

UNIVERSITY OF WASHINGTON
Consent/Assent Form
Study of Organophosphate Exposure

JAN 21 2011

UW Human Subjects
Review Committee

Researchers:

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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 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 may at sometime in the future 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.

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RISKS, STRESS, OR DISCOMFORTUW Human Subjects
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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).

BENEFITS OF THE STUDY

You may or may not benefit from the study. We hope the results of this 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.

If you are able to come to the University of Washington for the study, the required blood draw for the study will be performed at no cost to you. If the blood draw does not take place at the University of Washington, you will be responsible for the blood draw fee if your insurance does not pay for it. In addition, you will be responsible for the cost of shipping the blood sample to our research laboratory at the University of Washington, though your union council may reimburse you for the shipping costs.

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.

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

Physician Contact Information

Name: _____

Affiliation _____

Address: _____

Telephone: _____ Fax: _____

E-mail: _____

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

APPROVED

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