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**MUCOSAL Study**
**ImMUnologiCal memOry to reSpirAtory viraL infection in the airways (MUCOSAL)**

# NASAL TISSUE BIOPSY INFORMATION SHEET

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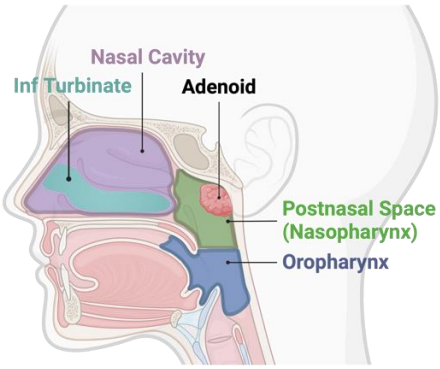
| **What is a nasal biopsy?** | Nasal tissue biopsies are procedures in which a trained Ear, Nose and Throat (ENT) doctor takes a small tissue sample from the inside of the nose. These procedures are done in outpatient clinics and use local anaesthetic spray (a medicine that will numb the nose lining). These procedures are typically used to collect nasal tissue samples to help diagnose cancer or inflammatory conditions in the nose. For this study, we will collect a nasal biopsy from an area at the front of the nose called the Inferior Turbinate and/or an area at the back of the nose called the adenoid or postnasal space tissue.<br><br>The figure below shows the location of the Inferior Turbinate, which sits in the nasal cavity, and adenoid tonsil tissue, which sits in the Postnasal Space.<br><br>  |
| **Why do we want to do a nasal biopsy as part of the MUCOSAL study?** | Getting tissue from the inside of the nose will allow us to study the way the body's immune system responds to germs at the site of infection. Performing a biopsy allows us to collect information about the immune system that cannot be collected by swabs, fluid samples or blood samples. |
| **Do I have to take part?** | No. Having the nasal biopsy procedure is entirely voluntary and optional procedure in the study. If you decide to participate, you can withdraw at any time without giving a reason. This will not affect your healthcare or ongoing participation in the rest of the study. |
| **What happens in the procedure?** | • You will have an examination by an ENT doctor to explain the procedure to you, assess your eligibility and determine if it is safe to proceed with a biopsy.<br>• If you are happy to go ahead, the doctor will numb the inside of your nose with a local anaesthetic spray and apply local anaesthetic on a small piece of specialised surgical cottonwool which sits in your nose for 10 minutes before the procedure. This has an unpleasant taste but is not painful. Typically, injections of local anaesthetic are not used for biopsies, but if this |

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| | is needed, it can feel like a mild bee sting. You will remain awake throughout the biopsy and will not be sedated.<br>• The doctor may use a small flexible tube with a camera (a nasal endoscope) to look at the back of your nose cavity and then collect a small piece of tissue from one or both areas on the inside of your nose. These samples will be roughly the size of a grain of rice.<br>• After the biopsy, the doctor may cover the with a small dressing which will get absorbed on its own. The doctor may also chemically seal (cauterise) the area where the biopsy was taken. These procedures are not typically painful.<br>• You will be observed in the clinic for 30 minutes after the biopsy. |
| **How long does it take?** | The whole visit takes between 60-90 minutes. |
| **What happens to my samples?** | The nasal biopsy samples will be processed in the Liverpool School of Tropical Medicine and the University of Oxford. They may be also sent to collaborators outside the UK for additional analysis.<br>Clinical samples are sent to local NHS laboratories and follow local sample labelling requirements (which may include personal identifiers). As part of processing clinical samples, local NHS laboratories may be required to add the results to your medical records.<br><br>Samples sent to research laboratories for processing, within and outside of the UK, will not have personal identifiers (they will be identified by study number and participant number only).<br>We will also ask for your consent to retain leftover samples to be used for future ethically approved research in the UK and overseas. This consent will be requested separately. If you consent, samples are coded and will be transferred to a research tissue bank at the end of the study. These samples will be transferred to a research tissue bank held at the University of Oxford.<br><br>For additional information, please refer to MUCOSAL Participant Information Sheet |
| **Risks of nasal biopsy procedure** | Nasal biopsies are safe and well-tolerated procedures but, as with any medical intervention, they carry some risks:<br><br>• **Pain:** The biopsy procedure should not be painful, but you may feel some pressure or tugging in your nose. You may feel some mild discomfort when the anaesthetic is applied. You can take a simple painkiller like paracetamol if you need it; avoid taking aspirin, as this may increase the risk of nosebleeds. Any tenderness or discomfort after the procedure will typically be mild and resolve within 24 hours.<br><br>• **Bleeding:** A small amount bleeding after the procedure is common, and this would typically be some mild blood staining to your normal nasal secretions for a few days after the procedure. Continuous nose bleeding is rare, occurring after about 1 in every 100 biopsies, and can happen up to three weeks after the procedure. If you have continuous bleeding from the nose, firmly squeeze the nostrils shut, holding the pressure for 15 minutes, and repeat if needed. If the bleeding does not stop after 30 minutes of pressure, you will need to attend your local hospital emergency department. If there is bleeding, the blood vessels may |

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| | be sealed with cautery or covered with a nasal dressing, and a nasal endoscope may be used to help with this. In very rare cases, participants may need an inflatable nasal tampon placed inside the nose to stop the bleeding and/or an inpatient stay in a ward for monitoring. Very uncommonly, a further surgical procedure may be required to stop nosebleeds. If you have had a continuous nosebleed, even if it has stopped on its own or has been treated, please contact the MUCOSAL study team on info@ovg.ox.ac.uk; telephone: 01865 611400.<br><br>• **Medications:** The risk of bleeding is higher if you are taking medications that thin your blood such as warfarin, apixaban-like medicines or clopidogrel-like medicines. People taking these medications are excluded from the MUCOSAL study. If for any reason you have taken any new medication in the 7 days before the biopsy procedure, do let us know. Please do not stop any regular medicines without medical advice to do so.<br><br>• **Infection**: infections following nasal biopsy are very rare. If you get redness and/or tenderness/pain in the next few days, you may need antibiotics.<br><br>• **Considerations**: Avoid blowing your nose for 2 weeks after the biopsy. Do not pick your nose or put your fingers over the area. Avoid strenuous exercise or straining on the daily of the biopsy if possible.<br>• **Follow up:** We will call you the day after the biopsy and 3 weeks after the procedure for a safety check and you will have 24/7 telephone access to a member of the study team for up to 3 weeks after the biopsy. |
| **Benefits of nasal biopsy procedure** | There is no direct benefit to you of taking part in this study. By agreeing to have a nasal biopsy, you will be helping research evaluating the immune response to viruses in the nose, the site of infection. |
| **Would my taking part in the study be kept confidential?** | All information that is collected about you during the research will be kept strictly confidential. Apart from clinical samples, any information about you that leaves the clinic would have your name and address removed so that you could not be recognised, except for your signed consent form. No one else will be told that you are involved in the study. |

For further information, please refer to MUCOSAL Participant Information Sheet

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## NASAL TISSUE BIOPSY INFORMED CONSENT FORM

Participant's initials: _____

Participant's number: _____

***If you agree, please initial each box***

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| Section 1: Study Procedures | |
| 1. I confirm that I have read and understood the Nasal Biopsy information sheet version __ __, dated __ __/__ __ __/__ __ __ __for this study. I have had the opportunity to consider the information, ask questions and have had these answered. | |
| 2. I have received detailed information about Nasal Biopsy procedure, potential side effects/risks and the importance to the study | |
| 3. I understand that I will also have the opportunity to discuss the nasal biopsy with the ENT surgeon performing the procedure and will be asked to sign an NHS consent form if I wish to proceed. | |
| Section 2: Withdrawal | |
| 4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, without my medical care or legal rights being affected. | |
| 5. I understand that if I withdraw my consent, the samples and other information collected before my withdrawal will still be used in the study, unless I specifically request otherwise. | |
| Section 4: Research Samples and Data | |
| 6. I understand that the nasal biopsy collected will be considered a gift to the University of Oxford and I understand I will not gain any direct personal benefit from these. I understand I have the right to ask for my samples to be disposed of at any time. | |
| 7. I agree that nasal biopsy analysis looking at the tissue structure and immune response can include some genetic tests, and I understand that the results of these investigations will not have any implications for me personally. | |
| 8. I agree that my de-identified data and biological samples may be sent and stored within and outside of the UK for analysis by collaborating research groups as described in the MUCOSAL Participant Information Sheet. | |
| 9. I understand that the nasal endoscope examination is for research, not for medical purposes. If an abnormality is identified during this examination, I will only be informed if a doctor thinks it is medically important such that the finding has clear implications for my current or future health. | |
| If all the applicable sentences above are initialled, meaning "yes," then please continue: | |
| 10. I agree to the collection of a nasal biopsy. | |

| _____ | _____ | _____ |
|---|---|---|
| *Name of Participant* | *Date* | *Signature* |
| _____ | _____ | _____ |
| *Name of person taking consent* | *Date* | *Signature* |

***Original – Investigator Site File, 1 Copy – Participant***