

## COVID-19 & IBD research:

### Information for Participants

We want to support clinical teams by collecting further information relating to COVID-19 and IBD. We also want to undertake research to understand more about the impact of COVID-19 on people with IBD. Some information collected will be made available to clinical teams, and all information will be made available for research into COVID-19 and IBD.

One specific study that your information will contribute towards is a research study looking at the risk, outcomes and impact on lives of COVID-19 for people with IBD. It is a data research study, so it does not involve any medical changes or procedures like blood samples.

As well as this study, the same data is also valuable for other COVID-19/IBD research studies.

To help you decide whether or not to take part it is important for you to understand why the data collection is being done and what it will involve.

### Why are you collecting this data?

We want to support research that will improve understanding of the care of people with Inflammatory Bowel Disease (IBD) related to a COVID-19 setting. To do this, we are collecting of data from adults with IBD in the UK that can provide insights about IBD and COVID-19 and how they relate to each other.

We hope that we can add significantly to the body of knowledge about IBD in relation to COVID-19, about protecting people with IBD in this pandemic and possibly future ones; and about the best care and use of medications in these COVID-19 times.

### What is COVID-19?

The virus that causes COVID-19 is a respiratory virus that is known to cause extreme reaction from people's immune systems, leading sometimes to death or severe disruption to people's health. This is a new virus, and while it is still being understood, there have been high concerns from the start about its impact on people with inflammatory diseases, such as IBD. Many of the treatments for IBD are immuno-modifiers, which means they work by changing the immune system. This has naturally put many people with IBD taking these medications into groups considered extremely clinically vulnerable.

### Why have I been invited to take part ?

In April 2020 we (the IBD Registry) created a COVID-19 IBD Risk Tool for people with IBD living in the UK. The tool was designed for people to self-assess their risk, so they could take the necessary steps regarding shielding and risk management during the pandemic. About 40,000 people have now used this Risk Tool. We have sent invitations out to individuals who used the Risk Tool who provided a valid email address or mobile number, to invite them to take part in a follow-up survey that will add valuable research data to their original Risk Tool data.

## What data are you collecting in this survey?

For this follow-on survey we are asking questions about you, your work and workplace, the medications that you receive for your IBD, how your IBD affects you, vaccination, your life and experiences including your exposure to COVID-19, and your experiences of health care during the COVID-19 pandemic.

We will be combining this survey data with the data you provided in the original COVID-19 IBD Risk Tool. This included personal data such as your name, contact details, age, etc.

## Why do I need to give consent and what is it for?

We are asking for your consent to store and use your data for research purposes, including any sharing and data linkage that may be part of a specific research study. We are also asking for your consent to allow certain parts of the information you provide to be made available to your hospital IBD care teams (see “about my data” section). We would also like to be able to contact you in the future, in particular about joining the IBD Registry.

As part of completing the second survey, you are also being asked to give your consent for the original confidential data, now combined with the new survey data, to become longer term research data that will be held indefinitely.

We are doing this because the original data was collected and is currently held under special permission granted by the UK Government. This allows the data to be used for certain purposes related to COVID-19. However this special permission is time-limited and when this expires the data must be destroyed, even if the research is not finished or other research could be carried out. Your consent will allow the data to be held for longer making it more valuable for research.

## Do I have to take part in the survey ?

No. Taking part in the survey is entirely voluntary.

If you decide to take part you will be asked to sign an online consent form, which can be downloaded at the end of the survey, including this patient information leaflet. You sign this form at the end electronically (on the screen). This works best on mobile phones and other devices with touch screens.

## How do I find more information or ask a question?

There is more information on our website, under '[COVID-19](#)' and '[Analysis and Research](#)'. We also have a separate online '[Feedback Form](#)' if you want to ask us a question or give us any feedback. This is separate so you can contact us before you have completed the survey, or if you are having difficulties. You can also contact us using our details on our website, but we are only a small team and if it is possible to use the 'Feedback Form' it really helps us.

## Why am I asked for my NHS/CHI/HSC number?

NHS Numbers are used in England and Wales; in Scotland CHI Numbers are used; in Northern Ireland, HSC Numbers are used. It really helps us if you have your NHS/CHI/HSC number, but it's not essential. Providing it means that your data can be linked to other datasets, for example your hospital admissions, for specific research studies.

## **Can I change my mind later?**

Yes. You can choose to have your data removed from the IBD Registry's COVID-19 database at any time using the link sent to you and you do not have to give a reason. However, any research or analysis that has already started on your data cannot be undone.

## **What happens if I do nothing ?**

We will have only the original data you supplied for IBD Registry's COVID-19 Risk Tool to use for research for a very short period of time, under the permissions given by the UK Government for COVID-19. Any research will have to be carried out within the shorter time allowed by the Government. If you have not given us consent to keep the data for longer for research purposes, then once the permission expires your data will be deleted.

## **What happens if I don't want to take part at all, including my original data not being used?**

You can tell us to withdraw all your original data from the database. This means none of your data from the COVID-19 IBD Risk Tool or this second survey (if completed) will be used in any future studies. You can tell us by using the link sent to you, or by contacting the Registry team. You can do this at any point, however your data can not be removed from any research studies that have already started at the time of withdrawal.

## **What are the benefits of taking part?**

The most important benefits for people with IBD come from the power of the research analysis that can be done on this large and unique dataset. You will also have access to a downloadable version of your answers, which may be helpful to your IBD team.

## **What are the disadvantages or risks of taking part?**

The only risks to taking part in this survey relate to data protection and confidentiality. We will store the data securely in readiness for it being used as part of research studies. You can read more about how we protect your data in the "about my data" section. You will not be identified in any results.

## **Can I correct data that I have submitted if I realise I made a mistake?**

If you realise you have made a mistake after you have submitted the survey, you can re-do the survey and submit an updated copy to us. We will use the copy with the most recent date and time on it in any new research studies, but if research has started on the previous data we may not be able to withdraw it.

## **The COVID-19 research study: risk of infection, outcomes and impact for IBD patients**

### **What is the study about?**

This study is to look at the risk for people with IBD of catching COVID-19; what severe things might happen if they do catch it (these are called severe outcomes, and include for example, hospitalisation and death) and the impact on their lives of the public health and protection measures designed to protect the population.

There have been a number of studies already on IBD and COVID-19, but this study has the potential to give results not otherwise achievable. The IBD Registry has collected a unique dataset on people with IBD, many of whom are taking these immune-modifying drugs, and it has collected this since the start of the first lockdown in April 2020. It contains 40,000 people's records, and we have permission to make contact for COVID-19 purposes. We also have a strong relationship with the NIHR IBD BioResource, and have been working with them already on secure data methods of linking de-identified data. This means that research can take place on a more informative dataset while still protecting people's identities.

We hope that we can add significantly to the body of knowledge about IBD in relation to COVID-19, about protecting people with IBD in this pandemic and possibly future ones; and about the best care and use of medications in these COVID-19 times.

## **How were the questions in the survey designed?**

The questions have been designed for a specific study which aims to look at the risk outcomes and impact on lives of COVID-19 for people with IBD. It is a data research study, so it does not involve any medical changes or procedures like blood samples.

## **Who is running this study ?**

The IBD Registry is the study sponsor. We are the national organisation for data about inflammatory bowel disease in the UK. Our aim is to improve the health of people living with inflammatory bowel disease in the UK. We collect and analyse data in order to improve understanding of the care of people with IBD and their treatments and to support research.

## **Who is leading this study and who is doing the research?**

The research is being led by Dr Nick Kennedy and Prof Stuart Bloom, who are both consultant gastroenterologists (senior IBD doctors).

The research is planned to be done with significant collaboration with an IBD clinical research group based at University Hospital Cambridge. The clinical researchers in this group are all senior gastroenterologists who also specialise in research in IBD.

The IBD Registry is the sponsor for the study, which means we are responsible for the study design and conduct (i.e. how it is run).

## **Who is paying for it ?**

The clinical researchers in the group are not being paid extra to help with this study. The IBD Registry is supporting the study with paid administrative time from its own staff.

The IBD Registry was given financial support from a number of pharmaceutical companies to set up the original COVID-19 IBD Risk Tool. These companies have no access to any data and had no influence or involvement in the design or running of the Tool. These companies are listed on the [COVID-19 IBD Risk Tool webpage](#).

## **What will happen to the results of the research?**

We plan to write up the results of this study as various research papers which will be published in academic and medical journals. The results may also be presented at conferences and similar public events. We will ask that any other research studies do the same.

We hope that the results will be important for public health and so we will share them also with national health organisations, including NHS organisations and policy makers. We will also share

the results with national charities for the benefit of people with IBD. All the results will be de-identified statistics so that no-one can be identified individually.

## **About my data**

### **What do you do with the data?**

We will store your data securely in line with information governance requirements, using the IBD Registry's secure data hosting facility at AIMES. Your responses relating to your medications, IBD activity, and COVID-19 vaccination status can also be shared with both the hospital teams that currently care for you. Your data will also be used for analysis and research relating to COVID-19 and IBD.

We might undertake this research ourselves, or we might approve other organisations to do specific studies. We will only share your de-identified data with approved organisations who are undertaking studies that the IBD Registry has approved.

In order for specific research studies to be undertaken, either by the IBD Registry or by approved organisations, it might be necessary to link your data to other national datasets, databases, or tissue banks. Only de-identified data will be shared and extra care will be taken to ensure no re-identification occurs.

We are careful about who has access to information held within the IBD Registry, and which other organisations and individuals this is shared with. Access to your de-identified information within the IBD Registry is restricted to authorised and trained individuals who are subject to contractual obligations of confidentiality.

We will only use your contact details to contact you if it relates to your involvement with COVID-19/IBD research. If you give us permission to do so, we will also contact you to invite you to join the main IBD Registry once the mechanism for this is in place.

### **Will my data be transferred back to my healthcare provider?**

Your responses from the medications, IBD activity, and vaccination surveys can be shared with both the hospital teams that currently care for you. Data will not automatically be shared - individual hospitals will need to request it. This gives them the opportunity to learn about your condition and treatment which could be relevant during this COVID-19 response period. Just because you have completed the survey does not mean that your healthcare team will receive the information.

Answers from the other surveys available will not be fed back to your healthcare teams at an individual level. You will be given the option of downloading a pdf copy of your answers at the end of each survey. You can choose to share these with your healthcare teams if you want to.

If there is information that you urgently want your IBD team to receive then please contact them directly.

### **Who will my data be shared with?**

Some of your responses may be shared with hospitals and specialist doctors that care for you, upon request from the healthcare provider. This means that they have the most up to date information about your condition and treatment which could be relevant during this COVID-19 response period.

To maximise the potential of the research, we would like to link the data with public health data, such as Public Health England and the equivalent NHS bodies in the devolved nations. This will mean sharing your NHS Number (CHI Number in Scotland and HSC Number in Northern Ireland) with these NHS organisations and another personal identifier such as date of birth. The NHS organisations will use these identifiers to find the matching record in their dataset and send us a linked set of data.

For specific research studies, we may also link your data with other national datasets, databases or tissue banks (for example, the NIHR IBD BioResource). The linkage of de-identified data with such organisations will be made possible by sharing a specially created unique key that is the same in both the datasets.

Your de-identified data may be shared with approved organisations who are undertaking research that has been approved by the IBD Registry. Special agreements covering data sharing and data protection will be in place with all of these organisations to make sure they will look after your data when we have shared it with them.

We will not share data that identifies you with any commercial organisations. We will never allow your data to be used for marketing or by insurance companies.

## **How is my personal data protected ?**

All data that we collect will be processed in accordance with the General Data Protection Regulation (GDPR) and the Common Law Duty of Confidentiality (CLDC). The data is securely collected and then held within secure data centres in the UK which are compliant with industry and NHS data security standards.

For further information, including details of our lawful basis, the purposes for which personal confidential data will be processed, your rights and how to contact us, please see the full [Privacy Notice](#) (also on our website).

## **How do you protect my identity and my data in research?**

We hold data about you (e.g. personal details and health information) securely within electronic databases, which are located in the UK and are subject to technical and organisational controls to ensure the security of your information. We follow and meet strict NHS requirements for data security, which is assessed annually. All data transferred to us is tightly and securely controlled. All analysis or research taking place on IBD Registry data is done within an approved secure data environment.

More information on our data security can be found on our website [here](#).

We follow best ethical and legal practice to ensure that all data collected about you is handled in confidence.

We employ privacy-enhancing techniques within the Registry. These include de-identification (where data items which could identify you directly such as your name or NHS Number are replaced with a code so that your identity is protected) and data minimisation (where data items which are not needed are removed before use). All of our analysis and research takes place using de-identified data so that the researchers will not be able to identify you. Analysts and researchers are only granted access to the specific data needed to address their study or research project. No one has access to any more data than is necessary for the activities they are undertaking.

For sharing data with national datasets and central NHS bodies, their process is to share only identifiers and then to use those to return the dataset that matches exactly those identifiers. For sharing with other organisations, such as the BioResource, we will use a privacy-enhancing

technique that means no identifiable data is shared. The enhanced records are then de-identified before further activity is undertaken.

Only aggregate data – statistics – will be used in reports and publications, and small number suppression will be used.

## **How long will my data be kept for?**

Inflammatory bowel diseases are usually lifelong conditions, so the Registry aims to keep information indefinitely. There may be other viruses which behave similar manner to COVID-19, which means that data on it may be useful for further research in the future.

Where an ethically approved research study is given access to data, it will be for a shorter period of time in line with the research protocol and agreed with us in advance.

## **How is research approved?**

The IBD Registry has an approval process for authorising new uses of data, including any research. This process seeks to confirm the purpose of any access, assess the minimum data required and determine who can access that data. The IBD Registry are responsible for ensuring all uses of data are lawful.

In addition to internal Registry analysis and research, we take requests for analysis and research from approved organisations, for example public bodies such as the NHS, charities, academics and commercial healthcare organisations.

Approved analysis or research groups will be given access to the data for their study through legally enforceable agreements. These will oblige them to use your data only for the agreed purposes, keep your data safe and comply with the law.

Research groups wanting to access Registry data must first ensure the right approvals are in place, including ethical approval. They then have to apply to the IBD Registry committee that safeguards the use of Registry data for research. This committee will check that the research questions are important and will produce scientific advances or benefit patients, or both. They will also consider whether the information requested is the minimum necessary for the project, as well as any ethical considerations.

Research groups share the results of their studies in reports or publications, which includes placing the results of research on the internet, in press articles, in medical research journals, in project leaflets and through other media. We hope that the research will be important for public health and so we may also share results with national health organisations, including NHS organisations, policy makers and national charities for the benefit of people with IBD. Under no circumstances will any information that identifies you personally be disclosed in any of these types of media.

## **About the IBD Registry**

### **Who is responsible for looking after the data?**

IBD Registry Ltd is the Data Controller for the personal data held within the COVID-19 IBD database. We are accountable for protecting that data in compliance with data protection and confidentiality laws. We are registered with the ICO (Information Commissioner's Office). Our ICO Registration Number is: ZA334069

## How is the Registry governed?

The IBD Registry is a not-for-profit organisation, wholly owned by three joint members – [the Royal College of Physicians \(RCP\)](#), [the British Society of Gastroenterology \(BSG\)](#) and [Crohn's & Colitis UK](#).

## How can I access the data you hold about me?

For details on how to access the data the IBD Registry holds, and for information about how you can exercise your other rights under data protection law, please see our [Privacy Notice](#).

## How can I contact the IBD Registry?

You can find out more about us on our website or in our [privacy notice](#). If you have any feedback or if you are unhappy about any aspect of the IBD Registry or how your information is being used, please use our [feedback form](#) to contact us to try and resolve the problem. The feedback form can also be used if you want to make a formal complaint about any aspect of the IBD Registry.

### IBD Registry

[www.ibdregistry.org.uk](http://www.ibdregistry.org.uk)

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