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

Thank you for taking the time to read this leaflet. You are being invited to take part in a research study. Before you decide, 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 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 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 have I been asked to participate?

You have been invited to participate because you have a diagnosis of IBD and you attend your local hospital for regular infusions of infliximab or vedolizumab.

Do I have to take part?

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

What will happen to me if I agree to take part?

We will first ask you to give consent 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 surname and date of birth to confirm your identity before completing the e-consent form.

You will be asked to complete a questionnaire and give a blood sample. The questionnaire asks about past or current symptoms of possible coronavirus infection and whether you have been shielding. The blood sample (1 teaspoon) will be taken alongside your routine blood tests, just prior to having your infusion. This will be sent to Exeter and tested for evidence of past SARS-CoV-2 infection. An email will be sent to you with a personalised link to the result. This will also be made available to your local team.

After visit 1 you will be asked to complete a shorter questionnaire every 8 weeks and have additional blood samples taken on 3-5 further occasions. These will be scheduled for when you attend your regular infusion or clinic appointments.

If in the future the way your treatment is given changes, it might be possible for your study visit to be conducted remotely using the Exeter home finger prick test kit.

What will happen to the blood sample?

You blood sample will be given a code number so that your 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 Hospital. It will be sent to the Royal Devon and Exeter Hospital for a test to see if you have antibodies to SARS-CoV-2.

Your 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 with 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. We will provide you with a copy of the publication if you request it. You 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 SARS-CoV-2 antibody test result to you and your local team. A positive test suggests you have had a past infection. It is currently not known whether, or for how long, a positive

test confers immunity. Therefore, you should continue to follow appropriate physical distancing measures as advised by the government and your local IBD team.

If I participate will my personal medical information be kept confidential?

We will need to use information from your medical records for this research project. In addition, we will need access to your name, date of birth, postcode, email address, mobile number, and NHS number. Your name, date of birth, email and mobile phone numbers are required so that you can receive electronic links to the consent form and questionnaires. Your 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 and your medical records.

We will keep all information about you safe and secure. The Royal Devon and Exeter Hospital NHS Foundation Trust is the data controller. Access to your 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 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 you, will be removed 12 months after the study has been finished.

Your rights to access, change or remove 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 collected.

We will write our reports in a way that no-one can work out that you 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 you take 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 Borders 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 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 and by contacting the team below: