Title:

INHALE: Personal pollution exposure and effects on the lungs in healthy and asthmatic individuals

Investigator: Professor K F Chung

What is the purpose of the study?

You are invited to take part in research study that will examine the potential effects of air pollution on your lungs. Before you decide, it is important for you to understand 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. Please ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Why is the study being done?

Air pollution has become the most important risk factor for various lung, heart and other diseases that include asthma, COPD, lung cancer, stroke and diabetes. Air pollution has also been associated with an increased risk of mothers having small infants and miscarriages. While steps are being taken throughout the world to cut down on the source of air pollution, we need to provide steps by which everyone of us can avoid being exposed to air pollution and reducing its effects on our health. In order to do this, one needs to be able to understand how pollution affects our cells in the lungs where pollution first enters into our body, and how our lungs are affected overall. In addition, to understanding how pollution can affect us as individuals, we should for each of us know how much pollution we are personally exposed to in our daily lives.

In this study, we will therefore study 80 individuals (including 40 suffering from asthma) in order to evaluate (1) their personal exposure to pollution, both inside and outside environments (2) how the cells taken from the nose react to the pollutants they are exposed to (3) how their lungs respond to the pollutants they are exposed to. In this way, we will understand how each individual can be affected by the pollutants present in their immediate environment.

Why have I been chosen?

You will have seen the advert for recruitment to this study in certain public places or through social media. We are asking you to take part in this study because you are a healthy person and who are not taking any medications. You should not be a smoker. We are aiming to recruit 45 healthy subjects for this. You should be living or spending a significant part of your time in specific localities of West London.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you will still be free to withdraw at any time without giving a reason. A

decision to withdraw at any time, or a decision not to take part, will not affect in any way any future treatments or services you might need from your doctor.

What will happen to me if I take part?

Prior to agreeing to take part in this study, you will be provided with this information sheet to read. After consideration of this information (usually one week), if you wish to participate, you will be asked to attend a visit in the Clinical Research Unit at the Royal Brompton Hospital. During this time, the study doctor or Nurse will discuss the study and answer any questions you may have. If you are happy to proceed, we will ask you to sign a consent form to confirm that you have understood this information sheet and are happy to participate.

The diagram below summarises what you will be asked to do during the study. At the first visit (Recruitment), we will collect personal information, you will fill up some questionnaires, some lung function tests will be performed, and we will arrange the next appointments over the following 12 months. This visit should last 30-45 min.

We will request that you wear 2 instruments that will record your personal exposure to pollution and the response of your lungs (Airspeck and Respeck) over a period of 2 weeks. You will attend the Clinical Research Unit at the Royal Brompton Hospital before the start of and after the end of the 2 weeks. At each of these visits we will request completion of questionnaires and there will be collection of samples. The first visit will last 45 minutes while the second visit 60-75 min.

This period of 2 weeks wearing the instrument will be done twice across the 12 month period, with one period done in the winter months when the level of pollution is usually higher. During this time, it will also be optional for you to consider having a Dyson purifier and a monitor of pollution (called ATMO tubes) in your home to obtain more information on the pollutants in the home. The purifier operates quietly, the sound of a gentle breeze, and dims its light at night, so it will not disturb sleep. Participants receiving these devices will have the cost of electricity consumption by the purifier reimbursed.

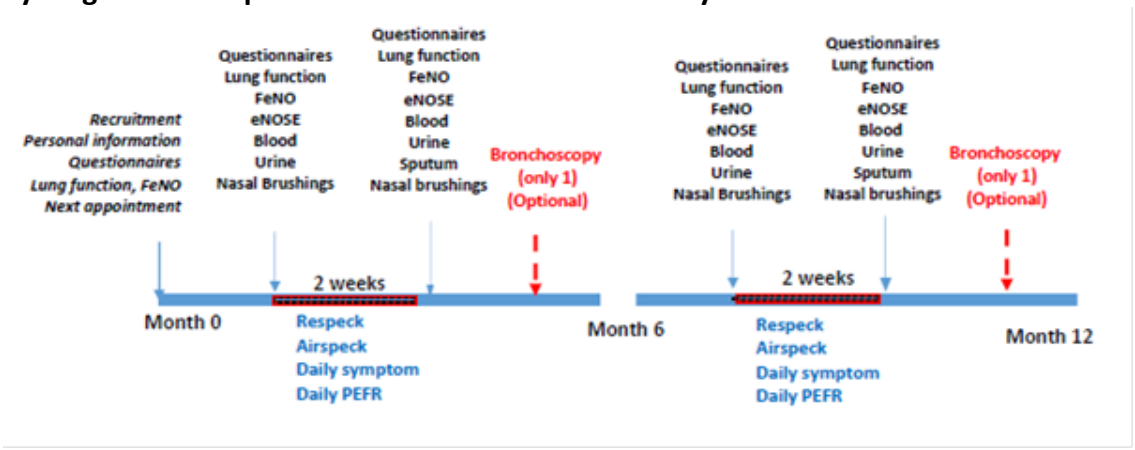
Please note that we will be requesting that you consider undergoing a procedure called bronchoscopy where we obtain samples from the lungs. This is optional and you are entirely free not to participate in this procedure if you do not wish to. This procedure if undertaken will take place after either the first or the second 2-week period of wearing the sensors.

Potential changes that might occur because of the current COVID situation

Because of the current situation with COVID, it is possible that certain tests will not be possible to perform and these tests are (i) sputum collection and (ii) lung function tests because they can potentially produce tiny droplets that can transmit any potential COVID infection. In this case, we will obtain lung function tests by lending you a portable instrument to do the lung function measurement at home. We will only perform sputum collection when we are allowed to do so.

Similarly, the procedure of fiberoptic bronchoscopy will not be possible currently and will only be performed when we are allowed to do so.

Summary diagram of the procedures to be done in this study:



Medical history

You will be asked questions about your general health, and will be examined. We will ask you to fill up standard questionnaires that relate to your life style, the way you travel to work, your diet, exercise pattern, (so that we obtain an idea of your potential exposure to pollution) and also standard questionnaire on any symptoms you may have. We may also ask you to fill up a Leicester Cough Questionnaire (LCQ) to check whether you have a chronic cough.

Questionnaire

The Short Form (36)(SF36) Health Survey is a measure of health status consisting of 36-items.

Asthma Control Questionnaire (ACQ). This documents the state of your asthma in the past week.

Asthma Quality of Life Questionnaire (AQLQ). This questionnaire documents the effect of your asthma on your quality of life.

Leicester Cough Questionnaire (LCQ). If you suffer from a chronic cough, this questionnaire will document the impact of this cough on your quality of life.

Lung function tests

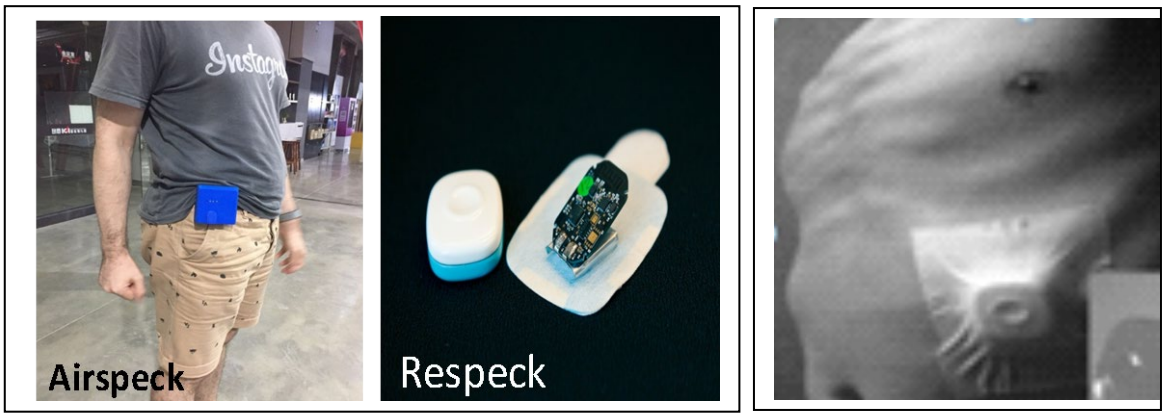
You will be asked to perform some simple breathing tests to find out how your lungs are functioning. These tests are called spirometry where you will be asked to blow into a machine that measures the volume of air you are expelling from the lungs in a forceful way. In addition, we will request that you measure the peak flow using a handheld machine at home twice a day, for the duration of 2 weeks that you will be observed. Together with this we will ask you to record your daily symptoms in a diary card.

Personal sensors (Airspeck and Respeck: See accompanying picture):

We will ask you to wear 2 personal sensors (Airspeck which measures the pollution around you, and Respeck which measures your breathing and your activity) for a period of 2 weeks each, over 2 occasions over the year, with one occasion during the winter months. You will also be provided with a mobile phone which will be used only to transmit all the information collected by the sensors to a Cloud server where the data will be stored.

The air quality sensor (Airspeck) will be placed in a a light weight belt which can be worn around the waist (like a camera pouch).

The Respeck sensor is a small sensor measuring 3cm*3cm and will monitor breathing



and activity levels. This will be placed using an adhesive tape in the lower part of the chest. The android phone will automatically record the data collected by the personal sensors. This phone will be locked and password protected and no other apps or games will be available on it. This phone should be carried by yourself or kept in close proximity so that it can record data continuously.

The sensors and phone do not cause any harm and you should continue your normal activities just as they always would without the sensors. The belt can be removed when going to sleep but the plaster with the activity monitor should be kept on and not removed. Before taking a bath, the plaster and the activity sensor should be removed and replaced on the chest with a new plaster after the bath. It can be taken off while sleeping but should be kept as close as possible to you. You will need to charge the phone once in 12 hours; this is essential for continuous air quality monitoring. We shall also send you text reminders to ensure that phone is kept charged. The sensors and phone should be worn most of the time.

Blood tests

Blood will be obtained from a vein in the forearm through a needle. In all 25 ml of blood will be taken. The needle insertion will cause a sharp momentary pain and will be done in the sitting position should there be any fainting that can occur. There may be some bruising at the site. The procedure should take one minute to complete.

Measuring nitric oxide level in the exhaled breath (FeNO).

In this test, we will ask you to breathe slowly into a tube and the level of nitric oxide which is a gas produced in the lungs as a result of inflammation will be measured. This will provide us instantaneously the level of a given type of inflammation in the lungs.

Exhaled breath analysis by eNOSE

This will be performed to measure the volatile organic compounds in your exhaled breath. You will be asked perform five normal breaths followed by a deep inhalation, 5 seconds breath hold and a slow exhalation. The obtained sensor data will be stored and sent off for further automated analysis. This test should take 5-10 minutes to perform.

Collecting exhaled breath condensate

We will ask you to breathe normally for up to 5 minutes onto a cooled tube to collect the water drops from the breath from which we can measure various substances and any potential organisms in the condensate. This will be performed twice during the study.

Nasal epithelial cell collection

A sample of nasal epithelial cells will be obtained from the nostrils of all participants using a sterile, flexible dental brush (Dento-O-Care 620, 2.7mm Interdental brush). The brush has small bristles which can collect cells when gently rotated against the inside lining of the nostril. This procedure will be done at the beginning and end of each of the 2 week period of observation. In total, it will therefore be done 4 times over the period of the study. This test causes only minimal discomfort but can cause some sneezing and may cause a small amount of bleeding. This test should take 10-15 minutes to perform.

Nasal fluid collection

A sample of nasal fluid will be collected using a mixed cellulose ester sampling strip (HAWG 04756 Millipore Sigma) that is 5 mm wide and 40 mm long. This strip is inserted into both nostrils for 2 minutes, allowing it to gently touch the surface of the nose. The strips will be taken out for measurement of several mediators including measures of oxidative stress and arachidonic acid metabolites. This will be performed at the start and end of the 2 weekly periods of observation (i.e. on 4 occasions during the study). The safe use and description of this method in participants with asthma has been described (Environ. Sci. Technol. 2020, 54, 11405−11413). The test should not take more than 4 minute to complete.

Sputum collection

You will be asked to provide a small sample of sputum (phlegm). We will ask you to inhale a solution of salt-water (saline) through a machine called an ultrasonic nebuliser. This enables you to cough out sputum from deeper in the airways, which you may otherwise not be able to do (this is called induced sputum). This sputum will be collected and examined for

cells that it contains that provides an idea of the type of inflammation in the lungs. The procedure can provoke an episode of wheezing and chest tightness, but this can be relieved by a reliever inhaler such as salbutamol.

Urine sample

We will ask you to provide a sample of urine that we will keep in the freezer for measuring at a later date various chemicals related to pollution such as the degree of oxidant stress and lipids associated with pollution.

Fiberoptic Bronchoscopy (for those who have agreed to take part)

If you have agreed to take part in this procedure, we will assess whether you will be fit to undergo the test by asking you some questions and by measuring your lung function. We will also advise you about the medications you can take for your asthma prior to and after the procedure. On the day of the procedure, we will give you salbutamol (a bronchodilator) to inhale from a nebulizer.

This procedure is carried out in the Bronchoscopy Unit, Royal Brompton Hospital. We will ask you to fast from midnight before the test.

A bronchoscopy is routinely used for the diagnosis of lung conditions. It involves passing a thin fibreoptic tube (made up of many small glass fibres which transmit light and has a small camera at the end) via your nose or mouth, into the air passages of your lung. This allows the doctor to examine directly the large air passages of your lung. You will be asked not to eat or drink anything from midnight prior to the bronchoscopy.

We will spray a local anaesthetic called lignocaine (the same as the local anaesthetic used by dentists) on to the back your throat, into your nose and onto your voice box, so that the bronchoscope can be easily inserted into the air passage without discomfort. This is not a general anaesthetic. We will insert a small needle into a vein on the back of your hand or arm. We will also give you a sedative medication (midazolam) into this needle. This medication will make you more relaxed and drowsy for the duration of the test. You may also be given salbutamol (a drug that opens up the airways) to inhale from a nebuliser after bronchoscopy.

We would like to retrieve the cells that are in the lung by the bronchoscope. We will pass a warm solution of sterile salty water down the tube, which will be quickly suctioned out. In all, about 60 ml (about 4 tablespoons) will be given on up to four occasions. We will also use a fine brush to collect some cells from the wall of the airways via the bronchoscope. Finally, we will take up to 4 samples of the airway lining called biopsies using biopsy forceps, which is not painful as there are no pain nerves in the airways.

The bronchoscopy lasts approximately 20-30 minutes.

After the bronchoscopy, you will be given salbutamol (a bronchodilator) to inhale from a nebulizer and you will be monitored for one to two hours in the recovery area within the endoscopy department. You may be given additional treatments if there is any deterioration of your asthma. You will be seen by the research doctor prior to discharge

home. If deemed necessary, you may stay a bit longer to make sure that you are well enough to go home.

As you may be given a sedative medication, it is important that a responsible adult friend or relative accompanies you. You should not drive, use heavy machinery or drink alcohol for the rest of that day.

Bronchoscopies will be performed by the doctors who work in the Bronchoscopy suite and who have a lot of experience in performing these tests. In the event of our finding an abnormality during the course of this study, you will be referred to the appropriate Consultant for further assessment.

What are the possible risks of taking part in a bronchoscopy?

Bronchoscopy is a standard diagnostic procedure and will be undertaken by an experienced doctor of the research team. It is a well-established procedure used on a routine basis at the Royal Brompton Hospital.

The small needle inserted into a vein may cause some minor bruising. Your mouth and throat may remain numb just in the same way as your mouth would after a dental procedure. You may experience a sore throat, hoarse voice or cough because of slight irritation in the airways. You may possibly notice some blood flecks in your spit. These discomforts will wear off within 2 hours or so. You should not eat or drink for at least 2-3 hours, in order to keep food or liquids from accidentally entering the windpipe or lungs. Occasionally, following the test people get a 'flu'-like reaction with a fever. This only lasts a few hours and can be helped by taking paracetamol.

A rare complication (1 in 2000) of bronchoscopy is pneumothorax. This is a collapse of the lung that is treated by inserting a tube through the chest wall that allows the collapsed lung to expand. Another rare complication is significant bleeding. Obviously, if you were unfortunate enough to experience these complications you would be given the appropriate treatment in hospital.

What else do I have to do?

We will check some blood tests as a routine before we proceed to doing the bronchoscopy.

How will my donated samples be used?

Sputum samples and those samples taken at bronchoscopy will be used to assess the amount of inflammation in your airways and whether there is infection within the lung. Blood samples will be used to extract the serum from which various chemicals or proteins can be measured to obtain an idea of the effect of pollution. In the urine samples, we will measure also chemicals or proteins that can tell us about the effect of pollution and also the state of the asthmatic condition. Nasal cells obtained by curettage will be allowed to grow in the test tube and tested with pollutant particles collected from the environment.

Samples taken at bronchoscopy will be used to assess the amount of inflammation in your airways and whether there is infection within the lung. The bronchial brushings, nasal

brushings and sputum cells will be stored in special liquid for measuring the genes present in the sample in order to analyse the genes that are related to the effects of pollution. We will look at these samples also under the microscope to look for inflammatory cells and we will measure various proteins.

Your samples may be sent to other research collaborators for analysis that cannot be done in our laboratory at Imperial College but it would not identify any personal details, including your name or your address. In addition, your samples will be stored in a secure freezer for a maximum of 15 years for future analysis.

How will information stored on computer be used?

Your anonymised medical information and any results will be put on a computer and stored in a secure electronic database. Some information may be sent to other research collaborators but it would not identify you or your address. When processing and storing personal information we will comply with the relevant laws to protect the confidentiality of research participants.

What is the drug or procedure that is being tested?

There is no drug being tested in this research.

What are the possible disadvantages and risks of taking part?

In order to produce a sample of phlegm for analysis, we may 'induce sputum' by giving you a nebuliser which produces a mist of salt-water which causes coughing and sometimes shortness of breath. You will be monitored closely with measurements of peak flow to ensure your safety and minimal discomfort. If there should be any significant degree of narrowing of the airway tubes as occurs in asthma, we will provide you with a nebulizer containing salbutamol to inhale.

Blood tests will only be taken by trained personnel. Occasionally you may find some minor bruising. The breathing tests should not cause any discomfort, although some patients find that this test causes coughing.

Nasal curettage may cause some discomfort and pain during the procedure, with some transient bleeding. There may also be some sneezing.

The risks of taking part in a bronchoscopy are described above.

What are the possible benefits of taking part?

We hope that you will benefit by knowing how much pollution you are exposed to during your daily life and what areas of high levels of pollution that you should avoid. In addition, the respiratory recordings will tell us to some extent how sensitive you are to the effects of pollution. You will be able to link levels of pollution to your respiratory symptoms.

We will be able to tell how your own cells obtained from the nose are sensitive to the effects of pollution that you are exposed to. This will also provide you with some idea of how your body reacts to the pollution you are surrounded with.

The information obtained from the bronchoscopy will also tell us how pollution may affect the cells in the lungs and from these information, we could work out how one can avoid these processes from taking place or how to prevent these processes from happening. Together with all the other information we will have gathered, we will provide you with some ideas of how your body is reacting to the pollution you are exposed to everyday.

This research may lead to ways of preventing the bad effects of pollution on the lungs.

We will provide you with a short summary of the findings on the sensors regarding your exposure to pollution, indicating particularly the areas that you could avoid because of their high pollution levels. This will be provided to you by post and you will be free to contact us for more information and advice should you need it.

Will I be compensated for my participation?

If you are participating in the main part of the study, you will receive up to £40 to cover travel expenses and £50 for participating in the study. For participating in the bronchoscopy studying, you will receive up to £40 to cover travel expenses and £150 for participating in the bronchoscopy study. Please note that reimbursement for travel costs , receipts will be required.

What if new information becomes available?

Sometimes new information is obtained that may have us change the course of the study. If this happens, you will be fully informed and the new measures will be explained fully to you. You will have the option of continuing or stopping your participation in the study.

What happens when the research cohort is terminated?

The study will be done in 2 years and we will analyse all the data collected at the end of the 3 years of this research. These results will be published in scientific journals but the outcomes of this research may lead to better ways of tackling pollution at a personal level.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Professor K F Chung. Telephone: 0207 594 7954). The normal National Health Service complaint complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Office.

Will my taking part in this study be kept confidential?

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep identifiable information about you.

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

Further information on Imperial College London's retention periods may be found at *https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf.*

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information [Professor K F Chung: 02075947954]

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

CONTACT US

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

How we collect the data and ensure anonymity.

At the Clinical Research Unit at the Royal Brompton Hospital, we will collect information from you and your medical records for this research study in accordance with our instructions. The Clinical Research Unit at the Royal Brompton Hospital will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Imperial College and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The Clinical Research Unit at the Royal Brompton Hospital will pass these details to Imperial College London along with the information collected from you and/or your medical records . The only people in Imperial College who will have access to information that identifies you will be people who need to contact you to confirm details or confirm scheduling times or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.
The Clinical Research Unit at the Royal Brompton Hospital will keep identifiable information about you from this study for 10 years after the study has finished.
Imperial College London will collect information about you for this research study from the Clinical Research Unit at the Royal Brompton Hospital . The Clinical Research Unit at the Royal Brompton Hospital will not provide any identifying information about you to Imperial College London. We will use this information to prepare final reports and manuscripts for publication in journals.

In the event you lose capacity, your data will be retained in the study.

Where data is intended to or likely to be used for future research

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research**.**

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

We will inform your GP of your involvement in the study

What will happen to the results of the research study?

The results of this research will be presented at national and international medical conferences and published in medical journals within the next three years. Medical abstracts are usually available from the internet at no cost. Medical journals can provide full publications at a cost. You will be able to find publications on the internet, or we will provide copies to you of the publications. You will not be identifiable in any report or publication.

Who is organising and funding the research?

Imperial College London is organizing the research. The research is being funded by the Engineering Physical Sciences Research Council.

Who has reviewed the study?

The National Research Ethics Service (Dulwich Research Ethics Committee) has reviewed the study.

Contacts for Further Information

Thank you for taking the time to read this information sheet. If you decide to participate in this study, you will also be given a copy of the signed consent form to keep.

If you have further queries or concerns or need help, you can contact the **Patient advice and liaison service (PALS) office** at

The Royal Brompton Hospital, Sydney Street,London SW3 6NP.

Telephone : 020 7349 7715

Email: pals@rbht.nhs.uk.

PALS is open Monday-Friday, 9am-4pm, excluding bank holidays. PALS will be able to provide you advice about the study project and clarify issues about patient confidentiality and can advise you about making a formal complaint.

Also, you can contact **Ms Sally Meah, Research Nurse,** for any information on the project.

Address: 1st Floor, Respiratory Research Unit,
Royal Brompton Hospital
Fulham Road, London SW3 6HP
Tel: 02073518051/Fax 02073518937
Email: Sally.Meah@imperial.ac.uk

INHALE STUDY CONSENT FORM
Healthy
1 for patient; 1 for researcher; 1 to be kept with hospital notes

Name of Researcher: .....

If you agree with each sentence below, please INITIAL the box: **INITIALS**

1. I confirm that I have read and understand the information sheet dated 19 11 2021 (version 1.5) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College London and from Royal Brompton NHS Trust or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to donate blood, urine and nasal brushing samples to the Royal Brompton Hospital and I agree to give my permission for the samples to be used for future ethically-approved research ☐
5. I agree to share my anonymised data with Breathomix Company for the development and improvement of clinical diagnostic tests ☐
6. I agree to my GP being informed about my participation in this study. ☐
7. I agree to take part in the above study. ☐
8. **OPTIONAL**
   I agree to participate in a bronchoscopy procedure and I agree to donate samples taken at the bronchoscopy to the Royal Brompton Hospital. I agree to give permission for the samples to be used for future ethically-approved research. ☐

   9. I agree to have a Dyson Air Purifier and ATMO tubes placed in my home for monitoring pollutants and for collecting pollutants in my home. ☐

Please print and sign your name below and add today's date:

N.B. The participant must date his/her own signature

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature