

November 2009

Dear Study Subject:

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, you will be asked to read and sign the accompanying consent and have your signature witnessed by another adult. If you have questions about the study you may call Dr. Abou-Donia at 919-684-2221. A stamped addressed envelope is provided. A second copy of the consent is for your records. Your doctor will collect blood from your vein by needle stick. A total of 1½ teaspoons (7 ml) will be collected. 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. Please mail your signed, witnessed consent and the questionnaire in the envelope provided.

### **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. There is a risk of loss of confidentiality. Provisions for protecting your confidentiality are explained below. 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 this research will lead to the development of treatments of problems involving chemical exposure.

### **Data Storage and Confidentiality**

Your medical information and test results will be identified only by a code number. The key to the code will be kept in a separate locked file. The key to the code will be



destroyed at the end of the study. Names or other identifying information will not be used in any report, scientific publication, or presentation of the results of this study. You are free to withdraw from the study at any time, and may withdraw your study records if you desire.

**Consent**

Before you agree to participate in this research, please discuss it with your physician, and if you need any further information contact Dr. Abou-Donia, collect, to answer any questions you may have during the investigations at 919-684-2221. Furthermore, you may contact Duke University Office Institutional Review Board (IRB) (919) 668-5111 with any questions concerning your rights as a research subject.

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