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

CLARITY Follow up Participant Information Sheet

Thank you for taking the time to read this leaflet. We are seeking your permission to **continue to access your medical records and to consent to allow a member of the research team to contact you (selected patients only) for a further 12 months in the CLARITY IBD study. No further study visits or blood tests are required**.

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. Ask us if there is anything that is not clear, or if you would like more information.

What is the purpose of the study?

Results from the CLARITY IBD study have shown that use of infliximab is associated with lower antibody levels and a higher risk of COVID-19 infection following vaccination. Further follow up information is required from the medical records of selected patients beyond the last study visit. 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 give further consent?

You have been asked to give a further consent because we cannot review your medical records or contact you via email or text message beyond the last study visit without your permission.

Do I have to give my consent?

If you do decide to give your consent, 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.

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

We will ask you to give consent to allow for health professionals at your local hospital to review your medical records for an additional 12 months. 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. We will also ask you to give permission for a member of the research team to contact you via the Redcap database, this will only involve selected patients.

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. You will not be identifiable in this publication.

If I agree to give my permission, will my personal medical information be kept confidential?

We will need to continue collecting 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 COVID-19 testing and vaccination data held by the UK Health Security Agency and NHS Digital. Your local hospital will pass these details to the Royal Devon University Healthcare 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 University Healthcare 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 University Healthcare NHS Foundation Trust, nominated by the data controller, who has 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 at the end of the 12-month follow up period.

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 rduh.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 give your permission for your medical records to be review for a further 12 months , 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, Takeda, Biogen, Galapagos, Celltrion, the Royal Devon University Healthcare NHS Foundation Trust and Hull University Teaching Hospital NHS Trust. It is supported by the National Institute for Health Research Clinical Research Network (NIHR CRN).

The sponsor of the research is the Royal Devon University Healthcare 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 or contacting your local hospital research team.