UCL INSTITUTE OF CHILD HEALTH

Great Ormond Street Hospital for Children NHS Foundation Trust

Joint Research and Development Office
Division of Research and Innovation

Study Information Sheet

Study Title: COVID-19 Staff Testing of Antibody Responses Study (Co-STARS)

Protocol Number: 20CB17

Chief Investigator: Dr. Louis Grandjean, Department of Infectious Diseases, Great Ormond Street Hospital, London.

Study E-mail Address: COVID.study@gosh.nhs.uk

We would like to invite you to take part in a study that seeks to measure your antibody levels to SARS-CoV-2 (COVID-19) infection over the following 6 years. Participation in this study is entirely voluntary. You have been selected as you are a healthcare worker at GOSH who may have had COVID-19 or might be at risk for COVID-19 in the future.

One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 15 minutes. Please feel free to talk to others about the study if you wish.

In this research study we will use information provided by you. We will only use information that we need for the research study. Everyone involved in this study will keep your data safe and secure. We will follow all privacy rules. Only people who need the details within the study will have access to it. At the end of the study we will save some of the data and samples and use it for future research. We will ensure no-one can work out who individuals are from reports we write.

Why Are We Doing the Study?

The reason that we are undertaking this study is to answer key questions such as:

a) Are antibodies protective of SARS-CoV-2 infection and if so what level of antibodies are required for protection?
b) How many people confirmed or unconfirmed with disease develop antibodies?

c) How long do these antibodies remain detectable?

Additional questions that the study will address are:

d) What factors contribute to an increased risk of COVID-19?
e) What are the symptoms and long-term complications of COVID-19?
f) What roles do T cells and IgA antibodies play in SARS-CoV-2?
g) After vaccines become available, what are the antibody responses to the vaccine and what protection is provided by the vaccine?
h) How do populations health workers at different hospital and in different countries vary in their incidence of COVID-19?

What the Study Involves, Who are We Recruiting and How Long it will Last?

- We will ask you to complete an online questionnaire which includes questions on COVID-19 contacts, symptoms and complications, as well as health, medication, lifestyle, home and work conditions.
- A phlebotomy appointment for us to take a sample of 4ml (one teaspoon) of blood so that we can test your antibody levels. An additional 4ml sample will be taken for future research if you consent to this.
- Then we will follow you up every 6 months for 6 years.
- If you have been tested under the staff testing program (PCR swabbing and serology) and give consent to these results being released to the study, we will incorporate these results as your initial results.
- If you are a confirmed case (positive or equivocal antibodies) we will also follow you up monthly for the first 6 months to see what happens in the short term to your antibody levels. You will also have the option of providing a 20ml sample for T-cell assays (T-cells are another component of the immune system that may have an important role in fighting the virus). You will also have the option of providing a 4ml saliva sample to test for IgA antibodies. As both of these tests are research based, participating helps to further understand the immune response to SARS-CoV-2, but individual results regarding T cells and IgA are not able to be interpreted at this stage.
- At the follow up visits there will be a review questionnaire and repeat blood tests. As more is understood about the factors that may influence COVID-19, the questionnaire will be updated with this and you may be contacted to complete new information. Questionnaires may take the form of an online app that is accessible via smart phone.
- In order to understand what factors increase the likelihood of becoming infected, further questionnaires will be sent to understand what may cause increased risk of COVID-19.
- The study will take place at Great Ormond Street Hospital (GOSH).

- We aim to recruit a minimum of 1000 GOSH staff to the study, but will recruit all GOSH staff if possible.

What are the Potential Risks/Benefits?

The only **risks** associated with this study are those associated with a blood test and the potential for a loss or inadvertent sharing of identifiable data. We have taken steps to maximise the confidentiality and security of your identifiable data as explained below. The common risks of a blood test include bruising, pain, infection and syncope (fainting).

The **benefits** of this study are that you will be able to establish if you have likely been exposed and infected with SARS-CoV-2 already. We will also establish how long we are able to detect these antibodies for. Although we do not yet know whether the presence of antibodies in the blood confers protection against SARS-CoV-2, your participation will help to determine if this is the case.

When the eventual vaccine becomes available antibody testing will indicate what your response is to the vaccine and ongoing review will determine how effective the vaccine is at preventing infection.

Additional benefits include helping to gather data on what risk factors there are for contracting SARS-CoV-2, how severe it is and what the long-term consequences are. Collaborating with other hospitals allows a comparison of how frequent and how severe COVID-19 is health workers in centres in the UK and Europe.

Important Advice in Relation to the Study

We cannot at this stage be certain what the significance of positive serology means with respect to future risk of re-infection. A positive serological test does not abrogate the need to wear personal protective equipment, self-isolate or test for SARS-CoV-2 as per government guidelines.

We **do not** recommend staff members who have antibodies, consider themselves risk free of re-infection with SARS-CoV-2.

We **do not** recommend that staff with antibodies refrain from wearing Personal Protective Equipment as per Trust Policy.

How Will You Hear About Your Results?

We will inform you about your results by email and/or text message and we will provide you with yearly updates of the progress of the study. Results, bookings and questionnaires may be completed over the phone if the study team need to contact

you via phone to do so. In case you leave the trust, we ask for a secondary email so you can be contacted to continue in the study.

We will provide you with a report of your results that will explain the significance of a positive, equivocal or negative test in context of the important advice detailed in the section above.

If you have antibodies (seropositive or equivocal) and additionally provide a sample for T-cell assay and IgA, the results of these will not be provided as both tests are in research stage of development.

What Will Happen to Your Data?

In order to maximise the confidentiality of your data, the online questionnaire will be stored on GOSH/UCL secure servers and will only be available to the study investigators or auditors of the Health Research Authority.

At the end of the study in 6 years time all your data will be pseudonymised. This means that your identifiable data (name, age, date of birth, email address) will not be linked to the your health record. Rather, we will store this data under a study identifier.

You may choose to have your data removed from the database at any stage (now or in the future). We will not pass any identifiable data to any third party outside those that are named on this research project. Completely anonymous data may be uploaded to a public database to enable other researchers to learn from the data.

During and at the end of the study, we will publish the findings in a peer-reviewed journal, but will not use any identifiable data for this purpose.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name
- Contact Details (email, telephone)
- Medical History
- Demographics and potential risk factors for COVID-19

Researchers will use this information to conduct research or to check records to make sure that the research is being done properly. Other staff members or individuals 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. We may choose to send fully anonymized non-identifiable data to research collaborators internationally. They must follow our rules about keeping your information safe. 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 identify that you took part in the study.

What Will Happen to Your Stored Samples?

We will test your samples for specific antibodies to SARS-CoV-2. We would also like to use your samples in the future to improve our diagnostic test and compare it to other tests that are developed over time and may be better. If a future test for SARS-CoV-2 is shown to be significantly more reliable and accurate, we will retest samples with this test and inform participants of the results.

We will not share samples with collaborators that are linked with any identifiable data, although we may choose to use your non-identifiable samples to collaborate with international colleagues to enable improved testing of SARS-CoV-2.

Future testing may involve genetic testing of your samples but this will only be undertaken with the appropriate independent ethical, institutional and regulatory approvals.

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.
- If you leave the study, you can choose either to allow your prior samples to be to be used in the study or for your samples to be removed from the study.
- 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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to COVID.study@gosh.nhs.uk

More information about HRA research can be found either on the HRA website link: www.hra.nhs.uk/patientdataandresearch or at the GOSH website https://www.gosh.nhs.uk/privacy

Should You Have Any Questions of Concerns?

You can contact the study team on COVID.study@gosh.nhs.uk should you have any questions or concerns about this research.