

## MUCOSAL study

### ImMUnologIcal memOry to reSpiRAtory viral infection in the airways (MUCOSAL)

#### ABBREVIATED PARTICIPANT INFORMATION SHEET

This document is a shortened version of the full PIS available here:

<https://www.ovg.ox.ac.uk/studies/mucosal>

#### Why are we conducting this study?

When viruses enter our breathing spaces, also known as airways, they can cause severe infections or no symptoms at all. When our body “remembers” these viruses (immune memory), it can act quickly and eliminate the infection before symptoms develop; this can protect the person from serious illness, but importantly also reduces the spread of disease.

Immune memory can be achieved by vaccination or previous infection, but we don’t know how long this lasts. Lung cells can live longer and potentially remember for longer. We can design better vaccines by understanding the differences between cells in our blood and those in our breathing spaces. This will give greater protection against disease-causing viruses thus protecting us and especially those at risk.

#### Who can take part?

##### If you are:

- ✓ A healthy adult aged 18-85 years
- ✓ Have capacity to provide written consent before any study procedures are performed and can understand and comply with the requirements of the study
  - ✓ Able to attend study visits at Oxford Vaccine Group

#### You may be able to take part!

Please see the **Participant Information Sheet** <https://www.ovg.ox.ac.uk/studies/mucosal> for a complete list of eligibility criteria.

#### What does the study involve?

1. Volunteers will self-collect nose swabs if they experience respiratory symptoms to confirm they have a respiratory infection caused by one of the viruses we are investigating. You will need to store these swabs temporarily in your home freezer. Volunteers do not need to test with the study swabs if they have already tested positive in a healthcare or workplace setting (for example, through your GP, hospital, A&E, or your workplace’s health service). Alternatively, it will be possible to collect the kit from the corresponding site or any other suitable location when you start developing respiratory symptoms. We

may ask you to confirm the day of collection and to wear a face mask, this will also apply if you want to drop-off your kit with the samples at the corresponding site or any other location.

2. Volunteers will then attend a face-to-face screening, give their consent and eligibility to take part will be assessed.

**This study will include 3 groups:**

**Group A:** All participants will undergo bronchoscopy, including nasal cells and blood collection at 2-8 weeks post confirmed respiratory infection. There will be a follow-up visit at 4 months post infection.

**Group B:** Some participants from group A will be followed-up for up to 12 months after the infection. These participants will undergo a 2nd bronchoscopy at 9-12 months post infection

**Group C:** If participants from group A have a new infection, they will be invited to have an additional bronchoscopy at 2-8 weeks after that 2nd infection.

Please see the **Participant Information Sheet** <https://www.ovg.ox.ac.uk/studies/mucosal> for a complete description of the study groups and optional procedures.

## What is a Bronchoscopy?

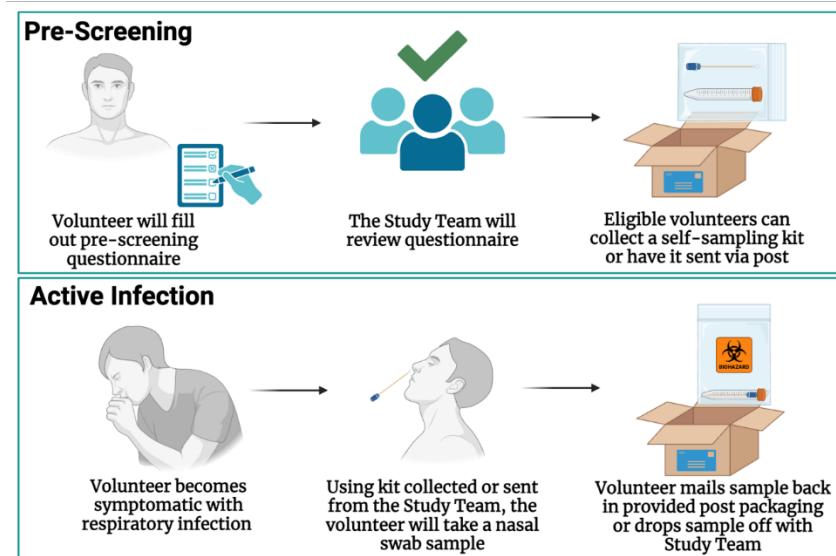
Research bronchoscopy is a safe, well tolerated procedure that involves looking into your lungs with a small, thin and flexible camera called a bronchoscope. It is performed under local anaesthetic and possibly sedation by an experienced respiratory doctor. Bronchoscopies are commonly performed for clinical reasons to diagnose and take samples to provide treatment for lung problems.

The samples we might take include washings (flushing a small part of the lung with some salty water and then sucking some of the sample back for analysis), brushings (where we brush part of your airways to obtain cells), or biopsies (where we take small rice-sized parts of the airways for analysis).

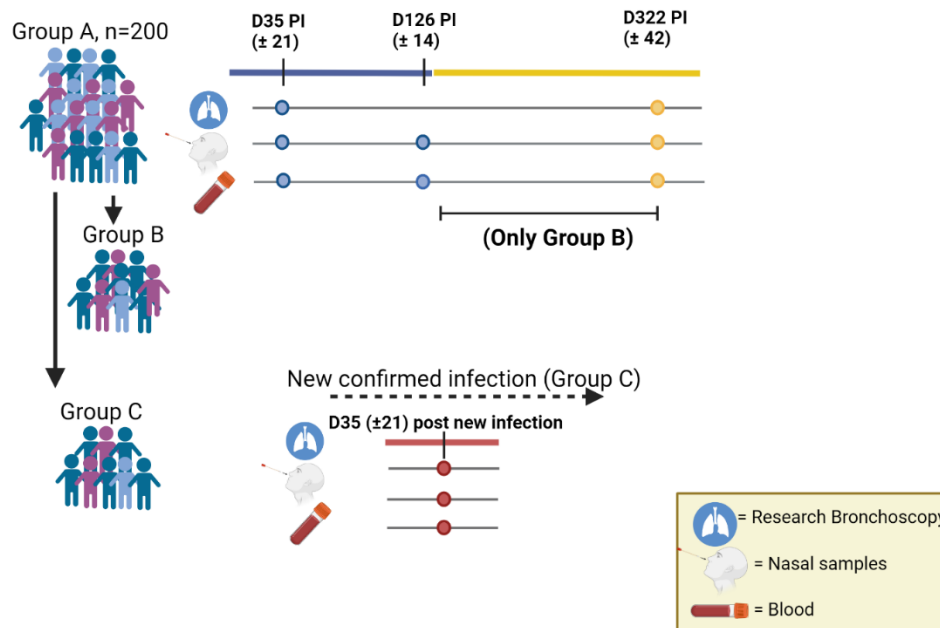
Having one bronchoscopy is a requirement for all study participants (Group A), and after the first bronchoscopy participants are invited for a follow-up that might include another bronchoscopy (Group B or Group C).

Please see the **Participant Information Sheet** <https://www.ovg.ox.ac.uk/studies/mucosal> for a complete description of the bronchoscopy procedure.

## What does the schedule look like?



**Figure 1. Volunteer pre-screening questionnaire and development of symptoms prompting self-sample collection for confirmation of the respiratory infection**



**Figure 2. Participants with confirmed respiratory infection and schedule of sample collection for Group A, B and C**

## What are the study procedures?

### 1. Pre-screening online Questionnaire

You will be asked for consent to share your information with us so we can assess if you are eligible for the study, this will include consenting to collect self-sample nose swabs to confirm the infection and to access medical records to confirm any recent respiratory infection and medical history. We will inform you if you are eligible to take part and the kit with the self-sample swab will be sent to your home. Alternatively, it will be possible to collect the kit from the corresponding site or any other suitable location when you start developing respiratory symptoms. When you develop symptoms compatible with respiratory infection you may collect the sample and send it to us (See Figure 1 above), only if you haven't already tested positive in a healthcare or a workplace setting. If your sample comes back positive for the viruses we are looking for, we will invite you for a screening visit. If your sample comes back negative, we can provide a new sampling kit for a future occasion.

### 2. Screening visits

We will discuss the study and if you agree to take part in the study, you will sign the consent form. We will conduct some tests to assess your eligibility for the study and conducting a breathing test (if required).

### 3. Bronchoscopy Visits

We will check it is safe to proceed with the procedure by measuring your vital signs and conducting a breathing test (if required and not done before). The study doctor will explain the procedure and will ask for your consent to the procedure.

### 4. Blood and nasal samples

During follow-up visits we will obtain blood and nasal samples to conduct research tests.

Please see the **Participant Information Sheet** <https://www.ovg.ox.ac.uk/studies/mucosal> for a complete description of the study procedures.

## Is there anything else I should know?

### Are there any risks or benefits of participating?

During the bronchoscopy, there may be some mild discomfort. After the procedure, participants may more commonly experience a sore nose/throat, cough or mild chest/back ache. More information can be found in the Participant Information Sheet

<https://www.ovg.ox.ac.uk/studies/mucosal>

**Participating in this study will not benefit you directly**, however, you will be helping research into understanding the differences between blood and lung/nose immune responses to respiratory viral infections and how these responses behave over time.

### **How do I sign up?**

#### **Thank you for your interest!**

Please complete our online questionnaire by: **visiting our website**

<https://apps.ovg.ox.ac.uk/redcap/surveys/?s=DAME8RK9KWNXMJAR> or scanning this QR code



The **questionnaire** takes 5 minutes and will ask questions to see if you could be eligible for participation. It will also ask for your contact details.

### **What happens next?**

The next step is to collect/receive your self-sampling kit and send that back to us when you experience respiratory symptoms. The postal kit will be pre-paid, you will not need to pay for any postage, but we will share your contact details including phone number with the courier for delivery of the kit. If positive, you will be scheduled for an in-person screening appointment with one of the study doctors. This appointment lasts 1-2 hours and involves a detailed discussion about the trial, review of the full eligibility criteria, blood tests and a medical examination.

### **How long are the other visits?**

The whole bronchoscopy visit can take up to 4hrs, but the bronchoscopy procedure itself can take up to 1hr. However, the other study visits are much quicker and generally take between 30 and 60 minutes.

### **How do I find out more information?**

- More detailed information about this study can be found in the Participant Information Sheet <https://www.ovg.ox.ac.uk/studies/mucosal>. **We require you to read this document before you can be part of this study.**
- Contact us using the details below. **We would be more than happy to answer any queries!**

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