

PARTICIPANT CONSENT FORM

Title of Project: **Inflammatory markers in welders**

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Why am I being asked to take part in this research study?

I am an investigator from the University of Alberta interested in monitoring exposure to welding fumes and the health effects related to this exposure.

We are collecting samples from professional welders from age 18 - 70 for this study. You have been approached by us since you are a full-time welder.

This form contains information about the study. Before you read it, a member of the study team will explain the study to you in detail. You are free to ask questions if there is anything you do not understand. You will be given a copy of this form for your records.

What is the reason for doing the study?

A better understanding of exposure and health effect may be beneficial for preventing lung diseases in welders. In particular, I am interested to look at metals and inflammatory markers in the blood and exhaled breath condensates (EBC) of welders after exposure to welding fumes. This will allow us to better understand the health effects associated to exposure to welding fumes.

In addition, your blood and exhaled breath condensate samples will be collected, transported, and stored to be analysed later for metabolites if we get extra funding. The metabolites are small molecules produced by your body and modifications in your metabolism can be seen through these small molecules. If there is any health effect associated with exposure to welding fumes, we want to know if we can see it in metabolites from your blood or your EBC.

What will happen in the study?

You will be asked to carry a personal sampling pump connected to a filter holder that contains a filter for trapping airborne particles. The pump will be fixed to your belt. The filter holder will be located on your shoulder to collect particles in your breathing zone. Each sampling pump weighs approximately 1 lb (0.45 kg).

You will also be asked to provide two blood and EBC samples, one pre-shift and one post-shift. The blood will be drawn by a licensed nurse or medical laboratory technician and will be similar

to a regular blood test.

All sampling will be carried out at your workplace. Sample collection will be performed in one day. The time to fill up questionnaires is about 20 minutes and we will be collecting air samples during your full work shift (i.e. 8 to 10 hours). The whole sampling will be completed in one day.

We will not be looking for drug use in the blood samples. We are just looking at any modification of regular metabolites due to exposure to welding fumes. Samples will be destroyed once the study is completed.

All data will be aggregated without any facility or group of welders being identified.

What are the risks and discomfort?

Participation in this research study poses minimal risk for research participants. This means that the risk of harm due to this study is equivalent to the harm encountered in your everyday life. The only risk of wearing the sampling pump is physical discomfort due to the weight of the pump. However, pumps are designed for personal sampling, and the belt and pouches used should make the equipment comfortable to wear. Collection of blood samples is similar to regular blood test and can cause slight discomfort to participants. There is a risk of bruising and/or a rare possibility of infection. We will bring some food and fruit juice for participants in case some participants start not feeling well due to blood loss (i.e. low blood pressure). All blood samples will be collected by a licensed nurse or a medical laboratory technician. There can be small discomfort collecting EBC as you have to blow for 10 minutes in a tubes but this should be minimal.

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator and/or institution from their legal and professional responsibilities.

Note that there is a risk of being exposed to Covid-19 by participating in this study. To limit the risk, our team has developed a specific procedure to collect samples safely. The risk should be lower than in your regular workplace since our crew will be wearing N95 masks. These masks are known to be very efficient in preventing transmission of Covid-19. In addition, hand sanitizer will be provided to you and the crew to sanitize hands as needed.

What are the benefits to me?

This research will provide feedback regarding the health effects of exposure to welding fumes. Although there might not be any direct benefit to you. Once the study is complete, the aggregated results will be sent to your employer. This will help your employer protect you better. Since data will be aggregated, there will be no risk of any punitive action towards you by your employer. With the results of the study, we will be better able to provide health and safety information and recommendations to your employer. In addition, you will know the level of exposure at your workplace. We will also provide your employer with recommendations on how to protect you.

What will I be asked to do while I am in the study?

You will need to ensure that you are not taking any alcohol or drugs for up to 48 hours prior to sample collection.

Do I have to take part in the study?

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time before sampling is completed. For example, if you feel uncomfortable wearing the pump you can stop participating. Your personal data and samples will be destroyed in case you choose to withdraw from the study. Although you may be worried to give blood samples, we will be collecting a maximum of three tubes, which is often less than what is collected for regular blood tests.

Can my participation in the study end early?

You can stop participating in the study at any time. All the information and samples collected from you will be destroyed.

Will I be paid to be in the research?

You will receive a payment of \$40 to participate in the study.

Privacy and Confidentiality

During this study we will be collecting information (or “study data”) about you. We will use the data to help answer research questions and we will share (or “disclose”) your information with others such as the study sponsor and other researchers. Your study data may also be shared with government departments involved in occupational health and safety such as the Ministry of Labour. These departments are often called “regulatory authorities”. However, only aggregated data will be provided with no personal information about you or your employer.

Below we describe in more detail how your data will be collected, stored, used and disclosed.

What data will we be collecting?

Should you agree to participate, you will be asked to fill a lifestyle and health questionnaire. You will have to provide your gender, age, height, weight, and dietary information. We will also be asking for some of your medical history, alcohol consumption, and drug/medication exposure. This is done to ensure that there are no confounding factors which could complicate the measurement of metals or metabolites in your samples.

In addition, we will ask you to fill in a welding fume exposure questionnaire in which you will be asked information about the welding activities you have done for your working life as a welder. You will also be asked how long you have been working as a welder. This will help us understand the metal levels in blood samples.

Finally, for the day of air sample collection, we will ask you to log information about welding activities that day. It will help us link the metals in air samples with the welding activities.

How will the study data be stored?

The study data we collect which will include your name will be securely stored in a locked cabinet in our office.

How will the study data be used?

Any personal information gathered for the research project will be protected and used in compliance with Alberta's Freedom of Information and Protection of Privacy Act. Your name will be associated with a code that we assign to it to ensure confidentiality in our laboratory records. We will never report personal information and the results from this study will not be associated with your name. Note that the personal data will be destroyed once the study has been published.

Results from blood samples will be linked to results from the air sample to see if we can link metal concentrations in air samples with metal concentrations in blood samples. Results in blood and EBC samples will be linked with some of your personal data such as your weight and height as they may influence the results.

Who will be able to look at my health data?

For our research studies, it is important that the data we get is accurate. For this reason, the study information, including your name, may be looked at by the study sponsor, the Health Research Ethics Board and the University of Alberta. By signing this form, you are giving permission to the researchers to collect, use and disclose information about you as described above.

If you would like to see the study data collected about you, please ask the principal investigator.

Who should I contact if I have questions?

If you have concerns about your participation in this study, you may contact the study investigator at 780-492-3240/587-921-1895.

You may also contact the University of Alberta Research Ethics Board Office at 780-492-2615 if you have any concerns about your rights as a study participant. If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office is independent of the study investigators.

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How do I indicate my agreement to be in this study?

By signing below, you understand:

That you have read the above information and have had anything that you do not understand explained to you to your satisfaction.

- That you will be taking part in a research study.

- That you may freely leave the research study at any time.
- That you do not waive your legal rights by being in the study
- That the legal and professional obligations of the investigators and involved institutions are not changed by your taking part in this study.

SIGNATURE OF STUDY PARTICIPANT

Signature of Participant

Name of Participant

Date

SIGNATURE OF PERSON OBTAINING CONSENT

Signature of Person Obtaining Consent

Name of Person Obtaining Consent

Date

SIGNATURE OF THE WITNESS

Signature of Witness

Name of Witness

Date

A signed copy of this consent form has been given to you to keep for your records and reference.