Assessing the effectiveness of PFAS exposure control in exposed occupational groups.

INFORMATION FOR PARTICIPANTS

Investigators: Professor Jochen Mueller and his team at The University of Queensland.

Please read the general information below and the attached document regarding Informed Consent. If you agree to participate in this study, the script in the consent document will be read to you over the phone during a recorded conversation with a member of the Research Team at the University of Queensland to obtain verbal consent for your participation.

General Information

PFASs (per- and polyfluoroalkyl substances) are manufactured chemicals that are commonly detected at low levels in the blood of many people in the general community. The PFASs in blood come from food, water, dust and everyday products. In Australia elevated levels of PFAS concentrations in blood serum have been detected in some community and occupational groups and are likely the result of environmental exposure to aqueous film forming foam (AFFF) during the 2000s.

You are invited to take part in a research project to be conducted by researchers at the University of Queensland and collaborators, and funded by the National Health and Medical Research Council.

This is a new study that will follow-up with some of the participants from the Airservices Australia Exposure Studies conducted in 2013 and 2018. The aim of the study is to measure the change across time in PFAS levels for individuals previously identified as having elevated levels of PFASs. Understanding these changes will help to understand what factors might reduce PFAS levels in the blood. Efforts have been made in workplaces to control the exposure of PFASs in the environment. Collecting blood samples from individuals at different times and analysing the level of PFASs in an individual’s blood can help determine how effective these efforts have been in controlling exposure to PFASs. It will also help us to understand why some individuals’ PFAS levels decrease faster than others and, for those people whose PFAS levels are not decreasing as we expect, try to understand why this may be the case.

This study will also help us understand more about the relationship between PFAS levels and levels of other biochemistry measurements of health. This study will not provide specific information about an individual's health status. The study is designed to contribute to the broader research into PFAS exposure and their potential association with human health issues.

Why am I being contacted about the new study?

When you participated in the Airservices PFAS Exposure study previously, the PFAS level in your blood was elevated when compared to the general population level. This means that you would be an ideal
candidate for this study because we expect to be able to track a reduction in your PFAS blood level over time using the results obtained in the 2018 study and the 2013 study (if you took part in this). If you participate in this new study, there would be nearly ten years of PFAS measurements available to provide an understanding of how PFAS levels change over time.

**What will my participation involve?**

You will be asked to complete a questionnaire and to provide two blood samples. The first sample will be collected in 2021 and a second blood sample approximately two years later.

The blood samples (3 tubes of blood will be collected = about 25mls in total) can be provided at any convenient Sonic Healthcare pathology clinic (details of clinics close to you will be provided). You are not required to fast before providing your sample. Your blood samples will be analysed for PFASs and related blood chemicals. The study team will also measure other common blood chemicals which have previously been shown to change in association with PFAS exposure (e.g. uric acid, blood fats, cholesterol, kidney and liver function and thyroid hormone measurements). Analysis of your blood samples will not involve genetic testing.

**How do you benefit from this study?**

There will be no immediate personal benefit to you from participating in this study. The level of PFASs in any person’s blood is the result of a lifetime accumulation from many different exposures. The main benefit of this study is to provide long term information that will assist us to better understand occupational PFAS exposure levels, to evaluate the success of exposure control measures and to understand the factors that may influence exposure to and elimination of PFASs in an individual’s blood.

You will receive results from your blood sample including biochemistry and PFAS levels for each blood test, as well as a summary report of final study results at the conclusion of the study. These results will show whether PFAS levels in the blood are changing (e.g. reducing) in a way that would be expected with the utilisation of effective controls of PFASs in the workplace.

More information is provided in the section below.

**Will I be told the results of the study?**

Your blood samples will be initially tested by Sullivan Nicolaides pathology to measure the uric acid, blood fats, cholesterol, kidney and liver function and thyroid hormone. Approximately one month after providing the blood samples, you will be sent a personalised report of your results from these blood biochemistry tests.

Your results will be reviewed by our GP researcher working with our research team. If any of these results are abnormal, the letter that you receive will include a recommendation for you to attend your
usual medical service to discuss these results and arrange further review. Abnormal findings are common in the general community, even when the person is not aware of these. The study staff will not be able to provide a clinical interpretation of these results because that interpretation requires a full medical history and examination. Your usual medical service will be able to interpret this information for you. It will be your responsibility to seek further medical follow up and there may be costs associated with this. It will be your responsibility to fund all costs related to any medical or clinical follow up required after you receive these results.

In addition, your blood samples will be sent to the researchers at the Queensland Alliance for Environmental Health Sciences (QAEHS) at the University of Queensland where they will be analysed for PFAS chemicals. These tests are done in batches so the results of these tests will take longer. You will be provided with a summary of your personal PFAS levels in a separate letter within six months of providing your first blood sample. This summary will contain a comparison with your PFAS levels from your previous participation in the Airservices Study from 2018 (and 2013 if you took part).

Towards the conclusion of the study (approximately the end of 2024), a report that summarises the research findings will be sent to all participants. You will also receive a personalised summary of your blood serum PFAS level from your two separate blood tests in 2021 and 2023 as well as your previous results from other Airservices Study. These results will be presented with information to help you understand them. It is important to note that the study will not provide definitive advice about any individual's health. Your PFAS levels will be compared to the range of results found in other individuals in the workplace cohort and with results found in the general community. Currently, there is only limited knowledge about the associations between higher PFAS exposure and specific health parameters. Because there is little known about the health outcomes of high PFAS, there is no recommended treatment for individuals with PFAS levels that are higher than levels in the general population. If you do not wish to receive any of your results then you can tell us when you provide your consent to take part.

Will the information you give be confidential?

Your information will always be treated with the utmost confidentiality. All information will be coded when it is collected. Your coding details will be stored separately. All personal information from the consent form will be kept securely and separately from the other material. Your completed questionnaire and blood results will be stored as de-identified information. Although the outcome of the study may be published in the scientific literature, your identity will not be revealed. Your participation in the study and your results will remain confidential.

Do you need to take part in this study?

Your participation is voluntary. You may choose to not participate in this research study and you may choose to withdraw your consent at any time and at any point in the study.
Are there any possible risks?

There are limited risks associated with this study. There may be some discomfort and/or bruising following the blood sampling but this is expected to be temporary. Specially-trained blood collectors will collect your blood sample.

Please make sure you are well hydrated before providing the blood sample. It is also recommended that you eat something within the hour prior to the collection or if this is not possible, to make sure you eat something soon after the blood test.

If, however, you have had any adverse effects in the past from providing a small sample for blood testing - e.g. felt unwell during or after your blood test or have previously fainted during a blood test – then please notify /discuss this with the blood collector at the time of your blood collection. Please note, however, that these effects are rare with the majority of people having little to no effect.

What if I change my mind?

If you do consent to participate, and you wish to withdraw this consent, you can do so by contacting the study team by phone on 1800 370 760 or by email to PFASstudyUQ@uq.edu.au. We will destroy any information about you that was collected during your participation (i.e. any results, samples or data), unless you want us to keep it.

What will happen to my stored blood sample at the end of the study?

With your consent, when the study is completed, your blood sample will be stored for future research on environmental pollutants. This future research WILL NOT include genetic research. If you do not wish your blood to be stored for future testing, then this will be recorded when you give your verbal or written consent. If you change your mind, you can withdraw your consent to participate at any time and request that your sample be destroyed. Your results will remain confidential at all times. You will not receive any results from future testing of this blood sample after this study is concluded.

Future plans for the study

With your permission we would like to contact you later in the study regarding a another phase of the project that will examine the external exposure to PFAS chemicals. This forms part of the overall study. Briefly, this involves the collection of water, food, dust and air samples in your home. This phase of the study will assist in identifying any ongoing sources of PFAS exposure. We are not asking you to consent to this now but asking if you are happy to be contacted about this in future.
Contacts
This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. While you are free to discuss your participation in this study with our project staff (Principal Investigator Jochen Mueller; telephone on (07) 3343 2450 or 1800 370 760; or by email qaehsadmin@uq.edu.au). If you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinators on (07) 3365 3924 or email humanethics@research.uq.edu.au.
INFORMED CONSENT from participants for their participation
– this verbal script will be read to you over the phone

I, (your full name)__________________, have read the Participant Information Sheet.

I have been given the opportunity by research staff to ask questions about the project and about my participation. I understand that this research will involve the completion of a questionnaire and the provision of two blood samples (approx. 25mls) for biochemical analysis and that each sample will be taken at two separate times during the project. I have been informed of the potential risks to my health and well-being related to this research study. I understand that my personal information from my questionnaire and my blood results will be kept confidential. I understand that a copy of my specimen results will be sent to my mailing address. I understand that I am responsible for the safekeeping of the results sent to me.

I understand that if any of the blood results are abnormal, then the researchers will alert me to this, but they will not be able to provide any clinical interpretation of these results. I understand that it is my responsibility to seek further medical follow up of my results with my usual medical service and that any costs associated with any medical follow up will be my personal responsibility,

I agree that any unused blood from my sample may be stored and used for future work on environmental pollutants, but that I will not receive any results related to any future testing.

I acknowledge that I am free to withdraw from the study at any time without comment or penalty,

Do you agree to participate in the PFAS Exposure Control Study 2020-2024? ______Participant response____

This consent was given by, ______(your full name)_________ to ______(name of staff member from UQ)____ for the University of Queensland.

Finally, I agree to be contacted by the researchers about a future external exposure study that is part of the current study, though I understand that I am under no obligation to participate.

Do you agree? ______Participant response____

This consent was given by, ______(your full name)_________, to ______(name of staff member from UQ)____ for the University of Queensland.