**Participant Information Sheet young adults and adults: Serology in the ImmunoCOVID19 study**

**Study Title:** Coronavirus infection in immunosuppressed children and adults.

**Chief Investigator:** H. de Graaf

**Principal investigators:** S.N. Faust, C.J. Edwards

**Paediatric clinical teams involved:** Rheumatology, Immunology and Infectious Diseases, Gastroenterology, Renal, Respiratory, Oncology

**Adult clinical team involved:** Rheumatology

**Sponsor ID:** RHM CHI1061

**IRAS ID**: 281544

**Information sheet: Serology in the ImmunoCOVID19 study**

**Version:** 1.1 **Date:** 12/11/2020

Dear Participant,

**It is important to remember that if you are unwell and need medical care, you should follow the usual NHS clinical pathways.**

Thank you for your ongoing support of the ImmunoCOVID-19 online survey study. In addition to the ongoing questionnaire study we would like to investigate COVID-19 serology in participants. This will be done by looking for the presence of antibodies to SARS-CoV-2, the virus that causes COVID-19.

You are being invited to take part in this new, optional part of the study. To help you decide whether you would like to take part or not, it is important you understand why this is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear. If you need more information please contact the study team.

**What is this part of the study about?**

This part of the study is for all participants who are already in the ImmunoCOVID19 study. So far the results of this study, up to October 2020, show that there has not been an increased occurrence of severe COVID-19 disease in this vulnerable group. This could either be because they have been protected from exposure to the virus by shielding effectively, or because they did not develop severe disease despite being exposed to the virus. We do know that many of these children have been negatively impacted in other ways by the restrictions required for shielding.

We would like to investigate this further by looking to see whether participants have antibodies to SARS-CoV-2. This could tell us a lot about how participants have been affected by COVID-19 such as whether there have been any COVID-19 cases without symptoms.

**Why have I been asked to participate and what will happen if I take part?**

You have been invited to take part as you are participating in the ImmunoCOVID-19 study. If you are interested in taking part in this serology study, you will be asked to complete a new informed consent form online. Next you will be asked to complete a short questionnaire which will provide us with the additional details required to send you a testing kit.

We will then send a testing kit to you by post. This kit will allow you to carry out a finger prick blood sample at home or you can take the kit with you when you need to have blood tests anyway and ask the person performing the blood test to fill the sampling device. We would like to get a blood

sample taken in [month/year]. The instructions for this can be seen at the end of this information sheet. After you have taken the sample you can send it back to the study team in the return envelope provided. We will then analyse the sample together with the University of Nottingham for the presence of antibodies. These results will then be anonymously matched with the data collected through the weekly questionnaires.

**Are there any benefits to my taking part and are there any risks?**

It is important to note that individual antibody results will not be provided. There are no monetary (financial) benefits to taking part. The study results may help the consultants caring for your condition and teams all over the UK and Europe to know how to better look after people like you. The NHS, Public Health England and Dept. of Health and Social Care will be kept informed of ongoing results. If any new information arises during this study which would change our advice to people with immune system problems, then Public Health England and the local services will be informed in order to adjust local guidance. The data may also be used to inform national vaccination policy. Once the results have been analysed we will send you a report of the overall study results.

There are minimal risks relating to the finger prick blood sampling; the amount of blood required is very small (less than ½ drop) though minor bruising at the site may occur. Provided with the testing kit are an alcohol wipe and plaster in order to minimise the very small risk of infection.

**What data will be collected, will our data be kept confidential and will the NHS be given the result as soon as possible?**

Additional identifiable information will be collected for this part of the study. This will be only visible to the study team. Your participation and the information we collect about you will be kept strictly confidential.

In addition to the information we already have from you, a postal address will be required to send you the testing kit. When the analysis of blood samples is complete, they will be destroyed.

Only members of the research team and responsible members of University Hospital Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research complies with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential. This will ensure no data is traced back to you following study completion.

**Do you have to take part?**

No, it is your decision whether or not you take part. We are inviting everyone who is participating in the ImmunoCOVID19 study to take part. If you decide not to participate in this part of the study, you may still continue to participate in the questionnaire study.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason and without your routine care being affected. If you want your information to be removed from the study, we will do that if possible, otherwise the information you have given will be included in the final analysis. Once data has been anonymised for analysis it will no longer be possible to identify it and withdraw it from the study.

**Where can I get more information?**

If you have any questions please ask your clinical consultant, all of whom know about this study if you have been sent this questionnaire. If you would like to get information in writing please contact the NIHR Clinical Research Facility:

Email: uhs.recruitmentCRF@nhs.net

Telephone number: 023 8120 3853

If you have further questions please contact the Chief Investigator Dr. Hans de Graaf

Email: immunoCOVID19study@uhs.nhs.uk

**What happens if there is a problem?**

If you wish to complain you may wish to contact:

PALS: 023 8120 6325 or patientsupportservices@uhs.nhs.uk

**Who has reviewed the study?**

The Yorkshire & The Humber - Leeds West Research Ethics Committee has reviewed the study.

**Data Protection Privacy Notice**

The University Hospital Southampton conducts research to the highest standards of research integrity. When you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. Personal data will be collected in this study. Only health related information will be collected as specified above. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Thank you for taking the time to read this information booklet

**ImmunoCOVID-19 study: Antibody testing kit instructions**

This antibody test kit is provided as part of the ImmunoCOVID-19 study. Please be aware that it will not be possible to provide individual results to you. Results will however be used to estimate how many participants in the study overall have been exposed to the virus which causes COVID-19.

This instruction sheet will guide you on how to carry out the test. You should do this with the assistance of someone in your household or a trained clinician. It will take roughly 5 minutes and takes less than ½ drop of blood in a very small sponge on the end of the sampling stick.

How to carry out the test:

Under sampled and over sampled

* Read all of the information in this instruction sheet.
* Prepare the testing kit in a clean and safe space.
* Follow the six steps below.
* Send the test in the pre-paid envelope provided.

Important points:

Correctly sampled

* Only use the device provided for the designated participant.
* Dispose of used lancet safely.
* Ensure correct sampling amount as shown to the right.

**1/ Organise kit**

Create a clean space on a table.

Lay out the test kit.

You should have the following:

* Mitra blood sampling device
* Lancet (finger prick device)
* Alcohol wipe
* Cotton ball and Plaster
* Label
* Pre-paid envelope

**2/ Preparing kit:**

Lay the Mitra sampling device ready for use.

Twist off the protective cap on the lancet.

Prepare cotton ball and plaster.

Wash hands with soap and water. Dry your hands.

Rub hands to warm them for 30 seconds**.**

**3/ Preparing for finger prick**

Choose a spot on the fleshy bit of the end of one of your fingers.

Wipe the area with the alcohol wipe provided.

Wait for a few seconds to allow the area to dry

**4/ Carrying out finger prick**

Place the narrow end of the lancet on the chosen spot.

Press the top button in, a click should be heard and a pinch felt.

Wipe away the first drop of blood.

**5/ Collect blood**

Touch the Mitra sampling tip to subsequent drops of blood.

If required, massage pricked finger upward until blood drop appears.

Please ensure adequate volume sampled (as above).

**6/ Complete and send**

Set cartridge down, wipe away blood and apply the plaster. Close the cartridge. Write the date on the label and stick it onto the cartridge. Place the cartridge into the return envelope and seal. Drop off in a post box or your local post office. Thank you