of a particular DNA difference with a certain condition or disease. If you participate in this type of follow-up study, you may or may not be given the results. That will be decided by the principal investigator of that study. All results generated from the EPR are strictly for research purposes only and cannot be used to diagnose or predict a condition or disease.

How will your privacy be protected?

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health which is valid for the duration of this study (31 years or through March 31, 2035). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

There are no conditions under which the researchers will make voluntary disclosures.

Researchers at NIEHS will keep a record of your name, sex, birth date, address, telephone numbers, e-mail address, and UNC patient ID. They might use this information to contact you for future studies. No subjects will be identified in any report or publication resulting from this registry.

All personal identifiers will be removed from your blood specimen and this will be encrypted with a secret identification number. The encryption system will be used on your blood and DNA samples and test results throughout the course of the study. Only the NIEHS investigators in charge of the registry, Drs. Perry Blackshear and Patricia Chulada, and other personnel who are directly involved in the registry, will have the key that connects your personal information to your samples and results. Test results will consist of DNA sequence data (changes in your genetic code) and will be stored in a password-protected, electronic database. NIEHS and UNC researchers and their collaborators will have access to your DNA and study results, but only in their secret encrypted form. Based on your study results, these scientists may want to contact you and ask you to participate in follow-up studies. These scientists will only be given your name and contact information (along with other people in the registry who have the same DNA differences) if their study is approved by a scientific review panel and the Institutional Review Board of NIEHS or UNC.

Information collected in the EPR is for research purposes only and will not be used for decisions concerning medical treatment and/or medical insurance payments. DNA samples, the encryption key, and all accompanying personal identification and contact information will be kept for no more than 25 years *from today's date* and will then be discarded. During this time, these samples are the property of the National Institute of Environmental Health Sciences.

Will you be paid for participating?

You will receive \$20.00 for participating in the EPR.

Will it cost you anything to participate?

There will be no cost to you for any part of this study.

Who is sponsoring the EPR?

This research is being conducted and funded by the National Institute of Environmental Health Sciences, National Institutes of Health.

What if you want to withdraw from the EPR?

Your participation in the EPR is completely voluntary. You may withdraw from this study at any time without affecting your current or future treatment at UNC. To withdraw, you should call or email Dr. Patricia Chulada (tel: 919-541-7736; e-mail: chulada@niehs.nih.gov) at the National Institute of Environmental Health Sciences. If you are unable to reach Dr. Chulada within a reasonable amount of time, then contact Dr. Perry Blackshear (919-541-4899) at the National Institute of Environmental Health Sciences. Once notified, we will discard what blood or DNA samples may be remaining and make sure that you are not contacted in the future concerning follow-up studies. If your DNA has already been analyzed for certain DNA differences and the data have been statistically analyzed, we will not be able to remove the data from our databases, but we will not give your name and contact information to other scientists for future studies. If your name and contact information have already been passed on, we will contact those scientists and ask that your name be removed from their list.

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 questions, you should call or email Dr. Patricia Chulada (tel: 919-541-7736; e-mail: chulada@niehs.nih.gov). If you are unable to reach her within a reasonable amount of time, call Dr. Perry Blackshear at 919-541-4899.

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

Creation of the EPR has been reviewed and approved by the Office of Human Research Ethics (OHRE), the Biomedical Institutional Review Board at the University of North Carolina at Chapel Hill and the Institutional Review Board at the National Institute of Environmental Health Sciences. If you have any questions or concerns regarding your rights as a research subject, you should first contact the Chairman of the NIEHS IRB committee, currently Marian Johnson-Thompson, Ph.D. (919) 541-4265. In addition, you may contact the chairman of the IRB at UNC who is currently Stephen A. Bernard, M.D. at (919) 966-1344.

Environmental Polymorphisms Registry (EPR)

1. Which category best describes your racial heritage?

- American Indian or Alaskan Native
- Native Hawaiian or Other Pacific Islander
- Asian
- Black or African American
- White
- More than one race, please specify _____
- Unknown or Not Reported

2. Which category best describes your ethnicity?

- Hispanic or Latino
- Not Hispanic or Latino
- Unknown or Not Reported

3. Subject's Agreement:

I have read the information provided above. I voluntarily agree to participate in this registry. My signature below signifies that my blood sample may be used for this research purpose.

Signature of Research Subject

Date

Printed Name of Research Subject

4. Address, Telephone Numbers and E-mail Address of Research Subject:

Street Address

City or Town

State

Zip code

Home Telephone

Work Telephone

Other Telephone

E-Mail

5. Person Obtaining Consent:

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

**You will be given a copy of this consent form for your own records.*

