INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

Nicotine delivery and user reactions to IQOS and different types of e-cigarettes.

Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Thank you for your interest in this study. Here we explain in detail what it is about and provide a contact at the end to ask any other questions you may have.

Different types and even different brands of e-cigarettes and other alternatives to smoking such as ‘heat not burn’ products, provide different amounts of nicotine to people that use them. We want to find out how much nicotine people obtain from them.

We are asking 20 experienced vapers to test several of these products. They will also be asked to smoke one of their own cigarettes (unless they already participated in our previous nicotine delivery study). On each test day, they will try and rate a different product while we collect blood samples to measure how much and how quickly, nicotine from these products gets in to the bloodstream. These samples will be analysed for nicotine only, and then destroyed.

Who can take part?
To take part, you should be aged 18 or over; have been vaping daily for at least one month; and are still smoking, occasionally or regularly (applies to new participants only).

The study will not be for you if you are pregnant or breastfeeding; have a current serious illness; or are taking part in other trials.

What will happen if you take part?
You will be asked to attend the Health & Lifestyle Research Unit in Stepney Green (close to the Stepney Green underground station) on at least five occasions. There will be at least one week in between sessions.

We will ask you to come in the morning after not smoking or vaping for at least 12 hours. At the first session, the product you will use will be your own cigarette (unless you already took part in our previous study). Otherwise, it will be one of the products we are testing. There will be a questionnaire to fill in about yourself and your smoking and vaping at the first session. At all sessions, we will measure the amount
of carbon monoxide (CO) in your breath (this shows much smoke you inhale and is used to confirm that you did not smoke for 12 hours).

A blood sample will be taken, and you will then be asked to use one of the products for 5 minutes. Further blood samples will then be taken at 2, 4, 6, 8, 10, and 30 minutes after starting product use. You will be asked to provide ratings of the product throughout this period. Only a small amount of blood will be taken (three to five millilitres at each time point). The sessions will take some 45 – 60 minutes.

You will receive £60 as a compensation for your time and travel expenses at the end of each session.

**Are there any risks or side effects?**
We do not expect there to be any risks from using the products that we are testing for five minutes.

The sessions will involve blood sampling, so only take part if you can tolerate it. Most people can give blood easily, and it is relatively painless.

**What happens with study data?**
Only study staff will have access to study data and your records will be kept confidential. The results of the study will contain no information that could identify participants.

**Who is funding and running the study and who reviewed it?**
This study is funded by Cancer Research UK.

The Principal Investigator is Dr Dunja Przulj, Health & Lifestyle Research Unit, Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry, 2 Stayner's Road, London, E1 4AH, Tel: 020 7882 8230

Please contact Dunja on the number above if you have any question.

The study has been approved by the Queen Mary Ethics of Research Committee. The Committee secretary can be contacted at the Queen Mary Ethics of Research Committee, Room W117, Queen’s Building, Mile End Campus, Mile End Road, London or research-ethics@qmul.ac.uk.