Consent to Participate in a Research Study
Nervous System Injury

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 study is being conducted by Dr. Mohamed B. Abou-Donia. The nature of the study, risks, and benefits are discussed below. Please contact the study doctor to discuss this consent form with you, ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. 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 saliva or 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 from diseases such as Alzheimer’s Disease, Amyotrophic Lateral Sclerosis, Attention Deficit Hyperactivity Disorder (ADHD), Autism, Concussion, Epilepsy, Guillain-Barre Syndrome, Migraine, Motor Neuron Disease, Multiple Sclerosis, Myasthenia Gravis, Parkinson's Disease, Stroke, Traumatic Brain Injury, mild Traumatic Brain Injury, anorexia, bulimia and binge disorders, anxiety disorders, bipolar disorders, cerebral palsy, depression, schizophrenia, developmental disorders, spina bifida, neuromuscular disease, fibromyalgia, pain (chronic), restless leg syndrome, blindness & visually impairment, macular degeneration, glaucoma, spinal cord injuries, stroke, substance abuse disorders, tumors of the brain and glioblastoma.

Autoimmune Diseases: Alopecia areata, Alopecia areata, Autoimmune encephalomyelitis, Autoimmune hepatitis, Autoimmune inner ear disease (AIED), Autoimmune myocarditis, Chronic inflammatory demyelinating polyneuropathy (CIDP), Crohn’s disease, Fibromyalgia, Lupus, Lyme disease, chronic, Psoriasis, Sjögren’s syndrome, Type 1 diabetes.

Drugs of Abuse: Amphetamines, MDMA (Ecstacy), Club Drugs (GHB), Rohypnol, Ketamine), Cocaine, Khat, Alcohol, Barbiturates, Benzodiazepines, Opiates heroin, morphine, codeine, Oxycodone, Marihuana (THC), Hashish, Lysergic Acid Diamide (LSD), Phencyclidine (PCP), Inhalants, Steroids (Anabolic), Tricyclic Antidepressants.

The purpose of this study is to test your saliva or 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 and after we have received your signed and dated consent form, your physician or person trained to take blood will collect blood from your vein by needle stick. A total of
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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. You can mail it back to us in a stamped, self-addressed envelope we have provided to your doctor.

In some cases the doctor will request to collect a saliva sample, according to the following procedure. You will be instructed to avoid eating, drinking, smoking, and using oral hygiene products at least one hour before collection. You will then be instructed to rinse the mouth thoroughly with deionized water prior to the collection procedure and to void the mouth of saliva. While seated comfortably with your eyes open, head tilted slightly forward, and instructed to rest for 5 minutes for the collection period. You will then spit into a pre-weighed test tube every 60 seconds and repeated for 5 minutes.

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.

Costs and Compensation
There are no costs to you for participating. You will not be compensated for your participation.

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 University Health System Institutional Review Board. 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.
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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.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Mohamed B. Abou-Donia, 919-684-2221 during working hours and 919-740-4773 any time 24-hour number after hours and on weekends and holidays.

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

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.
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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Dr. Abou-Donia at 919-684-2221 during regular business hours and at 919-740-4773 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.
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“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 been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. 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 and dated copy of this consent form."

_________________________  _______________________
Signature of subject        Date/Time

_________________________  _______________________
Signature of person witnessing consent  Date/Time