ReSET

Rechallenge Staphylococcus aureus Experimental nasal colonisation sTudy

Lead Study Location

Oxford Vaccine Group, Oxford

You are invited to take part in a research study called **ReSET** which is being carried out at Oxford Vaccine Group.

What is this information sheet for?

Before you take part in a clinical study, you need to know more about the study to help you decide if taking part is the right decision for you.

In this information sheet we will tell you:

Contact Us

You can contact us at any time before, during or after the study

01865 611400

info@ovg.ox.ac.uk

Churchill Hospital, Annexe Reception, Centre for Clinical Vaccinology and Tropical Medicine, Oxford OX3 7LE

For Office Use:

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What if I still have questions?

If you still have questions or concerns after reading this, you can contact us by phone, e-mail or letter.

If you're not sure whether to take part, you can talk to a friend, family member, your GP or another health professional. You can show them this information sheet.

Do I have to take part?

No. You do not have to take part in the study. If you start to take part you can stop taking part at any time, without giving a reason.

If you decide not to take part it would be really helpful to understand why. You can tell us about it by following this link https://ovg.to/feedback/reset. You will not have to give us any personal information. We hope that we can use the feedback to improve or change things about our studies in the future.

Study Summary

Who can take part?	People who are **aged 18-55** and **in good health**
What are we studying?	• Staphylococcus aureus are bacteria that live harmlessly in the nose or on the skin in about 2–3 in every 10 people – this is called '**colonisation**' • We are all exposed to the bacteria frequently, and most of us will be colonised with them in our lives, some repeatedly • It can also cause serious infections, especially after surgery or in vulnerable people • Some infections that are caused by the bacteria are difficult to treat with standard antibiotics – this is due to '**antibiotic resistance**' • Researchers have been trying to develop a vaccine against these bacteria for decades, but despite many attempts, no human vaccine has been found that works • It is important to study colonisation to develop better treatments and vaccines

	• We want to find out why some people are better than others at stopping the bacteria from colonising the nose • We will do this by intentionally and safely dripping a small amount of liquid containing the bacteria into the nose. This is called '**challenge**' • This type of study is called a controlled human infection model (CHIM) • We will also use the information collected in this study to train an artificial intelligence tool that will help us to understand the immune responses so that better vaccines can be developed
Will I be paid?	You will be reimbursed up to **£1300** for your time and inconvenience.
Where will study visits happen?	Study visits will be at the Oxford Vaccine Group, Oxford.
How much time will it take?	If you decide to take part in this study, you will have a screening visit and then **9 visits over around 2 months** and two short electronic diaries to complete**.** There will then also be **2 phone calls** at around **months 2 and 6**, to check you have been well.
What procedures are used?	• You will be given a special hair and body wash, as well as antibiotic cream for your nose before challenge and at the end of the study • You will be given a small, amount of the bacteria into your nose, in a carefully controlled way • We will collect samples from your nose, throat and some swabs of your skin • We will collect blood samples using a needle • You will take a pregnancy test (if applicable) • You will be asked to collect simple daily nose samples when you are at home and store the samples in your freezer until the next clinic visit
Are there risks to taking part?	There may be minor side effects from the challenge. There is a very small risk of more severe side effects.

	Full information about these risks and side effects can be found on page 16.
Are there benefits to taking part?	• You will be a valuable part of research that we hope will eventually lead to the development of new ways to prevent or treat Staphylococcus aureus • You will not directly receive any personal health benefits from the study or its procedures

Introduction to the study

This study has two stages. This information sheet tells you about **Stage 1**, anyone who takes part in stage one, will not take part in stage two. In Stage one, we want to find out whether we can safely and temporarily introduce common bacteria called Staphylococcus aureus (also known as Staph) into your nose so that they live there for a short time. This is called '**colonisation**'. We will test different strains of Staph and we aim to recruit up to **48 people** aged **18-55 years old** per strain to take part in this study.

When a person naturally has Staph living in their nose without causing any symptoms or illness, this is called '**carriage**', and people who have it are known as '**carriers**'. Around 3 in every 10 healthy adults are carriers of this common bacteria. Most of us are exposed to it repeatedly and will carry it at some time in our lives. Carriers usually do not have any symptoms and often don't know it is there. However, Staph can sometimes spread to other people who may be more likely to become unwell, such as older adults, young children, or people with certain health conditions. In these people, it can lead to skin or wound infections. At the moment, there is no vaccine to protect against Staph.

In this study, we aim to create a safe and carefully controlled version of Staphylococcus aureus carriage, using what is known as a **Controlled Human Infection Model** (**CHIM**).

We will deliberately give a small amount of Staph into the noses of participants in a highly controlled and monitored way, this is called '**challenge**'. We will then measure whether the bacteria stay in the nose and for how long. At the beginning and end of the study, all volunteers will receive a special antibacterial wash and an antibiotic nose cream to reduce or remove any bacteria from their nose.

When we have developed the **CHIM**, we will invite more volunteers to take part in **Stage 2** of this study. In brief, Stage 2 will 'challenge' some new participants with Staph, and

then later on, 'challenge' them again to see if they get colonised the second time round. If you take part in stage one, you will not be able to take part in stage two.

By learning more about carriage: how it begins, how long it lasts, and how the amounts of bacteria change over time, we can better understand how infections develop and, importantly, how to prevent them.

We will take lots of different samples during the study to help us understand how the immune system responds to Staphylococcus aureus. This includes measuring many different parts of the immune response. Advanced computer tools, including artificial intelligence, will be used to look for patterns that would be difficult to spot otherwise. By doing this, we hope it will allow us to develop new and better vaccines in the future.

Who are we?

Researchers at **The University of Oxford** have been studying infections involving healthy volunteers for over **30** years. We have a large amount of experience in running clinical studies like this.

Study Sponsor	**The University of Oxford** The Sponsor is the organisation that takes overall responsibility for the study rgea.sponsor@admin.ox.ac.uk	https://www.ox.ac.uk/
Study Location	**Oxford Vaccine Group** Churchill Hospital, Annexe Reception, Centre for Clinical Vaccinology and Tropical Medicine, Oxford OX3 7LE The study is taking place at a number of different locations. This information sheet is for the above study location. info@ovg.ox.ac.uk	https://www.ovg.ox.ac.uk/
Principal Investigator (PI)	**Robert Shaw** The researcher responsible for the research by the team at this study location. robert.shaw@paediatrics.ox.ac.uk	https://www.ovg.ox.ac.uk/team/robert-shaw

Chief Investigator (CI)

Andrew Pollard
The lead researcher for the study who is responsible for the overall conduct of a research project at all study locations

andrew.pollard@paediatrics.ox.ac.uk

https://www.ovg.ox.ac.uk/team/sir-andrew-pollard

Why is this research study needed?

Although Staphylococcus aureus often lives harmlessly in many people's noses and on their skin, it can sometimes cause serious infections. These include **skin infections, bone and joint infections, and sepsis** (a severe life-threatening infection). Around the world, Staph infections are responsible for over one million deaths each year.

Antibiotics are currently the only treatment, but some types of Staph have become **resistant**, meaning standard antibiotics no longer work well. Researchers have been trying to develop vaccines against Staph for several decades but despite many studies, no vaccine has yet been successful in humans. One of the main challenges is that traditional research methods have not allowed us to fully understand how Staph behaves in the human nose. This study uses a Controlled Human Infection Model together with new, advanced ways of analysing immune responses to try to overcome past barriers and provide the detailed information needed to guide the development of future vaccines. This could help stop the bacteria spreading between people and protect those who are at higher risk of becoming seriously unwell.

What is a controlled human infection model?

A controlled human infection model (CHIM) is a type of research study where we expose participants to small, measured amounts of bacteria or virus. In this study, this is done by placing a very small amount of liquid containing a known type and number of bacteria into a volunteer's nose. This is called '**challenge**'. We then carefully monitor

how the body responds. Our team has extensive experience running similar studies safely.

There are many **strains** or types of Staphylococcus aureus. In this study we will work out **which strains work best** in the **challenge**. We will also work out **how many bacteria** we need to colonise people's noses, this is known as the **'dose'**.

Because the bacteria are alive, there are some risks involved. You can find more information about these risks, and how we work to keep them as low as possible, on page 15.

Your safety is our highest priority. The strains of Staph used in this study have been carefully chosen so that they can all be treated with standard tablet antibiotics if needed. We do not expect participants routinely to require tablet antibiotics as Staph is so frequently carried in people's noses without problem.

Why have I been invited?

We are looking to recruit healthy volunteers who are aged between 18 and 55 years. We use various ways to contact anyone who may be interested in this study, including via the Electoral Roll, by requesting a data extract from NHS patient databases, via text messages or emails sent from your GP surgery or using a relevant mailing list(s) or registry(s) that individuals may have independently signed up to.

In the case of NHS databases, we will only request identification of persons based on postcode and appropriate age range or basic eligibility criteria. This may be carried out by an approved third-party provider, who securely identifies individuals meeting these criteria and may contact them directly to invite them to get in touch with the research team, without sharing their personal details with us. Alternatively, a mailing provider such as CFH Docmail or an equivalent company (who have been assessed under the NHS Data Security and Protection Toolkit) may be used solely for the purpose of arranging for the invitations to be sent.

Please note that we **do not** have your contact details, unless you have been contacted using the open version of the electoral register or you have previously provided us with this information. For more information about how we approach and invite individuals to take part in our research please visit: https://www.ovg.ox.ac.uk/

Can I take part in the study?

We are looking for healthy adults aged 18 to 55 to take part in this study.

You cannot take part if you:

- Have a medical condition (e.g., asthma requiring inhalers, chronic heart, kidney, or liver disease, diabetes)
- Have a condition or take medications that weaken your immune system (the study team can provide examples)
- Live with or care for someone who has a weakened immune system, is over 65 years old, or is under 5 years old. This includes healthcare providers having direct contact with patients
- Have an allergy to some antibiotics including penicillin or beta-lactam antibiotics or to the disinfectant wash (the study team can give more information)
- Use regular nasal sprays
- Are a current smoker/vaper or gave up smoking/vaping within the last 6 months
- Are currently enrolled in another research study involving procedures that could interfere on this study (the study team is happy to discuss if needed)
- Plan international travel during the study
- Live in the same household as someone who is or was taking part in the study

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If you are unsure whether you can join the study, you can contact the study team to discuss further. The criteria are available on the online screening questionnaire and will be discussed with you at the screening visit.

What will happen in the study?

All participants will:

- be given shampoo, body wash and antibiotic nose cream to use at home, for five days before the challenge and for five days after the last visit
- receive a challenge with Staphylococcus aureus
- complete an online symptom e-diary for 7 days following challenge
- complete an online e-diary daily for up to 5 days to record decolonisation therapy
- have samples collected during in-person visits, including
    - blood tests

    - throat, groin and armpit swabs
    - nasal samples
- take nasal swabs yourself at home and store them in the freezer

The whole study lasts around 6 months. However, your in-person visits will only take place during the first 2 months. After that, we will only contact you by phone at months 2 and 6.

Study Timeline – Overview

The next page shows the study visits and key procedures at each visit. Full details of what happens at each visit are given in the following section

Screening Visit
- Blood samples and urine pregnancy test (if applicable)

Decolonisation Visit — **Day -14**
- Nasal samples, skin & throat swabs
- Supplied with hair and body wash and antibiotic nose cream for 5 days
- Electronic diary starts

Decolonisation check — **Day -4**
- Nasal samples, skin & throat swabs

Challenge Visit — **Day 0**
- Challenge
- Electronic diary starts
- Blood sample (if applicable) & Urine pregnancy test (if applicable)
- Self-sampling instructions

Follow-up 1 (if applicable) — **Day 1**
- Blood sample

Follow-up 2 — **Day 3**
- Nasal samples, skin & throat swabs, blood sample (if applicable)

Follow-up 3 — **Day 7**
- Nasal samples, skin & throat swabs, blood sample (if applicable)

Follow-up 4 — **Day 10**
- Nasal samples, skin & throat swabs

Follow-up 5 — **Day 16**
- Nasal samples, skin & throat swabs, blood sample (if applicable)

Follow-up 6 and Final Decolonisation Visit — **Day 28**

- Nasal samples, skin & throat swabs, blood sample (if applicable)
- Supplied with hair and body wash and antibiotic nose cream for 5 days

Safety Phone Call — **Day 56, Day 182**

- Return nasal sample by post on Day 56

Study stages, visits and procedures

Study visits will be at your local study location, Oxford Vaccine Group. The online screening questionnaire, electronic diaries, self-sampling collection and final telephone call can be completed at home.

Sample collection

At each visit the study team will collect some of the following samples from you to tell us about the bacteria in your nose and on your skin, and how your immune system is responding to them. The types of samples taken at each visit are listed below.

- **Throat swabs** will be taken from your throat using a small cotton swab
- **Nasal swabs** will be collected by using a small cotton swab and wipe the inside of your nose
- **Nasal washes** are collected by gently squirting saline into your nose. After a few seconds the water runs out into a sample bowl
- **Urine samples** will be taken from participants who could become pregnant, to perform a pregnancy test before the challenge
- **Blood samples** are taken to understand the immune response and ensure it is safe to participate in challenge. Approximately 60ml of blood (4 tablespoons) will be taken from a vein, usually in your arm. We may need to take more blood tests if anything needs checking
- **Skin swabs**: You will be asked to self-collect skin swabs from under your arm, and from your groin
- **Self-Sampling:** We will ask you to collect nasal swab samples on days that you are not having in person visitsfor the first 16 days and on days 22, 42 and 56 after challenge. We will provide you with a step-by-step guide (ReSET Home sampling instructions) for the collection of these samples. We will ask you to take these samples at approximately the same time each day. You won't need to take the samples on the days you are coming to the clinic. We will also provide

guidance on how to post the sample taken on day 56. **Don't worry, we will send you a text reminder for the samples!**

Study Timeline – In Detail

Pre-Screening Questionnaire (before taking part)

We will ask you to complete an Online Screening Questionnaire to check if you can take part. The questionnaire asks about your medical history and records your contact details. This registers your interest in the study. We will ask you to provide your NHS number, and consent for the study team to:

- access your medical records through your GP and other NHS databases to check your health
- record your contact details

Your contact details will be kept secure and confidential. For more information, please see "**What happens to my data**?" section on page 21

Screening visit (about 90 minutes)

At this visit you will

- have the study information presented to you again and have the opportunity to discuss the study with a member of the clinical team
- ask any questions about the study you may have
- be asked to complete a short quiz to check you understand what will happen in the study, and to make sure the study team have told you everything you need to know
- sign a consent form, if you decide to take part

We will then

- check your identity
- check your medical and vaccine history
- perform a physical examination and check your vital signs
- take blood samples
- take a urine pregnancy test (if applicable)

You will also need to provide your National Insurance Number (UK citizens) or your passport number (non-UK citizens). This lets the team register you on “The Over-volunteering Prevention System” (TOPS).

This is performed as standard practice when volunteering in a research study and acts as a safety measure to prevent volunteers taking part in more than one study at a time that when combined, may negatively impact their health due to drug interactions or having to provide multiple blood samples.

We will give you a short information sheet to give to any people you share a house with. This will tell them a little about the study, and they will have contact details to discuss any concerns with the study team.

Once all the test results are available following this visit, the research doctors will confirm if you are eligible to take part in the study.

Decolonisation visit (between 30 minutes and 1 hour)

Because some people naturally carry Staph in their nose and/or on their skin, we will ask you to use an antiseptic hair and body wash and an antibiotic nose cream, to reduce any Staph you may have on your skin and/or in your nose. This will be for 5 days, a little before the challenge. We will give you these to use at home. This helps make sure everyone starts from the same baseline, which makes the study results more accurate.

Before starting the decolonisation treatment, we will:

- Ask you about any recent illnesses or important medical events.
- Collect the required samples
- Make sure you have all the study contact details, including a 24-hour number for the study doctor.
- Check that there are no temporary reasons you should delay starting the decolonisation treatment.
- Give you the decolonisation medicines and instructions.

About the decolonisation treatment:

- You will use a nasal ointment three times a day
- You will use a body and hair wash once a day
- The treatment will last for 5 days in total
- You will record each time you use the products in an electronic diary (e-diary)

Decolonisation Check (30 mins)

This will be a short visit after you have completed your decolonisation treatment to collect baseline samples before challenge

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Challenge Visit - Day 0 (about 2 hours)

- You will be asked about any changes in health since your last visit, check your vital signs and collect blood samples.
- Take a urine pregnancy test (if applicable).
- Take blood sample (if applicable)

We will ask you to lie relatively flat and then put a small amount of liquid containing the bacteria into your nose using a pipette. This procedure does not cause any discomfort, but it might tickle your nose and make your eyes water. You might feel some liquid trickle down the back of your throat. You will be observed for 15 minutes to watch for any reaction.

We will provide you with a safety pack to keep with you throughout the study, which includes:

- Thermometer to check your temperature at home
- Instruction leaflets
- Study contact card (with the information for you to contact one of the study doctors if you are concerned)
- ReSET Home sampling instructions and the swabs and equipment for you to self-sample

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Electronic Symptom Diary – For **7 days** after the challenge visit

At the challenge visit you will be given access to an online diary.

The diary records specific symptoms like headache, feeling tired, sneezing, sore throat or runny nose. For 7 days we will ask you to record your temperature and any symptoms and illnesses you experience, even if you think they are not related.

We ask for the diary to be completed every day (ideally before 8pm). It is important, as it helps to make sure you are well and to keep you safe. The study team will explain to you how to complete the e-diary and you can contact the team if you have issues completing it. If for any reason you do not complete the online diary, the study team may contact you by phone or email to check that you are feeling well, and to remind you to complete the diary.

We will also provide a paper back-up diary and tell you when and how to use it.

Self-sampling (maximum 5 minutes per day)

For 16 days after challenge, every day when you are not being seen in the clinic, and on days 22, 42 and 56 after challenge, we ask you to collect a simple swab from your nose.

- Specific details will be provided in the ReSET Home sampling instructions
- These will need to be stored in your freezer in a small plastic bag/container which we will give to you. We will also give you a box and some ice packs to bring the frozen samples to clinic
- Bring the frozen samples with you to the next clinic visit
- We will give you the container back, ready for the next time
- The last day of the study, is day 56. We will give you some packaging to send the last samples back to us. You will not need to pay for this and it will be simple for you to post

We will send you an SMS text to remind you that you need to collect a sample

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Follow-up visits – Days 1, 3, 7, 10, 16 and 28 (about 1 hour each)

After challenge you will attend the study location for short follow-up visits

At these visits we will

- Ask you about any symptoms or illnesses that you have had
- Review your electronic symptom diary (until 7 days after the challenge is given)
- Take blood (if applicable), throat swabs and nasal samples

At the Day 28 visit, we will also:

- Give you a box(es) to post your nasal samples. You will collect these sample(s) at Day 42 and 56 and return them to us by post
- Give you the final **decolonisation** treatment. This will be exactly as the same as you were given at the start of the study

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Safety Phone Call - Day 56, Day 182

A short phone 5–10-minute phone call to ask you about any symptoms or illnesses that you have had. At the Day 56 phone call we will also ask you to self-collect your nasal sample and to post it to us.

The study ends for you after the last phone call. You can still contact the study team after the end of the study if you have any questions or concerns.

If you cannot attend a scheduled visit, please contact the study team as soon as possible. We will help you reschedule.

Are there any risks in taking part in this research?

Risks related to the challenge

The natural carriage of Staphylococcus aureus (in the nose) is very common in the general population. Many people carry the bacteria without having any symptoms, and in most cases, it causes no problems at all.

Mild infections (such as small skin spots or pimples, small boils, or minor irritated hair follicles) are far more common than serious infections. More severe infections (such as bloodstream infections, joint infections, or pneumonia) are uncommon and tend to occur mainly in vulnerable individuals, for example very young children, older adults, or people with certain long-term medical conditions or weakened immune systems.

Because the bacteria we use are alive, there is a small risk of developing an infection yourself or potentially passing the bacteria on to close contacts. For this reason, you must be healthy to take part in the study and should not be in close contact with more vulnerable individuals for the period advised by the study team.

Because this is a new challenge model, we do not know exactly what symptoms you might have. However, there have been many challenge studies with other bacteria. Based on this we are not expecting you to have any severe symptoms. You may experience the following minor symptoms:

- headaches
- sneezing
- a sore throat
- blocked or running nose

- fever and chills
- general discomfort (malaise)
- headache
- tiredness (fatigue)
- itchy or painful nose
- redness around the nostrils

These symptoms are usually mild but if they feel worse than that, you can take simple medicines like paracetamol or ibuprofen. In rare cases, this bacteria can cause more serious infection including infection of the skin, joints, bone, blood or heart valves. We do not expect this to happen in this study.

We will monitor the symptoms as well as the samples we collect from you and given treatment early if there is any concern.

At the end of the study, we will prescribe another decolonisation course to reduce the amount of the bacteria that we have challenged you with. We do not check to see if the bacteria has definitely gone. The bacteria used in this study are ones that are normally found in people in the community and that you would be likely to encounter as part of your everyday life. People often come into contact with Staph in daily life. They may carry these bacteria for a while without becoming ill, and the bacteria often disappear on their own without any decolonisation treatment or antibiotics. Over time, one type of Staph is commonly replaced by another. We do not expect anyone to be at increased risk of infection following on from this study.

The study team will advise you on the best action to take and if you need to take antibiotics, we will give you the medicine and some instructions to follow. Sometimes symptoms can be caused by a viral infection (like a cold) or for other reasons.

A **24-hour on-call emergency telephone number** will be given to you. You can call this number at any time if you have questions or worries during the study.

Other potential risks from taking part in this study

- **Blood sampling** may cause slight pain and sometimes bruising. Occasionally, people feel light-headed, nauseous (feeling sick), or faint. The amount of blood taken at each visit is small and should not cause any problems to healthy adults.

- **Nasal sampling** may be uncomfortable and there is a small risk of a minor nose bleed.
- **Decolonisation** uses an antibiotic ointment for the nose and antiseptic hair and body wash, and will be given to all participants. There is a small risk (less than 1 in 10) of mild and short lived irritation in the nose or face, including itching, redness, soreness or a burning sensation. Uncommonly (less than 1 in 100) some people can develop a mild allergic reaction resulting in skin redness or soreness. Very rarely, a severe allergic reaction may occur (less than one in every ten thousand).
- **Antibiotics**: Because the bacteria are often carried without causing any problems, we will only treat someone with tablet antibiotics if it is really needed. There are common side effects from tablet antibiotics, such as upset stomach, feeling sick (nausea), or rashes. We will discuss the potential side effects of the specific antibiotic with you, should you need that antibiotic.

What if we find something unexpected?

As we carry out several medical tests during the study, it is possible that we discover previously unknown health issues (e.g., high blood pressure, abnormal blood results).

If abnormal results or previously undiagnosed conditions are found during the study, these would be discussed with you and, if you agreed, your GP would also be informed of these results. The study team may document the findings on your electronic health records. Sometimes findings might require your GP to carry out further investigations such as blood tests, scans or referral to specialists.

During the screening process, we will test your blood for **HIV, hepatitis B and hepatitis C**. In the UK, healthcare professionals have to report any new suspected cases of hepatitis B and hepatitis C to the UK Health Security Agency (UKHSA) by law. If you are found to have hepatitis B or C, we have to send a report to the UKHSA, including your personal contact information. It's important to understand that **you cannot opt out** of this due to UK reporting requirements.

Household contacts

Because this study involves giving small amounts of bacteria, we also think carefully about the health of people who live with you (your “household contacts”).

We do not routinely screen or test everyone in your household. Instead, we:

- Give your household contacts written information about the study and how it may affect them
- Advise them to contact the study team if they have any concerns about possible infection related to your taking part

If a household contact contacts us with concerns, a study doctor will:

1. Discuss symptoms by phone.
2. Offer an in-person review if there is a concern about a possible skin infection (for example, a **new painful, red, or oozing area on the skin**).
3. With their consent, take swabs from:
    - Any obvious skin lesion, and
    - The inside of the nose

The study team will not discuss any specific further aspect of your involvement in the study with your household contact.

The study team will not prescribe treatment for household contacts or provide results from any swabs taken. If the household contact is under 16 years of age, the study team will not offer an in-person review or collect a sample.

With their consent, we would collect a swab sample from them and also collect some basic information including degree of closeness to you, what they were worried about and the site of any swab taken.

If an infection which requires treatment is suspected, we will advise them to contact their GP or usual healthcare provider for assessment and treatment. In some circunstances, with their permission, we may inform their GP or healthcare provider that they have been exposed or in contact with Staphylococcus aureus. We will not share any information about you.

Any samples taken from household contacts are used to help us understand whether transmission of the study strain has occurred. Samples like these are not taken routinely in the NHS and results from these samples will not be used to guide their clinical care, which remains the responsibility of their GP or usual healthcare provider.

Are there any benefits from taking part?

There is **no direct benefit** to you of taking part in this study, but you will be helping us to develop a controlled human infection model that will

- help us to better understand how our body responds to bacteria
- potentially help us to develop vaccines and new treatments to reduce the amount of people affected by Staphylococcus aureus diseases

No specific additional medical care will be provided through participation. Medical procedures are performed with the aim of making sure you can take part safely and stay safe during the trial.

What else do I need to consider?

Pregnancy test

All participants who could become pregnant will have to take a pregnancy test at screening and before challenge. You will need to take the pregnancy tests, regardless if you are using any method of contraception.

Contraception

We require participants who could become pregnant to use contraception for at least one month before they receive the challenge, and then for the entire duration of the study. No contraceptive precautions are required for male participants.

Unless you are post-menopausal or have had a permanent sterilisation procedure, you will be required to use one of the contraception methods listed below.

Acceptable effective contraception methods include:

- Oral, injected or implanted hormonal contraceptives (“the pill”, “the depot”)
- Intrauterine device (IUD) or intrauterine system (IUS) (“the coil”)
- Condoms or occlusive cap with spermicide
- You have only one sexual partner, and that partner has had a vasectomy
- Complete abstinence from sexual intercourse which could result in pregnancy (Note - This must be normal for you. Telling us you will not have sex during the study will not be sufficient)

Pregnancy

If you were to become pregnant during the study, you should tell us immediately.

Study procedures such as decolonisation and challenge will be suspended if you find out you are pregnant before them. If you find out you are pregnant after challenge, we will need to assess the need for antibiotic treatment and will discuss it with you.

Other vaccinations

If you require any vaccinations for health, travel, or work **during the study**, you should inform the study team before you have the vaccine.

We ask you not to have any live vaccines in the 28 days before having the challenge.

Identification

We will ask you to bring a form of **photographic ID** and your **National Insurance number** (if you are a UK citizen) or your passport number (if not a UK citizen) to your screening visit. This will be checked at each visit by authorised members of the study team and a copy will be kept securely.

Medications

If you begin taking any new medications, including antibiotics, during the study, please inform the study team. This includes prescribed medicines or those bought “over the counter” without a prescription.

Blood donation

Under current UK regulations, participants must not donate blood during their involvement in the study. You will be able to restart blood donation after you have completed the study, but you should inform the Blood Service that you took part in this study.

Taking part in other clinical studies

You should not take part in other clinical studies where drugs or vaccines are administered or where repeated blood samples are taken while in this study.

What if I change my mind?

If you decide to take part and then change your mind, you can tell the study team at any time and withdraw from the study. This would not result in any penalty or change to your medical care. We would use the samples and data we have collected from you in our analysis of the study up until the point you informed us that you wanted to withdraw, unless you specifically request that the samples be destroyed before being analysed.

In exceptional circumstances (for example, if you were to become very unwell during the study), your participation in the study may be stopped early by the study team or the sponsor of the trial. If this occurs, we may ask you to still attend safety follow-up visits and/or access your medical records with your consent.

Will I be reimbursed for taking part?

Study participants will be reimbursed for their time, travel, and the inconvenience of taking part in the study. The maximum reimbursement for any volunteer who completes all visits is up to **£1300.** All participants will be reimbursed based on the following amounts:

Visit	Visit Type	Reimbursement
Screening	Screening	£110
Day -14	Decolonisation Visit	£90
Day -1	Decolonisation Check	£90
Day 0	Challenge Visit	£110
Days 1, 3, 7, 10, 16, 28	Follow-up	£90 per visit
Day 56, 182	Safety Phone Call	£5 per answered call
	Each Decolonisation (including diary)	£90
	Completion of all Home Sampling	£80

	Full completion of post-challenge diary	£30
	Day off work (if travel to challenge site required)	£150

You may also receive reimbursement for any **unscheduled** (extra) visits you are asked to attend by the study team. You would be reimbursed £90 per unscheduled visit.

We will also offer a £10 payment to study participants who have enrolled and then refer a friend who also takes part in the study.

The amount of money reimbursed is on a "pro-rata" basis. This means that you are only paid for the parts of the study that you complete. If for example, you choose to withdraw halfway through the study, or do not complete all study procedures, we would work out your reimbursement based on the visits that you did attend and samples that have been taken from you. The reimbursement will be provided at different times during the study.

We will not pay tax or National Insurance from the money due to you. It is your responsibility to pay these and to check how any compensation received from taking part in the study affects any state benefits to which you are entitled. Contact HM Revenue & Customs for information (http://www.hmrc.gov.uk/ or telephone 0300 200 3300).

Payments are made directly by bank transfer from the Oxford Vaccine Group to you. For this reason, we require participants to provide their bank details at the screening visit. Bank details are kept confidential. More information about how we handle your financial data can be found at section below "What happens to my data?".

What will happen to the samples I give?

- Most study samples will be analysed in **University of Oxford** and **NHS** laboratories.
- Some samples may be sent to other academic or commercial research partners in and outside the UK to support some sample analysis.
- Samples taken will be used to look at your **immune responses** to the Staphylococcus aureus bacteria.

- Some blood samples and nasal cells will be used to look at the **pattern of genes** being actively used by your body in response to staphylococcal carriage. Your body's response to infection is in part genetically controlled, so knowing the pattern of genes that are being used may help us to understand how individuals respond to staphylococcal carriage.
- **Clinical safety blood samples** are sent to local NHS laboratories and follow local sample labelling requirements (which may include personal identifiers). As part of processing clinical safety blood samples, local NHS laboratories may be required to **add the results to your electronic medical records**. If any other findings that are clinically important are found during the study, one of the study team may also record this to your electronic health records.
- Samples sent to research laboratories for processing will **not** have **personal identifiers** (they will be identified by a study number and participant number only). However, your **DNA** is unique to you so it can never be completely anonymous.
- If you choose to take part in this study, you will be asked if you agree for any remaining samples to be stored and **used in future research**. You will not be asked to donate any extra samples or undergo any extra procedures. You do not have to say yes to the storage of samples for future research and can still continue to take part in this study. All samples will be stored with a code, instead of information that would identify you directly. If you do not agree to the storage for future research, any remaining samples will be destroyed at the end of the study.

What happens to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor, Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you/from your medical records/your GP and/or hospital records for this research project. We will share your information related to this research project with the following types of organisations:

- **Local NHS Laboratories** as part of the processing the clinical safety blood samples. This information may include your name, NHS number, initials, DOB.

- **United Kingdom Health Security Agency (UKHSA)** (please see page 18). This information will include your name, NHS number, DOB, contact information.
- **Third-party service providers** to carry out activities specifically for the purpose of this research study and as explained in this information sheet, for example text messaging service providers/companies to send study-related text messages to you. This information will be limited to what is necessary for the purpose.
- Other researchers and collaborators including the study funder for the purpose of analysis of research samples but only de-identified data will be shared.

  We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

This information will include your initials, NHS number, name, and home address/contact details, including either home address or phone number or email address.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

Responsible members of the University of Oxford, regulatory authorities and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

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 by the following methods:

- Data will be collected and held by the Oxford Vaccine Group. It will be accessible to essential personnel only at the Oxford Vaccine Group, and responsible staff from the University of Oxford who may monitor/audit the data collection process.
- The University of Oxford Data Management and IT Team will be able to view your email address, which is necessary for the e-diaries to function.
- Any data held by the University of Oxford will be stored on secure servers

- Paper-based data will be stored in locked cabinets/storage with access restricted to authorised personnel

International Transfers

We may share data about you outside the UK for research related purposes to be analysed by collaborating research groups.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Approved academic or commercial research partners.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details see: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules https://ico.org.uk/for-organisations/report-a-breach.

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.

After the study ends, the retention period (this means the length of time we keep your data for) will begin and we will keep your data for a minimum of 25 years in line with the University Policy on Management of Data. Once the retention period has finished, the study data will be kept in a way that does not identify you.

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.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would ask if you are happy for us to continue collecting information about your health from central NHS records / your hospital / your GP for safety reasons. If you do not want this to happen, tell us and we will stop.

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.

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK by:

- asking one of the research team info@ovg.ox.ac.uk
- sending an email to the research team info@ovg.ox.ac.uk
- calling us on 01865 611400
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk

- looking at the University's privacy notice available at: https://compliance.admin.ox.ac.uk/research-data.

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at:

http://www.hra.nhs.uk/patientdataandresearch

The Oxford Vaccine Group will use your details, e.g., name, NHS number, home address, and contact details, to contact you about the research study, and to oversee the quality of the study. Your bank details will be stored in accordance with local policies.

- They will keep any other identifiable information about you from this study for up to 25 years after the end of the study, or as per national regulatory requirements after the study has finished.

Further information about your rights with respect to your personal data is available on the University of Oxford website at:

https://compliance.web.ox.ac.uk/individual-rights

Sharing of Data with Ellison Institute of Technology

As part of this study, the University of Oxford will share relevant research data with the Ellison Institute of Technology, Oxford. The legal basis for this is that the research is being carried out in the public interest. The Ellison Institute of Technology Oxford will be an independent data controller for these data.

In partnership with the University of Oxford, EIT will use advanced computer tools, including artificial intelligence and machine learning, to help us look for patterns in the data that would be difficult to detect otherwise. The data they receive will not include your name, contact details, NHS number or other direct identifiers. The data will be labelled only with a code.

You can find out more about how EIT use your information by looking at EIT's privacy notice available at

https://eit.org/privacy-policy

Additional Information

- The study is **sponsored** and organised by the University of Oxford.
- The study is **funded** by the Ellison Institute of Technology.
- **Private insurance**: If you have private medical or travel insurance, participation in a study will not usually affect your cover if conditions are unrelated to the study, but to be certain you must tell your provider before you take part.
- **Confidentiality**: Information collected during the study will be treated confidentially. We will ask for your consent to access your medical records to check your health before enrolling you in the study. We will inform your GP that

you are enrolled in the study and provide information so that your medical records can be updated.

- **Conflict of Interest:** Two of the lead scientists, Prof Daniela Ferreira and Dr Malick Gibani, hold part-time roles at the Ellison Institute of Technology, which is funding this study. However, their work on this study is carried out entirely through their roles at the University of Oxford, and their part-time employment elsewhere does not influence the study design, conduct, or outcomes. All potential conflicts of interest are managed according to University of Oxford policies to ensure the research remains independent and unbiased.
- **TOPS database**: Volunteers participating in this study must not be enrolled in another study that involves investigational medicines or vaccines at the same time. The Over-Volunteering Prevention System (TOPS) is a national database which helps prevent volunteers from taking part in too many clinical studies. To check this, we will need your passport number (for all non-UK citizens) or National Insurance number (UK citizens). We will update the database when you receive the challenge and at the end of your last visit in which there was a large collection of blood above 50 mL, the 2-month visit. The data is retained in TOPS for 2 years.
- **Patient and Public Involvement:** Members of the Oxford Vaccine Centre Patient and Public Involvement and Engagement Group were involved in the developing of the participant materials and will continue to be involved in the study.
- **New Information**: Sometimes during a study new information becomes available that is important to let you know about. This may mean signing a new consent form. We will review new information or safety concerns and you would be kept fully updated.
- **Harm**: The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment provided.

- We will provide compensation for any injury caused by taking part in this study. We will pay compensation where the injury probably resulted from:
    - A drug administered as part of the study protocol.
    - Any test or procedure you received as part of the study.

  Any payment would be without legal commitment (please ask if you wish for more information on this). We would not be bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the study protocol or where the protocol wasn't followed.

- **Complaints statement**: If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact the Chief Investigator at info@ovg.ox.ac.uk or 01865 611400 or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk
- **Results of this research**: The results will be published in a scientific medical journal and may be presented at scientific conferences or meetings. You will be provided with a summary of the results by email and access to the full publication. Information will also be available on the OVG (Oxford Vaccine Group) website This can take up to 2 years after the study is completed. **Your individual results would not be identifiable, and you would not be identified in any report or publication (de-identified).** The research data will be shared with collaborators who are organising or funding the research. Data from this study may be used to file patents or licence vaccines in the future or make profits in other ways. You would not be paid for any part of this. Data from this study may be used as part of a student post-graduate degree, for example an MD or PhD.
- **Review**: All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by South Central - Berkshire Research Ethics Committee. The Oxford Vaccine Centre Patient Public Involvement group have reviewed the main participant-facing documents associated with this study (Participant Information Sheet and advertising materials).

- **Future research studies**: If you choose to take part in this study, you will be asked if you agree to be contacted about other ethically approved research studies in the future, for which you may be suitable.
    - All contact will come from the Oxford Vaccine Group research team of this study in the first instance

- Agreeing to be contacted does not oblige you to take part in future research
- You can be removed from this register at any time you wish

Register for the study or discuss with the team

We hope this information sheet has given you enough information to decide whether to volunteer for this study.

If you would like further information about participating in research, please visit the following NHS website:

www.nhs.uk/tests-and-treatments/clinical-trials/

For independent advice about participating in this study, you may wish to contact your GP or other healthcare professional.

If you are interested in taking part in this study, then please complete the pre-screening questionnaire at:

https://www.ovg.ox.ac.uk/studies/reset

If you decide not to take part it would be really helpful to understand why. You will not have to give us any personal information. We hope that we can use the feedback to improve or change things about our studies in the future.

https://ovg.to/feedback/reset

If you have further questions about the study, please contact us at:

Email: info@ovg.ox.ac.uk

Tel: 01865 611400