IMPACT OF BIOLOGIC AND IMMUNOMODULATORY THERAPY ON SARS-COV-2 INFECTION AND IMMUNITY IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE.
CLARITY Parent/ Guardian Participant Information Sheet

Thank you for taking the time to read this leaflet. Your child has been invited to take part in a research study. Before you decide whether you would like your child to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your child's GP if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish your child to take part.

What is the purpose of the study?

Patients with inflammatory bowel disease (IBD) are usually treated with immunosuppressive drugs. By inhibiting the immune system, these drugs increase the risk of serious infections and prevent vaccines fully working. Because COVID-19 is caused by a new virus, SARS-CoV-2, we don't yet know if these drugs increase the risk of infection, life-threatening illness or reduce immunity that usually follows infection or vaccination. As a precaution the UK Government advised patients taking these medicines to follow strict social distancing measures, known as shielding, during the 12-week lockdown. This study will investigate the impact of specific drugs and shielding on COVID-19 infection and immunity that follows infection or vaccination. The results of this study will help inform public health policy decisions for patients with IBD as well as millions of other UK patients treated with immunosuppressive drugs.

Why has my child been asked to participate?

Your child has been invited to participate because they have a diagnosis of IBD and attend your local hospital for regular infusions of infliximab or vedolizumab.

Does my child have to take part?

It is up to you to decide whether or not they take part. If you do decide that they will take part, you are still free to withdraw your child at any time and without giving a reason. This would not affect the standard of care your child receives. Your child's GP will be informed of their participation (if you do not want this to happen then please let your nurse/ consultant know).

What will happen to my child if I agree to take part?

We will first ask you to give consent for your child to participate in the study. To do this an email will be sent to you with a personalised link. You will then be asked to enter your child's surname and date of birth to confirm your child's identity before completing the e-consent form.

At your child's first research visit they will be asked to complete a questionnaire and to give an extra blood sample. The questionnaire asks about past or current symptoms of possible coronavirus infection and whether your child has been shielding. The blood sample (1 teaspoon) will be taken alongside your child's routine blood tests, just prior to having their infusion. This will be sent to Exeter and tested for evidence of past SARS-CoV-2 infection. This result will be sent back to your child's local gastroenterologist who will then inform you whether your child's test is positive or negative.

After visit 1 you and your child will be asked to complete a shorter questionnaire every 8 weeks and your child asked to have additional blood samples taken on 3-5 further occasions. These will be taken at the same time as routine blood tests are carried out when your child attends their regular infusion or clinic appointments. If in the future the way your child's treatment is given changes, it may be possible that your child's visit can be conducted remotely and your child may be asked to use the Exeter home finger prick test kit.

What will happen to my child's blood sample?

Your child's blood sample will be given a code number so that their identity will not be revealed to anyone outside of your local hospital, and if you agree the data controller at the Royal Devon and Exeter NHS Foundation Trust. The blood sample will be sent to the Royal Devon and Exeter Hospital Clinical Laboratory for a test to see if your child has antibodies to SARS-CoV- 2.

Your child's blood samples will be considered a gift to the Exeter Clinical Research Facility and will be transferred to the Peninsula Research Bank. A steering committee will approve the use of these samples for future research. This research may form part of collaborations in the UK or overseas including collaborations within companies. Specifically, samples:
a) will not be sold for profit
b) will not be used in animal research
c) will not be used in research into the termination of pregnancy or reproductive cloning
d) will not be screened for genes directly predictive of rare disease (e.g. Huntington's)
e) will not be shared with non-research organisations, such as the police.

What will happen to the results of the study?

At the end of the study we will publish the results of this research and will be happy to provide you with a copy of the publication if you request it. Your child will not be identifiable in this publication.

Are there any benefits from taking part in this study?

There are no benefits to individual participants from taking part. However, this study will help inform public health policy, by determining how immunosuppressive drugs and shielding impact SARS-CoV-2 infection risk and subsequent immunity from further infection.

We will return your child's SARS-CoV-2 antibody test result to you and their local gastroenterologist. A positive test suggests they have had a past infection. It is currently not known whether, or for how long, a positive test confers immunity. Therefore, your child should continue to follow appropriate physical distancing measures as advised by the government and your local IBD team.

If we participate will my child's personal medical information be kept confidential?

We will need to use information from your child's medical records for this research project. In addition, we will need access to their name, date of birth, NHS number and postcode. In addition, we need your email address and mobile number so that you can receive electronic links to the consent form and questionnaires. Your child's NHS number is required to allow linkage with datasets held by UK government agencies. Your local hospital will pass these details to the Royal Devon and Exeter NHS Foundation Trust along with the information collected from you, your child, and their medical records.

We will keep all information about your child safe and secure. The Royal Devon and Exeter Hospital NHS Foundation Trust is the data controller. Access to your child's identifiable data will be restricted to the research team at your hospital and individuals at the Royal Devon and Exeter Hospital NHS Foundation Trust, nominated by the data controller, who have received appropriate training in handling personal data. Your child's personal data will be removed before it is made available to members of the central research team. Data from the study will be kept for up to 5 years but the identifiable information, linking this to your child, will be removed 12 months after the study has been finished.

Your rights to access, change or remove your child's information are limited, as we need to manage your child's information in specific ways in order for the research to be reliable and accurate. Your child can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have collected.

We will write our reports in a way that no-one can work out that your child took part in the study. For further information on how we use your data you can email rde-tr.clarityibd@nhs.net or http://www.hra.nhs.uk/patientdataandresearch

What if I have a complaint or concerns about the study?

Whether or not your child takes part in the study, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study,

the normal National Health Service complaints mechanisms would be available to you. Taking part in the study would not affect your legal rights.

Who is conducting the research?

This study is being carried out by a group of Gastroenterologists and scientists from the Royal Devon and Exeter Hospital Imperial College, London and Hull Royal Infirmary. The central study office is at the Royal Devon and Exeter Hospital. The investigators are not being paid to carry out this work.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by London-Surrey Research Ethics Committee.

Who is organising and funding the research? This study is funded by Roche. It is supported by the National Institute for Health Research Clinical Research Network (NIHR CRN).

The sponsor of the research is the Royal Devon and Exeter NHS Foundation Trust. The sponsor may decide to stop the study at any time and if this happens the reasons will be explained to you. This will not affect your child's on-going clinical care. Any anonymised data that has been collected up until this time point will be used for analyses.

I have some further questions, who can I ask?

You can find further information at this website www.clarityibd.org.