

CLARITY

Young Person's Information Sheet (used with consent form)

Introduction

We are inviting you to take part in a research project. Before you decide if you want to join in it's important to understand why the research is being done and what it will mean for you. So please read this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to.

Please ask us if there is anything that is not clear, or if you would like more information. Thank you for reading this.

Why are we doing this research?

We want to look at whether medicines commonly used to treat inflammatory bowel disease affect the risk of getting coronavirus or stop coronavirus vaccines working properly.

Why have I been asked to take part?

You are being asked to take part because you have inflammatory bowel disease, and you attend your local hospital for your biologic medication.

Do I have to take part?

No - not at all. It is completely up to you!

We only want people to take part if they want to. Just tell us if you don't.

Whatever you decide nobody will mind and it will not affect how you are looked after. If you decide to take part and then change your mind that is OK too. You can stop at any time, and you don't have to give a reason.

If you agree to take part, you will be asked to give consent. This is so that you understand the study, what will happen to you and that you are happy to take part. You will be given your own copy of the consent form to keep as well as this information sheet.

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What will happen to me if I take part and how long will it take?

If you take part, we will ask if it is OK to look at your medical records. We will also ask you some questions. We also need to take an extra blood sample. It will be taken at the same time as you have your normal blood samples taken, before your infusion. You will be asked if we can take the blood sample and if you can complete a questionnaire up to 6 times over the next 40 weeks. The questionnaire is short and takes about 5 minutes to complete.

Will it help me if I take part?

No, it won't. It is hoped that the information we get may help other people in the future.

Is there anything to be worried about if I take part?

There are no risks from taking part.

What will happen to my blood sample?

Your blood sample will be given a code and sent to the Royal Devon and Exeter Hospital.

We will test your blood sample to see if you have had an infection caused by coronavirus.

Your blood sample will be stored for a long time in a research bank and may be used for future research.

What will happen to my data?

Information about you, including your name and date of birth will be kept securely at the Royal Devon and Exeter NHS Hospital but this will not be shared with the research team Your NHS number will be shared with government agencies so that information they hold about you on coronavirus infections can be linked together.

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What will happen to the results of the study?

We hope to be able to write about the results of this study. We will be happy to provide you with a summary of this if you want. You will not be identifiable in this publication. You and your doctor will be told your blood test results

Who has reviewed the study?

The study has been looked at by people who decided whether it is okay for us to ask you to take part in this study. They are called the London- Surrey Borders Research Ethics Committee.

Who is organising and funding the study?

This study is being organised by doctors in Exeter, London and Hull. The study is helped by the National Institute for Health Research Clinical Research Network (NIHR CRN) and people in your local hospital.

Thank you for reading this. Please ask if you have any questions.