



(add local hospital logo)

Participant Information sheet

Title of project: Stratification of Clinically Vulnerable People for COVID-19 Risk Using Antibody Testing (STRAVINSKY)

Sponsor: University of Birmingham

Why have I been invited?

We are writing to invite you to take part in the STRAVINSKY study. This study is for people who either have a medical condition which may increase their risk of developing a serious COVID-19 infection, or a condition which affects their ability to produce a strong antibody response to COVID-19 vaccines. Because of this, we would like to investigate whether antibody levels predict risk of COVID-19 infection. We plan to recruit patients with different conditions to see if protection differs in each and why.

What is this study about?

Although the COVID-19 vaccination program has proven very successful for most people, clinically vulnerable patients remain at a higher risk of COVID-19 despite vaccination. We have previously identified patients who have had little immune responses to COVID-19 vaccines, and those at highest risk of severe COVID-19. There is some evidence that the antibody response to vaccination is a critical factor in COVID-19 outcomes but it is not clear whether this is true in all clinically vulnerable groups and there appears to be a lot of variation between individuals even those with the same condition. It maybe that other parts of the immune system or specific underlying health conditions or particular medicines or individual features such as age are as important as antibodies and this study will investigate which factor or combination of factors predicts an individual's risk.

What will happen to me if I take part?

Before you decide, we will ask you to read all of the information in this patient information sheet and sign the consent form. It will take you approximately 20 minutes to read the patient information sheet and provide consent. The consent form for this study will be online and you can access this via a link that will be issued to you by email when you have indicated to the study team that you would like to take part. Should you want a paper consent form, please ask your local study team who's details are towards the end of this information sheet and they will post this to you.

If you decide to take part in the study, there are two pathways you can choose from and the choice is entirely yours. You can either:

- 1) Attend 4 appointments face to face with your local clinical team at the hospital. If you choose to attend face to face appointments, you will have the option to either sign the online consent form or be consented at your first appointment with your local study team.

If you wish to do this, you will be asked on each occasion to provide:

- Blood samples - approximately 60mls of blood (around 4 tablespoons) will be taken from your vein. We will undertake a COVID antibody test on this sample.
- Saliva test- this will require you to drool into a vial for up to 4 minutes.



- Nasal secretion test - synthetic absorptive matrices (Nasal swab) will be inserted in nostrils for 60 seconds to collect fluid.

The above procedures will be performed each time you attend an appointment which will be a minimum of 4 visits. On the first visit you will be asked about your medical and treatment history, whether you have suffered from COVID-19 and your vaccination history. For the further visits, you will also be asked about any COVID-19 infections or vaccinations and whether your medical conditions or treatments have changed.

Before considering this route of participation, please ensure you are comfortable and able to attend these appointments. Travel expenses for these visits will be reimbursed

- 2) Or, you can join the study remotely. You will be able to sign the consent form online. The central study team will then send you a home sampling kit, called a dried blood spot, this allows you to prick your own finger and collect spots of blood. This will be issued to your home address to complete without attending any hospital visits. You will return this dried blood spot to the central study team and COVID antibodies will be measured from this by a laboratory test.

A dried blood spot sampling kit, return packaging and instructions of how to use and return this kit, will then be issued to your home address. You will have access to a video of how to complete the dried blood spot kit enclosed with your instructions. You will also be sent a link so you are able to tell us when you have returned the dried blood spot kit. This will enable us to know when we might receive your completed kit and if we should send you another one should it get lost in the post. Completing the dried blood spot kit will take approximately 30 minutes to collect the blood spots, allow your sample to dry and complete the return packaging. Details of how to do all of this, will be in your instruction pack

Should you at any point feel you are having any problems completing your dried blood spot kit or you do not feel comfortable doing this alone, please contact your local study team and they will arrange an appointment for you and take this sample face to face.

For both pathways, after consenting to take part in the study, you will be asked to provide your contact details (full address, contact number, NHS number if you know it, and GP information) to allow us to contact you and check your medical and vaccination details. If you are using the online consent form, after you have signed, it will take you to another page to provide these details. However, if you choose to be consented face to face at an appointment, the study team will ask you for this information. This will take approximately 5 minutes to complete

Once you have consented and provided your contact details, a member of your study team will call you and take your medical history details over the phone. This phone call will take approximately 30 minutes. If you choose face to face appointments, you will have the option to provide your medical history details at this appointment.

At the beginning of the study, we will ask you to call the central study team should you at any point during the study, test positive for COVID-19. You will then be sent a COVID-19 swab test kit, return packaging and details of how to complete this test kit. We will ask you use this when you test positive for COVID-19, please complete the swab kit using the instructions and return it to us. Again, you will be asked to provide the date you have returned the sample using your online link and the date you have tested positive for COVID-19. We will send you a swab test every 2 weeks until you test negative on two occasions. We are doing this because some clinically vulnerable patients carry the virus for a longer time than individuals with a healthy immune system. We will genetically type the virus to see if it changes when someone is infected.

You also have the option to call the central study team to inform them that you have tested positive for COVID-19. They will then take your details and send you a swab testing kit in the post. We may ask you to complete swab and dried blood spot tests again should your kits be returned with not enough sample to process.



During the study, you will be asked three times to fill in a questionnaire to understand whether your medical conditions or medications have changed and to check that you haven't suffered a COVID-19 infection. If nothing has changed, you will not need to do anything further, if they have changed significantly, you will be called by a member of the study team to ask you about these changes.

Throughout the study, you will be kept in contact with the study team about how the study is progressing, to see if you are happy with your ongoing participation in the study and to offer any support you need with the study. You will be contacted with your antibody test results, and to get information on any new vaccinations you may have had. You will be asked to provide the dates of your vaccinations and types of vaccinations. Should you not remember dates and types of your vaccinations, we will be asking for your consent to use your NHS number to access the National Immunisation Vaccination System (NIVS system). This will allow us to access your vaccination information to use in this study.

How long will I be followed up for?

We would ask to follow you up for the duration of the study to monitor you after any potential COVID-19 infection or vaccine. The study is currently scheduled to complete in spring 2025 but we would ask that we can contact you to continue in the study should it be extended.

We will be asking for your consent to use your NHS/CHI number on the NHS digital system. This will allow us to collect long-term follow up data relevant to the study.

We will issue you with an electronic link at the start of the study to be able to conveniently and quickly report any COVID-19 infection. If you can no longer find this link, please contact the central study team. We would also like to be able to contact you for further appointments if we learn more about the immune response or vaccination over the duration of the study.

What results will I receive as part of the STRAVINSKY study?

You will receive your STRAVINSKY blood antibody test results and any COVID-19 swab test results by text message through the our 3rd party distributor FIRETEXT within a few days of you returning your them in the post. If you do not have a mobile phone number, your results will be sent directly to your home address via letter; You will be provided with helpful and easy to understand links to explain your results in detail.

Will I receive any other results from this study?

An overall summary of the study results will be made available to all participants via the British Society of Immunology and associated patient groups when the study has completed.

What personal information do we need for the study?

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it and for future research if you have agreed to this. We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.



How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your:

- Your contact details (email, phone number and address) and your age, ethnicity, gender.
- Your GP contact details – this is to collect further clinical follow up data via your medical records.
- Your NHS/CHI number – this will be used to access NHS-digital or National Immunisation and vaccination System to enable accurate collection of your NHS data and enable longer term follow-up with your consent. If you don't know your NHS number, you can give us permission to find this on your behalf.
- Your medical history and medication records.

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

What are your choices about how 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.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and your hospital records. If you do not want this to happen, tell us and we will stop. 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 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.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- by asking one of the research team who's contact information is towards the bottom of this information sheet
- by sending an email to dataprotection@contacts.bham.ac.uk

We have a data sharing and confidentiality agreement with Firetext. We are using Firetext to send you text messages to inform you of your test results; this means, we will share your mobile phone number with Firetext with your consent. The Firetext systems are compliant with UK data protection laws and subject to robust security processes. Data is held within an integrated platform and will never be shared with third parties within or outside of the UK.



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. The anonymised data will be published at international scientific meetings/journals – you will not be individually identifiable through this process. If you agree to take part in this study, you will have the option to take part in future research using your data and samples saved from this study. We will ask you on the consent form if you agree to this.

How will my data be stored?

The University of Birmingham is the sponsor for this study based in the United Kingdom. We will be using information you provide 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. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. 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. 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.

In this research study we will use information from your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Your data will have a code number instead. Your personal information will only be used to contact you about the research study and only designated members of the research study team will have access to these personal details. The exception to this is that sometimes-designated individuals from the University of Birmingham and regulatory organisations may look at your research records to check the accuracy of the research study. Your test data will not have your name on it but will be linked to your personal details by the study number. This test information will be kept and analysed on University of Birmingham computer servers. Your information will be kept securely for 10 years. At the end of the study we will save some of the data in case we need to check it and for future research, we will make sure no-one can work out who you are from the reports we write.

What will happen to my samples?

Your blood samples will be tested for COVID antibodies in a NHS accredited laboratory at the University of Birmingham. Your samples will be sent to the University of Birmingham and other participating centres such as The University of Southampton, The University of Oxford and Imperial Collage London for study analysis. We will replace your personal details with a unique study code so you cannot be identified from your samples. Your local centre and the central study administrators will have access to the link between the study number and your details so your clinician can discuss any personal results with you.

Testing will be undertaken and completed within two years of the study finishing. We will also ask you to consent to your samples being donated to biobanks for long term storage of samples to be used in future studies. The reason to store the sample is so that repeat or further testing can be performed. We will ask you to consent to your anonymised samples and the information you provide to be used in future, ethically approved research projects. We will also ask for your permission to store your genetic material such as your DNA to be tested and stored for the purposes of future ethically approved research projects. Agreeing to this is entirely optional on your consent form

Are there any other disadvantages to participating?

Having a blood or finger prick sample taken can lead to discomfort and bruising when the blood is taken. A nose and throat swab can be uncomfortable and can make you feel like you are gagging. If you swab too hard you can damage the nose or throat and this may cause local bleeding.



Will I be reimbursed for my time?

Any travel expenses for the clinic visits will be reimbursed. You will be entitled to claim up to £25 per visit for travel expenses with a maximum of £100 for four visits. Your local clinical team will provide you with a claim form to do this, please ensure you save all of your receipts for travel

What happens if I change my mind and no longer want to take part in the study?

If you no longer wish to take part, please let the central study team know. Your participation is completely voluntary and if you change your mind then you can choose not to take part at any point and you do not need to provide a reason. Samples and data, up to the point of withdrawal from the study, will be stored as per the study protocol.

Who is organising, funding and insuring this study?

This study is being sponsored by the University of Birmingham. The University of Birmingham has in place Clinical Trials indemnity coverage which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the study and may alternatively, and at the University's discretion provide cover for non-negligent harm to participants.

The NHS Trust has a duty of care to its patients, in the event of clinical negligence being proven, compensation will be available via the NHS indemnity.

Funding for the STRAVINSKY research study is being provided by the National Institute for Health and Care Research (NIHR).

What if I have a complaint or have any further questions about how my information is used?

If you have any questions or concerns about any aspect of the study please contact a member of the research team in the first instance.

If you are still unhappy with their response and wish to make a complaint then the PALS (Patient Advice and Liaison Service) at your local Hospital can offer support and advice.

Your data will be stored confidentially in line with the Data Protection Act 2018 and General Data Protection Regulations (GDPR). We will keep all information about you safe. Your personal details will be stored securely in the REDCap database. Postal forms will be filed in a secure and locked office.

If you have any concerns about your data or wish to make a complaint about the way your data was handled, you can contact the University of Birmingham's Data Protection Officer on Dataprotection@contacts.bham.ac.uk

Further information and contact details

This study has been reviewed by – East of England - Cambridge Central Research Ethics Committee

The University of Birmingham is the Sponsor of the study.

Central study team telephone: 0121 371 5339

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