



## Participant Information Sheet

### **(IONA) Assessing the impact of non-tailpipe emissions from traffic on the asthmatic airway**

**Queen Mary Ethics of Research Committee reference number: QMERC22.170**

IONA is a research study to find out how different air pollution environments impact markers of health in people living with asthma. Specifically, we are interested in how lung function changes immediately following exercise in air pollution. We will also study respiratory symptoms (like wheezing, sneezing, coughing), ask to collect blood and nasal mucus samples for further air pollution based analysis.

This document will explain why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. You do not need to provide a reason if you do not wish to participate and it will not affect your rights or your care. Please ask the research team if you would like more information.

This study is led by Queen Mary University London (QMUL) in collaboration with Imperial College London. QMUL is the study sponsor.

#### **What is the purpose of the study?**

- Air pollution from traffic harms people living in cities and especially people living with asthma, increasing asthma symptoms and attacks.
- Global governments and industry is encouraging electric vehicles sales and use. Due to their increased weight, electric and hybrid vehicles increase air pollution from tyre and road wear. There is uncertainty whether brake wear contributes to this also.
- We want to find out if these changes pose a risk to human health.

#### **What would taking part involve?**

- We will ask you to attend one screening visit and three testing visits with follow up assessments.
- The field testing sites are located in gazebos near air pollution measurement sites (Marylebone st, Imperial college in White City and Honor Oak Park).
- During the screening visit you will be asked to perform an exercise cycling test, and perform lung function assessments.
- You will be asked to use four puffs of a blue inhaler (salbutamol) during the screening assessment.
- This allows us see if there is any restriction in your airways.
- You will also be asked to provide a 10ml blood sample. This will allow us to identify if you have allergic asthma.
- The three testing visits will occur between 10am and 2pm and you will be asked to cycle on an exercise bike intermittently for 2.5 hours with respiratory health assessments performed before and after.
- We will ask you to produce a small urine sample before leaving home, which you will bring to the testing sites in sealed envelopes provided by us.

- Urine samples will allow us to assess pollution build up following the exercise.
- We will provide you with a taxi to the test sites.
- During the 2.5 hours you will alternate between 15 minutes cycling and 15 minutes resting.
- Before, after and halfway through the exercise you will perform lung function assessment (by spirometry, Oscillometry, FeNO), complete symptom questionnaires
- Before the exercise you will be asked to provide blood samples (40ml will be drawn from your arm).
- This blood sample will tell us how your body reacts to air pollution particles.
- Before and after the exercise you will be asked to provide mucus samples (also known as nasal lavage).
- Mucus samples are collected by pouring saline solution into one nostril and allowing gravity to let it run back out through the nostril.
- Lavage is not uncomfortable, but it may make you sneeze.
- Mucus samples will tell us which types of non-tailpipe pollutants are being inhaled.
- Before testing you will be asked to wear a personal air quality monitor and activity monitors for three days to calculate the air pollution you have been exposed to.
- The day after your field testing visit you will visit our laboratory in Whitechapel, to do all the same tests one more time (FeNO, Spirometry, Oscillometry, blood, urine and mucus samples), again a taxi will be provided.

### **Why am I being invited?**

- You have been invited to take part as you have been identified as someone with mild or moderate stable asthma and you live in London.
- You should not take part if you have been in hospital with asthma in the last 12 months, have had chest surgery or three asthma attacks in the last 6 months or are currently smoking or live with someone who does or have any other major lung disease in the last 12 months. Work in an occupation where you are exposed to high air pollution, under 18 years old, if you are pregnant or breast feeding.

### **Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you decide to take part, you will need to sign the consent form and return it to the research team. You can stop taking part in some parts of this study, or all of it, at any time and without giving a reason. If you do decide to take part you will be free to withdraw at any time without needing to provide a reason, and with no penalties or detrimental effects.

### **Optional sample storage:**

- We will store blood and urine samples for future air pollution research by our team.
- Agreeing to this storage is optional (see point 9 in Consent form)
- If you do not wish to consent to storage, the samples will be securely destroyed following the human tissue act guidance.

### **What are the possible benefits of taking part?**

- You will get a free spirometry check for your lungs and if we find anything wrong we can provide you with a letter for your GP to let them know.
- The findings from this research will be used to inform government air quality policy
- Results will inform health guidance given to people with asthma.

### **What are the possible disadvantages and risks of taking part?**

- All measures in this study are commonly used and we will follow established procedures.

- Exercising in areas of air pollution can pose a risk of increasing asthma symptoms.
- Exercise intensities are designed to be representative of everyday activity, we will not ask you to exercise harder than you would do regularly.
- Salbutamol (the asthma inhaler medicine) can sometimes give the feeling that your heart is beating harder, but this only usually happens if someone takes more puffs than we are using.

### **Expenses and payments**

- We will reimburse your travel and the time you provide for the study up to £200.
- We will provide you with £200 in cash at the end of the study (£20 first visit, £60 thereafter).

### **How will we use information about you?**

We will need to use information from you for this research project. This information will include your:

- Name
- Contact details
- Your ethnicity and sex (we need this to interpret your lung function results)

People will use this information to do the research to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

### **What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study, on confidential research databases of Queen Mary University of London, including the Medical Research Council HDRUK BREATHE Secure Research Platform.

### **You can find out more about how we use your information:**

- Email: [j.scales@qmul.ac.uk](mailto:j.scales@qmul.ac.uk)
- By sending an email to the Data Protection Officer, Queens' Building, Mile End Road, London, E1 4NS: [data-protection@qmul.ac.uk](mailto:data-protection@qmul.ac.uk)
- By ringing us on 02078827172

See also: <http://www.arcs.qmul.ac.uk/media/arcs/policyzone/Privacy-Notice-for-Research-Participants.pdf>

### **How will my data be stored and who will have access to it?**

Any information we collect from you will be transferred to, stored and analysed secure servers of Queen Mary University of London. Your data will be stored in de-identified format, your name and other identifiers will be replaced by a unique code to reduce the risk of disclosure, personal identifiers will be stored separately from the research data on secure computers. Paper records of data (e.g. consent forms) will be stored either in locked filing cabinets within lockable offices within an access restricted building, or will be sent off site to

a secure storage facility that complies with our security requirements. All data handling, processing, transfer and storage procedures comply with our obligations under the General Data Protection Regulation, and comply with our local data handling and security policies and procedures. Personal data will only be accessed and used by those members of the research team at QMUL and representatives of the sponsor who have been granted permission.

### **When and how will my data be destroyed?**

- Your personal data will be destroyed 1 year after the conclusion of the study.
- Your research data will be destroyed 20 years after the completion of the study.
- All data will be destroyed in accordance with best practice at the time of destruction.

### **How will my data be used and shared?**

- Data you provide will be used to support publications in peer reviewed medical journals.
- This data will be presented as group averages, no individual data will be presented.
- QMUL is committed to Open Access to research data. This means we may place your anonymised data in an online data safe haven, where other research teams can request access via Dr James Scales to the data.
- This is done to support future research and to increase the cost effectiveness of publicly funded research.

### **How will my samples be used?**

- Samples you provide will be stored in locked freezers in laboratories in the Environmental Research Group laboratories; Imperial College London.
- We will store these samples until funding is secured for further analysis
- These samples will be used to explore mechanistic reasons for the observed respiratory health responses.
- Your samples may be accessed by members of the study team, including Dr Ian Mudway, Dr James Scales and a laboratory technician from Imperial College London.
- Your samples will be used by research lead by Dr James Scales.

### **What will happen if I want to withdraw from this study?**

- You can withdraw your participation in the study at any time without providing a reason.
- You can chose to withdraw from future participation but allow the data you have already provided to be used by the research team.
- Alternatively you may also chose to withdraw your data.
- You can chose to have your data destroyed any time prior to the anonymised data being placed in an online open source safe haven.

### **What should I do if I have concerns or something goes wrong during this study?**

- If you have any concerns about the manner in which the study was conducted, in the first instance, please contact the researcher(s) responsible for the study: Dr James Scales.
- If you have a complaint, which you feel you cannot discuss with the researchers then you should contact the Research Ethics Facilitators by e-mail: [research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk).
- When contacting the Research Ethics Facilitators, please provide details of the study title (IONA), description the study and QMERC reference number QMERC22.170, the researcher(s) involved, and details of the complaint you wish to make.
- QMUL has no fault compensation for human clinical trials Insurance (reference:B1262FI0152822) if you wish to make a complaint, please contact the Research Ethics Facilitators by e-mail: [research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk)



IONA Participant information sheet V3.0 12.4.2023

IRAS ID: 320784

Principal Researcher: Dr James Scales

- In the event that something goes wrong, and you are harmed or injured during research, you are covered by our insurance. You do not need to prove negligence.

**Who can I contact if I have any questions about this study?**

- Dr James Scales
- [j.scales@qmul.ac.uk](mailto:j.scales@qmul.ac.uk)
- 0207 882 7172

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