

UNIVERSITY OF WASHINGTON  
Consent/Assent Form  
Study of Organophosphate Exposure

APPROVED

SEP 17 2009

UW Human Subjects  
Review Committee

**Researchers:**

Clement E. Furlong, Ph.D. Research Professor, Departments of Genome Sciences and Medicine,  
Division of Medical Genetics, University of Washington, Seattle, WA (206) 543-1193

Michael MacCoss, Assistant Professor, Department of Genome Sciences, University of  
Washington, Seattle, WA (206) 616-7451

Dr. Sarah Mackenzie Ross, Clinical Health Psychology Department, University College, London,  
UK

**Researchers' statement**

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent". We will give you a copy of this form for your records.

**PURPOSE OF THE STUDY**

We want to know more about exposure to harmful compounds. We are interested in studying exposure to organophosphates (OP). It is possible that proteins in the blood are modified by exposure to OP. We are asking people who may have been exposed to OP to provide a blood and saliva sample.

**STUDY PROCEDURES**

If you choose to be in this study, we will ask you to provide a blood sample. If we see you in person, we will either take up to six teaspoons of blood from a vein in your arm, or we will take a few drops of blood from a finger stick. This will take only a few minutes. If you are not able to come to our lab, you may arrange for your own blood draw, and to have the blood sent to us.

We will send the blood to the lab. We will test the blood for proteins that are modified by OP. The test is not certified by the U.S.A. Food and Drug Administration (FDA) or any other regulatory agency. If you choose, we can give your individual research results to your doctor who may choose to share the results with you. The results may indicate whether you have been exposed to OP. However, the results are not conclusive.

We may also ask you to chew on a cotton plug for a short period of time to collect saliva. We will analyze your saliva to determine if any salivary proteins have been modified by OP exposure.

Sometimes people provide us with video recordings, or we ask people to let us make a recording. In either case, we will have a separate consent form that allows you to state clearly how you will let us use any such recordings. You don't have to be recorded, or give us a recording, to take part in the study. If we do make a video recording, we will give you a copy if you would like one.

**RISKS, STRESS, OR DISCOMFORT**

Having blood drawn may cause some pain. A bruise may form where the needle enters the vein. Occasionally people have an infection or faint. There should be no discomfort from chewing the cotton plug. There is a risk of breach of confidentiality (see the "Other Information" section, below, for information on how we will protect your confidentiality).

SEP 17 2009

## BENEFITS OF THE STUDY


UW Human Subjects

You may benefit from the study if your doctor can make use of the test results. We hope the results of the study will help us find out more about exposures to toxic organophosphorus compounds. We want to learn more about being able to tell who has been exposed to these compounds, and how they may be affected by them.

## OTHER INFORMATION

Taking part in this study is voluntary. You can stop at any time. You will continue to receive health care whether or not you choose to take part in this study. Information about you is confidential. We will code study records. The link between the code and your name will be kept in a secured location, separate from the study information. Only the researchers at the University of Washington will have access to information that will identify you. We will keep the information linked to your identity indefinitely. If we publish the results of this study, we will not use your name. If you would like us to send the results to your physician, please give your permission below.

Government or university staff sometimes reviews studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

	Clement E. Furlong	10-12-09
Signature of investigator	Printed name	Date

**Subject's statement**

Initial one:

I give my permission for the researchers to send my test results to my physician. \_\_\_\_\_

I do NOT give my permission for the researchers to send my test results to my physician. \_\_\_\_\_

The study has been explained to me, and I voluntarily consent to participate. I have had an opportunity to ask questions. Future questions I may have about the research will be answered by one of the investigators listed above. If I have questions about my rights as a subject, I may call the University of Washington Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

_____ Signature of subject	_____ Printed name	_____ Date
-------------------------------	-----------------------	---------------

**Parent's or guardian's statement (If subject is a minor, or otherwise unable to give consent)**

I give my permission for the researchers to send the test results to the subject's physician. (Initial) \_\_\_\_\_

I do NOT give my permission for the researchers to send the test results to the subject's physician. \_\_\_\_\_

The study has been explained to me, and I voluntarily consent to allow \_\_\_\_\_ to participate. I have had an opportunity to ask questions. Future questions I may have about the research will be answered by one of the investigators listed above. If I have questions about the rights of research subjects, I may call the University of Washington Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

_____ Signature of parent or guardian	_____ Printed name; relationship to subject	_____ Date
--	--	---------------

APPROVED

**Physician Contact Information**

SEP 17 2009

UW human subjects  
Review Committee

Name: \_\_\_\_\_

Affiliation \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

Please remember that we cannot guarantee the confidentiality of any information sent by e-mail.