CHIRP-01 Study
Participant Information Sheet

Study Title: Novel Mucosal Correlates Of RSV Protection In Older Adults (A **C**ontrolled **H**uman **I**nfection Study with **R**SV in older **P**eople)

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. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

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Eligibility Criteria

Before reading this Participant Information Sheet (PIS) further, it may be worth reading the study's key eligibility criteria to assess whether you might be eligible to take part. For this study, we aim to recruit up to 20 volunteers who are **healthy, non-smokers and aged between 65 – 75 years**. We can enrol ex-smokers with a pack year history of 10 pack years or less. Pack years can be calculated by the number of cigarettes packs (20 cigarettes) smoked per day times by the number of years smoked for. To be eligible, participants must also have been vaccinated against COVID-19.

We **cannot** enrol anyone who:

- Has a chronic respiratory disease such as asthma and Chronic Obstructive Pulmonary Disorder (COPD).
- Uses inhalers or inhaled steroids
- Has received an RSV vaccine

- Has close domestic contact (i.e. sharing a household with or caring for) anyone who is clinically vulnerable and/or immunosuppressed or any children under the age of 3 years old
- Has a known or suspected immunodeficiency
- Has a history of frequent nosebleeds
- Has a history of difficulty with having blood tests performed or fainting from blood tests

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1. What is the purpose of the study?

Respiratory syncytial virus (RSV) is one of the most common causes of lung infection, affecting around 64 million people each year worldwide. In healthy young adults, it causes a ‘common cold’ illness but, in infants, it frequently causes severe lung disease. It is also commonly

involved in lung infections of elderly people, contributing to 5% of hospital admissions with pneumonia. In the elderly, RSV is responsible for approximately 20% of general practitioner visits for acute winter respiratory illness and can result in death, particularly in those living with frailty and in poor general health. Incidence increases with older age, such that RSV has an attributable mortality of up to 5% in the most vulnerable age groups.

There are currently two RSV vaccines licensed for use in the UK since July 2023 and there are some ongoing clinical trials of other potential RSV vaccines. The Joint Committee on Vaccination and immunisation (JCVI) have advised a vaccination programme to offer over 75 year olds the licensed RSV vaccine in the UK. However, whilst these vaccines have been shown to be efficacious in preventing severe disease, there is much less evidence on the duration of protection afforded, their impact on milder disease and the ability of these vaccines to prevent onward transmission of the virus.
Partly this is because it is not fully understood why some people are protected from infection whilst others are not only infected but develop severe disease. As there are few available vaccines and no specific treatments available, further research in this area is therefore needed and the aim of this research project is to identify how the human immune system responds to infection with RSV and how this changes with aging. As these are understood, we will be able to design new therapies and possibly create new vaccines against this virus.
In order to meet these aims we will infect healthy, non-smoking volunteers aged 65-75years with RSV in order to examine their immune response to these viruses in their blood and lung secretions. We will record any symptoms experienced, take blood samples, perform breathing tests, and take samples from the nose and throat. Similar studies have been done many times in the past, both at Hammersmith Hospital and elsewhere. Infections with viruses have even been undertaken in volunteers with asthma and other underlying lung diseases, with no serious side effects.

2. Why have I been chosen?

We are inviting you to take part in the study because you have expressed an interest in taking part. Before participating in this study, we need to make sure that you fully understand and agree to what is going to happen and that you are healthy and unlikely to get severely ill from the virus.

Please make sure you read and understand this participant information sheet before you make the decision to take part. If you have any questions or concerns, please ask a member of the study staff and, if you want to, discuss any of this information with your family, friends, and your General Practitioner (GP) before you decide to take part.

3. Do I have to take part?

No, taking part in research is entirely voluntary. 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. You will be paid for the time you have spent in the study (see Section 11).

If you are not eligible to take part, you will be sent a letter, by post or email, thanking you for your time and explaining that you were not eligible.

4. What should I do if I want to take part?

If you have not done so already, you will need to register your interest in taking part in the study with the study team by contacting flu-rsv-study@imperial.ac.uk or by visiting https://www.imperial.ac.uk/infectious-disease/research/human-challenge/chirp01/ to complete an online pre-screening questionnaire and submitting your details if you are eligible.

The study team will then contact you to discuss the study in detail and answer any questions you may have about the study and ask you some further questions relating to your eligibility for the study. Following this discussion with the study team, you may then be invited for a screening visit (see Section 5.1). During this visit, you will have the chance to discuss the study further and ask the study team more questions. Once you are satisfied that all your questions have been answered, the study doctor will ask you to sign a consent form before proceeding with the full screening visit procedures (see Section 5.1). If after all this, you are still eligible for the study, you will be invited to the residential part of the study at the Imperial Clinical Research Facility (ICRF) at Hammersmith Hospital, White City (see Section 5.2).

5. What will happen to me if I take part?

If you are eligible to take part in the study based on your pre-screening answers and discussion with the study team, they will invite you for a screening visit.

5.1. Screening Visit

Screening visits will be conducted at the Imperial Clinical Research Facility (ICRF) at Hammersmith Hospital, White City. These visits can happen up to 90 days in advance of the residential stay. First, the study team will discuss the full screening visit process and the main study with you and answer any questions you may have. If all your questions have been answered and you would like to go ahead, the study doctor will ask you to read, sign and date the relevant consent form. They will then also sign this consent form and provide you with a copy.

Following informed consent, the following assessments will be completed at screening:

- Collect contact details and demographic information
- Full medical and medication history
- Questions about current weekly alcohol and/or smoking consumption
- Mental health questionnaires
- Check of any current or previous participation in clinical trials via The Over-Volunteering Prevention System (TOPS).
- Examination for signs of illness or disease (a physical examination).
- Height and weight measurements to calculate BMI
- Pulse rate, blood pressure, temperature and breathing rate checked (Vital Signs).
- Electrocardiogram (ECG)
- Urine samples to test for drugs of abuse & cotinine (a nicotine urine test used to determine current or recent smoking or vaping)
- Blood samples obtained for:
    - Safety blood tests, including full blood count, renal and liver function tests.
    - Hepatitis B and C and/or HIV (the virus that causes AIDS)
    - Human leukocyte antigen (HLA) typing
- Lung function test (spirometry).
- Nasal SAM (“synthetic absorptive material”, a bit like tissue paper) and swabs
- Chest X-Ray

Full study visits and procedures can be found in Appendix 1.

To reduce your risk of COVID-19 when attending for study visits, we will only enrol participants who have received a full schedule of an approved COVID-19 vaccination.

We will also need to review your medical history records. Sometimes, the study doctor or nurse can review a summary care record for you on the hospital's electronic patient records system (called Cerner). The study team will not look at this until you have signed the informed consent form.

If your GP practice is signed up to ACCURX, we can use this system to view your medical records. The study nurse or doctor will request access to view your record and it will send an authorisation code to your mobile phone. You will then share the authorisation code with the study team so that they can get access to the summary. Again, this will only be looked at once you have signed the informed consent form for the study. The study doctor can then review your medical record with you during the visit and discuss any relevant medical history that appears on your record.

If we cannot find your medical records on these systems, then the study team will send a letter and enclose your consent form to your GP practice so they can send us a summary.

Once all the test results have come back, the study team will review everything to determine if you are eligible to take part in the study.

If you are still eligible to take part, you will then be invited to take part in the study and a date will be arranged with you to be admitted to the residential facility at the Imperial Clinical Research Facility (ICRF) 1 day prior (known as Day -1) to you being given the study virus on Day 0.

If you are not eligible, because the test results have identified something that makes you ineligible for the study, the study team will discuss this with you. If any abnormal results are found and deemed clinically significant, we will ask for your permission to inform your GP so they can arrange to follow up with you. If your blood tests indicate that you have Hepatitis B or C, we will inform you of this and discuss next steps of management. Hepatitis B and C may be transmitted by contact with infected blood or body fluids and is therefore a statutorily notifiable disease. The study team would be required to notify the local health protection team to enable timely risk assessments and the prompt delivery of public health actions.

You will be paid £50 for your time and inconvenience for attending a screening appointment.

After deciding to take part in this initial screening, you can still change your mind at any time and withdraw from further assessments and study participation.

If at any time before the residential stay you develop any cold symptoms, you must tell the study staff. This is because you need to be four weeks free of symptoms before taking part in the residential part of the study.

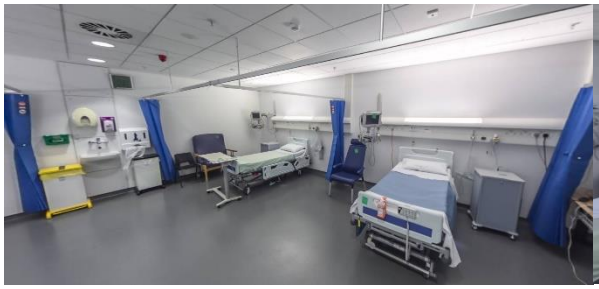
5.2. Residential Stay

If you choose to take part in the study, a date will be arranged with you to be admitted for the residential stay at the Imperial Clinical Research Facility (ICRF), where you attended for screening, 1 day prior (known as Day -1) to you being given the study virus (Day 0).

Depending on current guidelines at the ICRF at the time of your admission, you may be asked to self-isolate (stay at home) prior to admission or be asked to take a COVID-19 Lateral Flow

Test. The study team will contact you if this is a requirement and will help you arrange. Upon admission, you will be seen and briefly examined by the study doctor to ensure you have remained in good health.

On Day 0, we will infect you with RSV to measure how this affects the nose and lungs. The virus is given in the form of drops into each nostril. We will observe you for one hour after this, to ensure you do not experience any early side effects. Once you have received the virus, you will stay within the residential facility until Day 8 or 10.




During the inoculation procedure (when we give you the virus via droplets in your nose) and each time study staff enter the residential space, study staff will wear Level 2 PPE. Level 2 PPE includes a facemask, long sleeved gown and disposable gloves as seen in the picture. When the research nurses collect samples from you, they will also wear a face visor to reduce the risk of transmission

For the next 8-10 days, you will stay in the clinical research facility, and the study team will visit up to twice daily to monitor your health and to take samples from your nose (washings and SAMs), throat, and blood. You will be asked to complete symptom diaries. On some of these days, we will perform further breathing tests as well as nasal scrapes and brushings from your nose. During this time, we will also be collecting stool swabs. This will involve you rubbing a cotton swab on the toilet paper you have used.

At all other times during this period, you must remain in the residential bay in the clinical research facility. You will not be allowed visitors as you may be contagious to others.

During your stay, the staff at the facility will be able to assist you if needed. Internet access will be available, and we may be able to provide you with an iPad if you don't have a laptop/tablet to bring with you. There will be no restrictions on what you can do as long as you stay within the designated area and as long as it does not damage the equipment related to the study. Food, drinks and snacks are provided, and you may bring as many additional snacks with you as you wish. Towels and linen are provided during your stay. You are welcome to visit the residential facility in advance; please let us know if you wish to do so.

On Day 8, if you have been uninfected by RSV throughout your stay, the study doctor will assess you to see if you can be discharged. You will then be asked to return to the study site on Day 9 and Day 10 so the study team can continue to monitor your health and collect samples and data from you.

If you have been infected by RSV, you will need to remain in the residential facility until Day 10. The study doctor will then assess you for discharge and you will be allowed home as long as you have no significant symptoms, and the study doctor thinks it is safe.

5.3. Follow-up visits (outpatient)

You will be asked to return to the ICRF on Day 14, Day 28 and Day 180 post infection. At these visits, you will have a brief medical examination, blood test, nose samples, a throat swab, and we will collect your completed symptom diary on Day 14.

Your final study visit will be on Day 180. At this visit we collect the final samples so we can look at whether your immune responses have lasted.

6. Samples and Procedures

Tests/Procedures	
Documents	
Informed Consent Form	You will be given an informed consent form to read and sign before any study procedures are performed.
Symptom Diary Card	During Quarantine, you will be given a symptom diary card to complete which asks you questions about how you are feeling and any cold-like symptoms you may have.
Health Questionnaires	You may be given two short questionnaires. The Patient Health Questionnaire (PHQ-9) and the Generalised Anxiety Disorder Questionnaire (GAD-7)at screening, admission to quarantine and discharge from quarantine. These are so the study doctor can identify and discuss any concerns for your mental well-being either before or during your participation in the study.
Measurements/Scans	
Height and weight	You will be asked to remove your shoes and then stand against a height stick to record your height. You will also be asked to stand on scales to record your weight.
Vital Signs	We will measure your heart rate, breathing rate, blood pressure, oxygen saturation and temperature). Using an observation machine, we will place a cuff around your arm that will inflate and then deflate to measure your blood pressure, a small device will be clipped onto your finger to check the amount of oxygen in your blood, and it will also tell us your heart rate. A study doctor/nurse will measure your breathing rate by watching your chest expand as you inhale. A temperature probe will be given to you to place under your tongue to measure your temperature.
Physical Examination	A study doctor will look at your skin, listen to your chest, feel your abdomen, look in your mouth and feel the lymph nodes in your upper body (around your neck and in your armpits).
Chest X-Ray	This is performed once at the screening visit and is a safe and painless test that uses a small amount of ionising radiation to take a picture of your chest and lungs. You will be provided with a hospital gown to change into and asked to lie down or sit up for a short while during the scan.
Electrocardiogram (ECG)	This looks at your heart's activity. It is a painless procedure where small pads will be stuck to your arms, legs and chest (which may need to be shaved) while

	you lie still for a few minutes. You will be required to undress to the waist. The pads can sometimes cause minor skin irritation.
Spirometry	Spirometry is a type of lung function test. It is either a small machine attached by cable to a mouthpiece or a handheld device with a mouthpiece. You will take the deepest breath you can, then exhale long and hard into a tube. This can make you cough or feel short of breath for a short time.
Peak Nasal Inspiratory Flow	A small handheld device attached to a mask is given to you and you will be asked to breathe deeply in through your nose to assess how blocked or stuffy your nose is. 
Samples	
Urine test	You will be asked to provide a urine sample to test for drugs of abuse, nicotine (from smoking or vaping).
Nasal sampling	Nasal swabs: nasal swabs will be obtained by placing a swab into your nostril. Swabs may be taken from the middle or back of the nose. Nasal wash: nasal fluid will be obtained by placing a nasosorption strip inside your nostril for 2 minutes. This strip is flexible and absorptive like filter paper. At all visits and every day during the quarantine, the study team will perform a nasal wash to collect cells and mucous from your nose. Nasal scrape: nasal cells may be obtained by a member of the study staff using a small plastic scoop that goes into your nose up to 3cm into your nostril to collect cells. Nasal Brush: at the beginning of the study and at later follow up visits, the study team will use a small brush to collect additional cells from the lining of your nose. These nasal sampling procedures are not painful and do not require local anaesthetics. They may cause minor discomfort for a few seconds, and can cause a small nosebleed, make you sneeze, and/or temporarily leave you with watery eyes and a runny nose. The study team will monitor your nose for any irritation and the samples will be collected from alternate nostrils.
Throat swabs	We will ask you to tilt your head back and open your mouth while a swab is rubbed along the back of your throat. You will need to resist gagging and closing your mouth.
Blood Samples	We will take blood to test for: • Anaemia (low red blood cells) or problems with your immune system • Blood clotting problems • Liver, kidney, thyroid and heart function • HIV, Hepatitis B and Hepatitis C infection • Diabetes or impaired blood sugar control • HLA type (this tells us the types of proteins or “markers” on your cells, and will only be performed if you consent to genetic analysis) We will take between one teaspoon and 5 tablespoons each time. The total amount of blood we collect will not exceed 550ml over 8 weeks (the same amount taken at a blood donation session), unless for safety reasons when additional samples may be required. So that you don’t give too much blood, you should not donate blood from the time of the Screening visit until 3 months after the last study visit. You may feel dizzy when you have blood taken. Sitting or lying down when blood is taken should stop you feeling lightheaded or fainting.
Stool swab	You will be asked to collect a stool swab by rubbing a cotton-headed swab on used toilet paper after opening your bowels during the quarantine stay only.

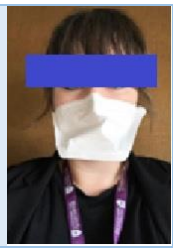
Duck Beak Mask Wearing Sample	During the residential stay, you may be asked to wear a duck-beak mask for 60 minutes each day to measure any virus that you breathe out while going about your daily activities.	

Table 1. Tests and Procedures performed during the study

7. Where did the virus come from?

The RSV virus has been used in many previous studies, where it has been shown to be safe. This was prepared especially for research and has been stored carefully in our laboratory since that time. They have been made specifically for human infection under the most stringent conditions and have been carefully tested to ensure they are free from other bacteria or viruses. Unlike medicines, there are no special rules for preparing viruses in this country, but the conditions of production were fully compliant with the US Food and Drug Administration (FDA – the US organisation that approves foods and medicines) approved methods.

8. What are the side effects of these research procedures?

The main side effects you are likely to experience when taking part in the study are those associated with infection by a common cold virus. Typical symptoms include mild fever, tiredness, a blocked nose, a sore throat, a runny nose, and sneezing, which usually last for 3-4 days. Symptoms may last for up to two weeks, but this is unusual. No one in previous studies like this developed any serious side effects, including volunteers aged up to 75 years old in a similar earlier study, who only had mild symptoms and no serious problems. However, we will monitor you closely to ensure that any side effects are detected. These may include difficulty in breathing, wheeze or change in breathing tests, which we will watch for closely. If you were to develop any signs of becoming more unwell than expected, we would arrange for you to have prompt treatment at Hammersmith Hospital.

The blood samples we will take may cause minor bruising around the area where blood is taken. The brief nasal lavage, SAMs, and the nasal scrape may tickle, make your eyes water slightly or feel slightly uncomfortable, but it should not be painful. The throat swab is not painful but can make some people gag – this is completely normal. The nasal brushing may cause light bleeding and temporary nasal discomfort.

As with any x-ray procedure, there are risks associated with being exposed to radiation. Ionising radiation can cause cancer which manifests itself after many years or decades. The chest X-rays do expose patients to radiation, the amount of radiation used is kept to a minimum and the risks are very small. The amount of radiation used is equivalent to about 3 days of natural background radiation in the UK. The estimated lifetime additional risk of fatal cancer per chest x-ray is around 1 in a million.

9. What are the possible benefits of taking part?

It is unlikely that this study will help you directly, but we hope that the information we get from this study will help to improve the future treatment of people affected by RSV infection. We would like to design new therapies and possibly make vaccines to prevent these infections.

It is possible that we may identify something of medical significance from the tests we perform on you for this study (for example, a respiratory illness). If this is the case, we will inform you and your GP so the results can be followed up.

10. What if new information becomes available?
Sometimes during a research project, new information becomes available about the disease or virus that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will arrange for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form.

Also, on receiving new information, your research doctor might consider it to be in your best interests to withdraw you from the study. They will explain the reasons and arrange for your care to continue.

11. Am I paid for taking part in this study?
You will be paid for your participation in the study as follows:

Visit	Amount	Payment
Screening	£50	Paid after screening visit
Residential stay	Day -1 to Day 8 is £1,900 Day -1 to Day 10 is £2,300	Paid after the residential stay
Day 9 outpatient visit (if applicable)	£50	
Day 10 outpatient visit (if applicable)	£50	
Day 14 Follow Up Visit	£50	Total of these three visits (£150) will be paid after final Day 180 study visit.
Day 28 Follow Up Visit	£50	
Day 180 Follow Up Visit	£50	

Table 2. Participant payment breakdown

You will receive £50 for attending a screening visit for your time and inconvenience even if you are then not enrolled into the study.

As an uninfected participant who leaves on Day 8, your total amount will be around £2,200.
As an infected participant who remains in until Day 10, your total amount will be around £2,500.

If you do not complete all the study visits, then the amount paid to you will be on a *pro rata* basis for the visits you have completed.

In addition, we will reimburse up to £50 per visit for reasonable travel expenses, such as buses, tubes, trains, parking and mileage, with receipts provided.

It is your responsibility to declare these payments to HMRC and the benefits office (if applicable). It is also your responsibility to ensure that your participation in the study doesn't affect any private medical insurance policy you may have.

12. Is everything kept confidential?
Yes. No personal information is taken out of the hospital, and we use a code in the laboratory so you cannot be identified. Only authorised members of the clinical and research team will have access to your identifiable information. With your consent, we will write to your GP to let them know that you are taking part in the study.

If you join the study, some parts of your medical records and the data collected for the study may be viewed by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. All have a duty of confidentiality to you as a research participant and we will do our best to meet this obligation. Data is securely stored for 10 years after the study ends.

13. Can I withdraw my permission to take part in this study?

Yes. 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. Being part of this study will not affect your normal medical care, either now or in the future. If you decide to withdraw after being inoculated but within 10 days of having been given the virus, we will ask you to confine yourself to your home and avoid any contact with babies, older persons and those with heart or lung problems so that the risk to others in the community is minimised.

The study doctor may also withdraw you from the study at any time if considered appropriate. The study doctor will have access to your hospital records, but your confidentiality will be maintained and all records from the study are stored in the strictest confidence. Results from the study may be published in medical journals but you will not be identified. Any surplus samples will be stored pseudonymously for future research using a unique identifier, with your consent, but you can ask for these to be destroyed at any time.

If you lose capacity to consent during the study, then you will be withdrawn from the study. Any identifiable data or tissue already collected with your consent would be retained and used in the study as outlined in this information sheet. No further data or tissue would be collected from you and you will not undergo any other research procedures.

14. Why are you looking at my genes and can I refuse?

Our genes (or DNA) supply the body's cells with the instructions on how to work. Some genes are involved in determining things like our eye and hair colour while other genes have other roles. The genes we will be looking at are those which are involved in protecting us from infection. We are interested in looking at these differences in these genes between different people. We will primarily be looking at genes that are known to influence the immune system. This will involve looking at genes that are turned on and off during infection and whether the patterns of these are linked to the likelihood of developing more severe disease with RSV.

We will do genetic tests on your blood samples to look at the patterns of genes that regulate your own individual immune response (these are called Human Leukocyte Antigen HLA genes). Doing this helps us to work out which aspects of the immune response to vaccines are due to genetic differences between individuals. We may also try to identify and study the genes that appear to be important in response to challenge. Samples will be tested in pseudonymised form (direct identifiers removed); however, your DNA is unique to you so it can never be completely anonymous.

15. What will happen to my blood and respiratory samples?

Samples of tissue, cells and fluids will be stored at Imperial College London and used in experiments to examine the immune response to infection.

With your consent, these may also be used in other ethically approved research studies at Imperial College London, or in collaboration with scientists at other sites in the UK or abroad. Your samples will be pseudonymised using a unique identifier and only the study team hold the records that can link these samples to you.

16. What happens when the research study stops?
Your time in the study will end once you have completed your final follow up visit at 6 months post viral challenge. You will not need to do anything further. You will be thanked and reimbursed for your time and expenses.

After the study has completed, you will not be informed of any individual results of your research tests. With your consent, the study team will contact you if any publications arise from the results of this study.

17. What if something goes 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, Professor Chris Chiu (c.chiu@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: Research governance and integrity | Research and Innovation | Imperial College London.

18. How will we use information about you?
Imperial College London is the sponsor for this study and will act as the Data Joint-Controller with MSD 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 stated to finish in February 2025.

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, from your medical records, and your GP for this research project. This information will include your name, date of birth, NHS number, hospital number 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
• MSD – legitimate interests held by the data controller or a third party

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), both organisations rely on "scientific or historical research purposes or statistical purposes.

19. 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.

20. 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.

21. 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.

22. COMMERCIALISATION

Samples and 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.

23. 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.

24. 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 flu-rsv-study@imperial.ac.uk
- by ringing us on 07872 850212
- by visiting https://www.imperial.ac.uk/infectious-disease/research/human-challenge/chirp01/

25. 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 flu-rsv-study@imperial.ac.uk or by ringing us on 07872 850212.

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.

26. Media
We may ask to take photos and/or videos of you during the study. This media could be used in press releases, news articles, to promote the study on our website and social media platforms, and also for training purposes. You may be identifiable in these images and videos.

Agreeing to this is completely optional and if you do not consent, you will still be able to continue in the study. Your decision will not affect the care that you will get from the study doctor. If you do consent to this, any photos or videos that are taken will be securely stored.

If you do consent to this, you can change your mind at any time and withdraw your consent. If you wish to withdraw your consent, please notify the study doctor. If you withdraw your consent, we may not be able to remove images of you that are already public but we can ensure they are not used going forward and we will not take any new images or videos of you.

27. What will happen to the results of the research study?
If any results or publications are made publicly available during your participation in the trial, the study team will inform you where you can read these or provide you with a copy. If any results or publications are made publicly available after you have completed the trial, information about these can be found on https://www.imperial.ac.uk/infectious-disease/research/human-challenge/chirp01/. You will not be identified in any report/publication.

There is also an optional statement on the consent form for you to agree to the study team contacting you after you have completed the study to send you relevant publications.

The study team plans to report and disseminate results in peer-reviewed scientific journals and by presenting at conferences.

28. Who is organising and funding the research?
The research is being run by the Department of Infectious Disease at Imperial College. The research is funded by MSD.

29. Who has reviewed the study?
This study has been reviewed and given a favourable opinion by the London Fulham Research Ethics Committee.

30. Contact for Further Information
If you require further information about the study, please contact:

Principal Investigator: Professor Chris Chiu
Email: flu-rsv-study@imperial.ac.uk
Phone: 07872 850212

Now that you have read this participant information sheet and a study team member has gone through it with you in detail, there will be a break. Please take the opportunity to make sure everything is clear to you and ask as many questions as you want.

31. Appendix

Table 1: Study visits and procedures – the yellow shaded area indicates the period of residential stay

Study Day	Screening	-1	0	1	2	3	4	5	6	7	8	9	10	14	28	180
Procedures																
Informed consent	X															
Medical history	X															
Medical examination	X	X									X			X	X	
Mental health questionnaires	X	X									X			(X)	(X)	
Chest X-ray	X															
ECG	X	X				X				X			X			
Infection with RSV			X													
Breathing tests	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood sampling	X	X	X	X	X	X	(X)	(X)	(X)	X	(X)	(X)	X	X	X	X
Urine tests	X	X														
Throat swab	X	X		X	X	X	X	X	X	X	X	X	X	X		
Stool swab		X	X	X	X	X	X	X	X	X	X	X	X			
Nasosorption (SAM)	X	BD	X**	BD	BD	BD	BD	BD	BD	BD	BD	BD	BD	X**	X**	X**
Nasal wash	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X
Nasal scrape	X			X	X	X				X			X	X	X	X
Nasal brushing	X	X														X
Nasal swab	(X)	X		X	X	X	(X)	(X)	(X)	X	(X)	(X)	X	X	X	X
Duck Beak Mask		X		X	X	X	X	X	X	X	(X)	(X)	(X)		(X)	
Symptom diaries		Twice daily from Day -1 to Day 13 and once in the morning of Day 14														

Note: In addition, SARS-CoV-2 samples may be taken as per local guidelines.
X:** Nasosorption (SAM) performed on both nostrils on Day 0 and at follow up visits.
BD: Twice daily.
(X): the nasal swab at screening and the nasal swab and blood collection on days 4, 5, 6, 8 and 9 are optional at the investigator's discretion.