



Consent to Participate in a Research Study

Screening Test for Nervous System Injury (Pr000003202)

We are asking you to participate in a research study with the Laboratory of Neurotoxicology, Department of Pharmacology and Cancer Biology, at Duke University Medical Center. The nature of the study, risks, and benefits are discussed below. Please read the information carefully before agreeing to participate. Your participation is voluntary. You are free to take part in the study or leave at any time.

Purpose and Background of the Study

If you choose to participate in this study, we will collect blood from you. We are collecting blood from people who are healthy, people who have been exposed to certain chemicals, and people who have problems with their nervous system. The purpose of this study is to test your blood for antibodies, the proteins that help fight disease and infection. Based on work we have done, we think the amount of certain antibodies in your blood may relate to diseases people get and chemicals to which they have been exposed. We hope the results of this study will help us understand the way diseases of the nervous system develop, and any similarity or relationship this has to exposure to chemicals.

Design and Procedures

If you agree to participate, your physician or person trained to take blood will collect blood from your vein by needle stick. A total of 1½ teaspoons (7 ml) will be collected. This is the normal procedure for taking blood. You will be asked to complete a questionnaire about your medical history, medications you take, and the chemicals to which you were exposed, as well as your age. This questionnaire will take about 15 minutes to complete.

Risks and Benefits

Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Since you are not being tested for a disease, or the likelihood of developing a disease, you will not be notified of the results of this study. You will not benefit directly from participating in this study. However, knowledge may be gained that will benefit others. We hope that this research will lead to the development of treatments of problems involving chemical exposures.

Data Storage and Confidentiality

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Abou-Donia's office. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Duke



Consent to Participate in a Research Study

University Health System Institutional Review Board, a. If any of these groups review your research record, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations a.

The study results will be retained in your research record for at least six years after the study is completed. At that time the research information will be destroyed or information identifying you will be removed from such study results at DUHS.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. You may withdraw your authorization for us to use your data that have already been collected (other than data needed to keep track of your withdrawal), but you must do this in writing. If you wish to withdraw please write

Mohamed B. Abou-Donia, Ph.D.
Department of Pharmacology
LaSalle Street Extension
LSRC Building, Room C 173
Duke University Medical Center
Durham, NC 27710

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study Dr. Abou-Donia at 919-684-2221 during regular business hours.

For questions about your rights as a research participant, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

THIS SPACE INTENTIONALLY LEFT BLANK

“STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have



Consent to Participate in a Research Study

been told whom to contact if I have additional questions. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed copy of this consent form."

Signature of subject

Date

Signature of person witnessing consent

Date