**PARTICIPANT INFORMATION SHEET**

**BARRIER: human BronchiectAsis RhinoviRus challenge to define Immunopathogenesis of ExaceRbation**

**Chief Investigator:** Dr Aran Singanayagam

**Co-Investigators:** Dr Anand Shah, Prof. Sebastian Johnston

You are being invited to take part in a research study. 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

**WHAT IS THE PURPOSE OF THE STUDY?**

Many people with bronchiectasis have disease flare-ups. It was previously believed that these were mainly caused by bacteria but recent evidence suggests that viruses could be an important trigger. This study will recruit volunteers with and without bronchiectasis to compare their immune responses to cold viruses. We will do so by infecting participants with a cold virus.

**WHY HAVE I BEEN CHOSEN?**

You have been invited to take part in this study as you have bronchiectasis or are completely healthy. As part of this study we will be recruiting 36 individuals with bronchiectasis and 18 completely healthy individuals.

**AND 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 are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**WHAT WILL HAPPEN TO ME IF I TAKE PART?**

If you are interested in participating we will ask you to attend a dedicated clinical research facility, Imperial Clinical Respiratory Research Unit (ICRRU), at St Mary’s Hospital for a screening visit lasting 30-60 minutes. This will involve taking details of your medical history including medications and a blood test to find out if you are suitable to take part. We will also provide more detailed information about the study and answer any questions. If you are eligible decide to take part in this study, your participation will last around 10 weeks and require 13 visits to St Mary’s Hospital.

You will have screening tests and if relevant further questions and tests to check your current bronchiectasis symptoms and medication, how well controlled your bronchiectasis is, and any other medical problems. They will help us determine whether your bronchiectasis is too mild or too severe for you to take part.

Everyone will be given a spray of a virus that causes the common cold (rhinovirus 16) into their nose. This is known as virus inoculation. The following procedures will also be performed in this study (we will not do every test on every visit):

* **Pregnancy test -** If female, as we cannot include pregnant volunteers in the study.
* **Spirometry** - Breathing tests will be done at the research unit to measure the amount of air you have in your lungs and how well you can push the air back out. This is done to check how bad your bronchiectasis is. You will be asked to blow out into a machine that measures how much air you can blow out. You will be coached on this procedure by the research staff. You will also be asked to measure your lung function daily at home during the study using a hand held ‘spirometer’, which should only take 10 minutes. The study staff will show you how to do this.
* **Exhaled nitric oxide (FeNO)** - Nitric oxide is a chemical that is released when your lungs are inflamed and tells us important information about the profile of disease you have. It is again measured by a breathing test where you blow gently into a machine. You will be coached on this procedure by the research staff.
* **Exhaled breath collection** – We will take samples of the air you breathe out which will be collected within a bag and then analysed in the laboratory for the presence of various chemicals.
* **Sputum collection** - We will take samples of sputum and look in the sample for inflammatory chemicals and cells, as a measure of how bad your bronchiectasis is, both before and after we infect you with the common cold virus.
* **Blood test** – Blood will be taken on 8 occasions, including the screening visits, over a 9 week period during the study, to a total of ~375mL (25 tablespoons). We will check blood counts, your kidney, liver and clotting function, and check measures of your immune system.
* **Nasal lavage -** We will gently wash one nostril with 5mL (1 teaspoon) of salt water. We look for virus and inflammatory chemicals in the sample, to check if you get infected with the cold virus and how your body responds to it.
* **‘Nasosorption’** - We will place a small piece of absorptive material on the lining of your nose in your nostril to absorb the lining fluid, for 2 minutes. We will do this in both nostrils. We look for the same inflammatory chemicals in the sample as in nasal lavage samples.
* **Nasal brushing-** A plastic probe is inserted in the nose and gently pressed against the inside of the nostril. The probe will collect nasal cells from both nostrils. This may be uncomfortable but is not usually painful. We look for inflammatory cells and expression of chemicals in the sample.
* **Stool sample**- we will send you a kit to take a sample of stool at home with a stamped envelope to send this sample back to us. We will use it to characterise your stool microbiome (spectrum of bacteria residing in your gut).
* **Chest radiograph** - You will need to have a single chest radiograph (X-Ray) performed prior to your bronchoscopy.
* **Bronchoscopy** - This is a test performed frequently in Respiratory departments. It is usually done as an outpatient (meaning you don’t have to stay overnight) and involves passing a small telescope tube (about the width of a biro pen) into the lungs. There is no need for a general anaesthetic but we use mild sedation (medication in the vein to make you sleepy) and local anaesthetic. You are able to breathe normally around the tube. This enables us to look into the lungs and take samples. We will wash the airways with salt water (like the nasal lavage), take samples with absorptive material (like ‘nasosorption’), and take small samples of cells and tissue (brushings and biopsies).

When you attend for your bronchoscopy you will need to come to the Endoscopy Unit with an empty stomach. We ask you to have nothing to eat for six hours before the test. We will put a small needle into a vein in your arm to give you medications. The test usually takes about forty minutes. We ask you to stay in the department until the sedation has worn off. The test is performed with nursing staff and another research doctor or nurse present. It is generally very well tolerated with minimal discomfort, but if there are any concerns we can stop the test at any time.

Bronchoscopy will occur twice during the study – once at the start and once more seven days receive the virus infection

* **Symptom diary** - You will be given a symptom diary to complete, detailing any respiratory symptoms you are experiencing (e.g. sneezing, coughing, wheezing). You will be asked to complete this every day during the study (9 weeks).

**What will happen to the samples collected?**

* All samples collected with be linked anonymised, i.e. have a code number used so that people who do not need to know who you are will not be able to see your name or contact details.
* We will use samples to understand your immune response to the cold virus. With your permission we would also like to perform genetic analysis from DNA isolated from the samples such as blood, nasal and airway samples as detailed above.
* Any samples collected during the study will continue to be stored after the study ends so that these can be used potentially in future ethically approved research.



**What do I have to do?**

During the study if needed, you should take your regular medication as normally directed by your doctor. You should not normally be involved in any other drug stdies at the same time

**ARE THERE ANY SIDE EFFECTS OR RISKS INVOLVED?**

**Virus inoculation**

You may get a cold and have typical cold symptoms during the study. Typical symptoms therefore include a sore throat and runny nose which usually lasts for 3-4 days. You may also notice a worsening of usual bronchiectasis symptoms with increased cough and wheeze. From previous studies we have conducted in subjects with similar conditions such as asthma and chronic obstructive pulmonary disease (COPD), we anticipate that these symptoms will be mild and usually settle within 1 to

2 weeks.

Some symptoms such as an increase in mucus production may last longer than this and may persist for up to 5 weeks, but this would be unusual. From our previous experience with similar studies, no volunteers have required additional treatment with either steroid tablets or hospital admission but we will carefully monitor you for this. The virus we use was prepared especially for research and has been stored carefully in our laboratory. We have used it in many previous studies over 20 years, where it has been shown to be safe.

**Procedures**

* Breathing tests - You may have shortness of breath while doing the breathing tests. Treatment will be available if this occurs.
* Blood test - There is a risk of bruising at the site where the needle enters the skin and a remote risk of infection. The area will be wiped down with alcohol prior to placing the needle in the vein.
* Nasal brushing - Very occasionally a slight nose bleed may occur but there are no long term effects
* Chest X-ray - The overall additional radiation dose associated with this procedure is equivalent to 3 days of background radiation and carries a minimal risk of inducing cancer (1 in 1,250,000).
* Bronchoscopy - Bronchoscopy is a safe procedure with little risk and complications are relatively rare. It is common to experience a mild sore throat, hoarseness and cough after the procedure. Occasionally after taking the tissue samples (biopsies) people cough up small amounts of blood but this stops without further treatment. The test can be stopped at any time if you wish. There is a small risk of infection and bleeding associated with the procedure, but every effort is made to prevent this from happening. It is important that you **do not drive a car or operate machinery for 24 hours after sedation**.

**WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?**

We anticipate that you are at low risk in taking part in this study. No one in our previous studies like this has developed any serious side effects, but we will monitor you closely to ensure that any serious side effects are detected. We will arrange for you to have prompt treatment at St Mary’s Hospital in the unlikely event that this did occur.

It is possible that we may identify something important about your health or wellbeing from the tests we perform on you for this study, for example an additional respiratory illness. If this is the case we will inform you, and if you agree, additionally your GP, so the results can be followed up.

The disadvantages of this study will be the inconvenience of trips to the hospital for research purposes. We will cover expenses for these visits and provide compensation for your time.

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART?**

You are not expected to benefit from being in this study. However we hope that the information we get from this study will help to improve the future treatment of people experiencing bronchiectasis attacks.

**WHAT IF SOMETHING GOES WRONG?**

We do not anticipate that anything will go wrong. ‘Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will 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 (Dr Aran Singanayagam a.singanayagam@imperial.ac.uk). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

**AM I PAID FOR TAKING PART IN THIS STUDY?**

We do not pay people specifically for taking part in the study. However we will cover any travel expenses and you will be reimbursed for the time you donate to the study, up to a maximum of £1200. If you are asked to attend the research facility for additional visits, you will be reimbursed accordingly. Payments will be made on a pro-rata basis, which means that you will be reimbursed for how much of the study you complete. The payment will be made after you have attended for your last study visit.

**WHAT WILL HAPPEN IF I DON’T WANT TO CARRY ON WITH THE STUDY?**

Your participation in this study is voluntary. You are free to withdraw at any time and do not have to give a reason for this, even after you have agreed to take part by emailing or contacting the study investigators with details as listed below. Being

part of this study will not affect your normal medical care, either now or in the future. If you decide to withdraw consent, we will keep the information that we have collected on you up until the point of withdrawal.

**Summary Information sheet**

Research Study Title: **BARRIER study: human BronchiectAsis RhinoviRus challenge to define Immunopathogenesis of ExaceRbation**

IRAS ref: 332594

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. These will include Imperial research Team members and support staff. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy laws and legislation that are relevant to the specifics of the study.

At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

**HOW WILL WE USE INFORMATION ABOUT YOU?**

Research Study Title: **BARRIER study: human BronchiectAsis RhinoviRus challenge to define Immunopathogenesis of ExaceRbation**

IRAS ref: 332594

Imperial College London is the sponsor for 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 appropriately. Imperial College London will keep your personal data for:

· 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.

The study is expected to finish in July 2027

For more information / confirmation regarding the end date please contact the study team, see ‘WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED’ for contact information.

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

* your initials
* NHS number
* Name and contact details.

People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact) details is accurate. 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.

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. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

* Imperial College London - “performance of a task carried out in the public interest”); 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.
* Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on “scientific or historical research purposes or statistical purposes.

**INTERNATIONAL TRANSFERS**

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. 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 UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

**SHARING YOUR INFORMATION WITH OTHERS**

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

* Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

**POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH**

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and 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, used against you or used to make decisions about you.

**COMMERCIALISATION**

Samples / data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate ‘personal data’.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

**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 because some research using your data may have already taken place and this cannot be undone.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.

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.

**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?**

You can find out more about how we use your information

• at www.hra.nhs.uk/information-about-patients/

• by asking one of the research team

• by sending an email to a.singanayagam@imperial.ac.uk>, or

**COMPLAINT**

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to a.singanayagam@imperial.ac.uk.

Following our response, if you are not satisfied please contact Imperial College London’s Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied 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)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

**WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?**

The results of this research study may be published in a scientific medical journal. This may not happen until 1 or 2 years after the study is completed. In addition, the media department at Imperial College publicises research that is of public interest, and we will aim to publish a lay summary report for participants. You will not be identified in any report or publication.

**WHO IS ORGANISING AND FUNDING THE RESEARCH?**

This study has been funded by the Medical Research Council through an experimental medicine project grant.

**WHO HAS REVIEWED THE STUDY?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the XXX Research Ethics Committee.

**CONTACT FOR FURTHER INFORMATION?**

If you require further information about the study, please contact:

Dr Aran Singanayagam

MRC Clinician Scientist and Consultant Physician

Email: a.singanayagam@imperial.ac.uk

OR

Dr Anand Shah

MRC CARP fellow and Consultant Physician

Email: s.anand@imperial.ac.uk