



Information Sheet for CARRIAGE Study Participants

Version 4.1
27/01/2020

What are the purposes of the research?

The aim of this research is to investigate why some people carry the bacterium *Staphylococcus aureus* (*S. aureus*) in their nose while others never do. The research will provide a better understanding of the biological, genetic and environmental determinants of *S. aureus* carriage.

Why is the research important?

S. aureus is a common bacterium with about one person in every three carrying it in their nose, or elsewhere on the skin. Some people carry it all the time, some only now and then, and others never carry it. Currently, we can't explain why. For most people, carriage of *S. aureus* is harmless. However, a small number of people are susceptible to *S. aureus* infections due to a weakened immune system and, in some cases, these infections may be serious and resistant to antibiotic treatment. Understanding why only some people are carriers while others aren't will help design new ways to prevent and treat such infections.

How will the research be carried out?

We propose to conduct a large study of ~20,000 blood donors to understand what determines the carriage of *S. aureus* in humans. We will ask participants to take nasal swabs, which will be returned by freepost and to fill in online questionnaires. We see INTERVAL and COMPARE participants, who are willing to take part, as an ideal group for this research because we have already collected some essential data from them (e.g. blood sample measurements, genetic results, lifestyle factors, health records, etc.). Also there is some evidence that *S. aureus* carriage could be linked to the body's iron levels.

Why I have I been contacted about this?

We are aiming to recruit approximately 20,000 blood donors to take part in the study. We are inviting blood donors, like you, who have taken part in INTERVAL or COMPARE and for whom there is data available on biological, genetic, health, and environmental factors, because we suspect such factors may be important in determining *S. aureus* carriage.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you do decide to take part, you will be asked to complete a brief online screening questionnaire and consent form. You are free to withdraw at any time and without giving a reason.

Am I eligible to take part?

You are eligible to take part if you:

- Have an email address and internet access for study participation
- Reside in mainland England

- Have a good understanding of the English language, both written and oral (as study materials are not tailored to support non-English language speakers).

You are not eligible to take part if you:

- Have any abnormalities or on-going medical conditions that affect the nose (e.g. recurrent nosebleeds, nasal polyps, rhinitis, etc.)
- Have undergone nasal surgery or suffered a broken nose in the last year
- Are not going to be available to take part in the study during the next two months.

What will happen to me if I agree to take part?

You will be asked to provide your contact details so a researcher is able to post a CARRIAGE study 'participant pack' to you. Before sending this we will ask you to complete a short (no more than 10 minute) online questionnaire which will ask for health and lifestyle information about you, your family and the people who live in your household. Once you have completed this you will receive your 'participant pack' which will contain:

- Three nasal swabs and sample tubes (containing a liquid preservative)
- Pre-prepared barcode stickers each with a unique anonymous study identification number, one for each tube
- Step-by-step instructions (including a video-link) to show you how to take your swabs
- Postage-paid FREEPOST envelopes to return your nasal swabs.

Once you have returned your swabs, we will ask you to complete a further short (5-minute) questionnaire asking for feedback on your experiences of taking part in the study.

Periodically, and only when necessary, we will send you email and text reminders to take swabs and to fill out questionnaires.

We will access data about you held as part of the INTERVAL or COMPARE studies, including information obtained from your health, blood donor and other health related records. We may also need to request additional information from your health and health related records from the organisations responsible for these, such as NHS Digital, Public Health England and others to understand your medical history and current health and to track this over time.

These records include medical tests and their results, diagnoses, treatments and visits to your GP or to hospital, as well as other relevant information. For example, we plan to request results of microbiology tests held by Public Health England to study any links between carriage of *S. aureus* and serious infections. To access these records we will securely send your NHS number and other personal details to the relevant organisation to allow them to identify you and provide the requested information.

How is data kept confidential?

The following steps will be taken to ensure the confidentiality of your samples and data during the CARRIAGE Study:

- Your samples and data will not include any person identifiable details. Therefore, researchers working with your samples and data will never know your identity. Your data are stored using a unique, anonymous study identification number.
- In order to retrieve relevant health information we will use your NHS number. A single table linking your anonymous study identification number to your NHS number is stored on a separate password-protected location, which may be accessed only by the study data manager.

- The link table is used to retrieve only relevant health information from your medical and other health-related records. The retrieved information is -'de-personalised', meaning any details that directly identify you – such as your name or address – are removed before it is added to the study database..
- All study data is stored in a restricted-access, study database on secure computers at the University of Cambridge. The study data is linked to your study identification number, but your personal details (surname, first name, address) never appear in this database. Access to the study database is password-protected and used only by named researchers working on this study under the direct supervision of the senior scientific investigators
- Your personal details provided during the study will be stored in a secure location, separately from the study database and used for the purpose of study communication and retrieval of your NHS number.

What information will be stored on the research database?

Information that will be stored on the database will be anonymised and will include:

- Data from the online questionnaires (described above).
- Relevant data collected during your participation in the INTERVAL or COMPARE study including email address and results from blood samples (including genetic information)
- Results from all laboratory measurements using your nasal samples
- Information on health outcomes collected from routine medical and other health-related records at the time of joining the study and from time to time thereafter.

Your - de-personalised data will be used by the study investigators to look at characteristics that influence nasal carriage of *S. aureus*. Stored anonymised data will be used for future medical and health-related studies, which have relevant scientific and ethics approval.

What will happen to my nasal swabs?

They will not be labeled with your name or contact details, but only with a unique study number. Once returned to the processing laboratory we will try to grow *S. aureus* from them. We will also extract bacterial DNA from the swab material so we can identify other bacterial species. A small amount of the nasal swab material will be stored in the freezer for future health-related research purposes.

Who will have access to my information?

Your samples and all the information collected about you during the course of this study will be kept strictly confidential. Any information you have provided will be de-personalised , therefore researchers working with your data will never know your identity. Your de-personalised information and samples are available only to researchers who have relevant scientific and ethics approvals for their planned research. This could include researchers who are working in other countries and in commercial companies who are looking for new treatments or laboratory tests. Insurance companies and employers will not be given any individual's information, samples or test results, and we will not allow access to the police, security services, relatives or lawyers, unless forced to do so by the courts. All data will be stored securely by the CARRIAGE research team and will be encrypted where necessary.

Cambridge University is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after

your information and using it properly. Cambridge University will keep identifiable information about you for 5years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <https://www.information-compliance.admin.cam.ac.uk/data-protection/research-participant-data>

What will happen to the study results?

The findings from this study will be written up for publication in scientific journals and presentation to other researchers. You will not be identified personally in any report or publication. In due course we will also provide details of the findings of the study on the CARRIAGE website.

Will the research benefit me?

We will not provide feedback on your *S. aureus* carriage status as, at present, this information has no actionable clinical implications for you. We will not provide any new information or advice based on the samples or data you provide which means participating will have no direct benefit to you. However, it is an opportunity to help research, which addresses an important public health issue. We do not pay participants for taking part.

What are the possible disadvantages and risks of taking part?

There are no known disadvantages or health risks associated with this research.

Can I withdraw from the study?

You can choose to withdraw from the study any time.

Who is undertaking this research?

The University of Cambridge is running the CARRIAGE study.

Who has reviewed the study?

The research has been reviewed by an independent group of people, called a Research Ethics Committee, which is there to protect your safety, rights, wellbeing and dignity. This project has been reviewed and was given a favourable review by the North West – Lancaster Research Ethics Committee.

What if there is a problem?

If you have any reason to complain about any aspect of the way you have been approached or treated during the course of this study, please contact the Helpdesk on **0800 064 0089** or email helpdesk@carriagestudy.org.uk

What should I do next?

If you are interested in taking part, please click the link in your invitation email which will take you onto the next stage of enrolment.

Contact for further information

If you have any questions then you can contact: **The CARRIAGE helpdesk on Freephone 0800 064 0089 or email us at: helpdesk@carriagestudy.org.uk**

Thank you for considering taking part in our study and for taking the time to read this information leaflet