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

**Version:** 1.1 **Date:** 02/08/2021

Dear Parent,

Thank you for your ongoing support of the ImmunoCOVID-19 online survey study. In addition to the ongoing weekly questionnaire study we would like to invite you to participate in a new part of the study. The COVID pandemic has changes all of our lives. Things are different when we see family, meet up with our friends, do sports, go to school or work.

We have all had to make different changes to our lives. Sometimes it is nice that you can hang out at home, at other times you miss your old routine of seeing your friends, doing your favourite activities like sports, art, music, or dance clubs. A lot of us have had to adjust to working from home, while at the same time home schooling and performing regular household activities. Our moods can change depending what we do or how we feel, we can feel happy, cheerful but can also feel anxious, stressed, lonely or bored. We can even have multiple different feelings at the same time.

In this new part of the study we would like to see how the COVID pandemic has changed the lives of young people and their families.

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

For the past year you have kindly provided us with information on how the COVID pandemic has impacted the physical health of immunosuppressed children and young people. Your comments and concerns have shown us that the uncertainty of the pandemic and the COVID restrictions have also impacted your social life, education, and employment, and for some of you, your mental wellbeing.

This new part of the study would therefore focus on your quality of life and the feelings your child experiences during these uncertain times and the way you have been able to cope. We would like to invite all participants who are already in the ImmunoCOVID19 study to complete a psychological survey. For parents the questions will focus on how you have been able to cope with the pandemic. For children and young people, the questions will focus on how the pandemic is restricting their activities and how they feel about these restrictions.

The psychological survey takes about 10 minutes to complete. If you decide to participate in this new part of the study a link to the online survey will be sent to you in September 2021, December 2021, and March 2022. We would really appreciate it if you could complete the survey at these 3 different time points so we can investigate the social-psychological impact of the COVID pandemic on vulnerable families like yours.

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

You have been invited to take part as your child is participating in the ImmunoCOVID-19 study. If you are interested in taking part in this psychological study, you will be asked to complete a new informed consent form online. Next you will be asked to complete 3 short questionnaires, one in September 2021, one in December 2021, and one in March 2022.

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

There are no monetary (financial) benefits to taking part. The study results may help the consultants caring for your child’s condition and teams all over the UK and Europe to know how to support families like your families through unpredictable times. The NHS, Public Health England and Dept. of Health and Social Care will be kept informed of ongoing results. Once the results have been analysed we will send you a report of the overall study results.

Completing the questionnaire should not feel much different than talking to a best friend or a family member. However, some people might be uncomfortable putting their feelings or thoughts to paper. There are some useful websites with lots of resources to help:

<https://youngminds.org.uk/>

<https://www.childrenssociety.org.uk/information/young-people/well-being/resources>

<https://www.mind.org.uk/information-support/for-children-and-young-people/>

www.kooth.com

However, if you are still concerned, please do not hesitate to contact Emma Lee, Paediatric Psychologist in the rheumatology department at University Hospital Southampton, at 02381 204657 or reach out to her via email [e.lee4@nhs.net](mailto:e.lee4@nhs.net) if you or your child are worried or have difficult feelings after completing the questionnaire. She will be able to explain where you can get support locally. Please note, she may be unable to respond to you immediately. If you require urgent support, or your child experiences significant distress, we recommend that you contact your local GP or CAMHS team, or contact NHS 111 for advice.

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

All of the information you and your child give us will be kept strictly confidential. The psychological survey will have a unique research number and staff will know you only by this number. The results of this psychological study will then be anonymously matched with the data collected through the weekly questionnaires. Your name and address will not be asked in any part of the psychological surveys so that you cannot be identified from it.

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 weekly 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](mailto: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