Participant Information Sheet

Open-IBD

A long-term study of human cells and gut microbes in people with newly diagnosed Crohn's and Colitis

Invitation

We would like to invite you to take part in the Open-IBD research study as you have been referred to hospital with symptoms that may be caused by Inflammatory Bowel Disease (IBD). There are two common subtypes of IBD: Crohn's Disease ("Crohn's") and Ulcerative colitis ("Colitis"). Crohn's and Colitis are long-term conditions that cause inflammation of the digestive tract and can result in challenging symptoms including diarrhoea, abdominal pain, weight loss and fatigue. Crohn's and Colitis symptoms and disease behaviour can vary significantly from one person to the next. An individual's disease can also behave very differently throughout their life. While some patients will have mild symptoms that respond to simple treatments, others will develop more severe symptoms and problems over time. The exact cause of Crohn's and Colitis, as well as what influences this behaviour in different individuals, remains unknown.

Our team of researchers think that studying the behaviour of human cells in the blood and gut, plus studying diet and gut microbes (bacteria, viruses and fungi) at the time of Crohn's and Colitis diagnosis, and repeatedly over the first 2 years may help to better understand why everyone's experience is so different. We hope that doing this will allow us to work out who most needs treatment early after diagnosis, and which treatment to choose.

We are contacting you prior to your diagnostic tests as we want to identify what factors influence the disease in the very early stages. By enrolling in this study you will be participating in the largest study of its kind related to Crohn's and Colitis.

This Participant Information Sheet outlines what taking part in the study entails. It should help you to reach an informed decision as to whether you would like to take part in the study.

Your local hospital research team will get in touch with you to discuss the study. In the meantime, if you have any concerns or questions, you can contact them via the details at the end of this document. Thank you for taking the time to consider participating in the study and be assured if you decide not to join, your care will not be affected in any way.

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Study summary

We are trying to understand why Crohn's and Colitis behaves differently in each person and why certain treatments are effective for some people but not others. To do this we need to collect data from a large number of people with Crohn's and Colitis, starting before they are diagnosed and have not received treatment.

This study involves collecting information and samples from people who have symptoms that mean they might have Crohn's or Colitis:

Up front tests

- We will collect a stool sample, blood sample and you will complete some questionnaires about your lifestyle, diet and the impact of your symptoms.
- We will take additional biopsy samples during your diagnostic colonoscopy (an exploration of the bowel with a flexible camera) that you will have as part of your standard hospital care.

If you are not diagnosed with Crohn's or Colitis

- No further research visits are needed, but we would like to access your medical records later on to collect information on any Crohn's or Colitis-related symptoms or conditions you may subsequently develop.
- You will continue to be seen by the hospital for any NHS tests or follow up you need.

If you are diagnosed with Crohn's or Colitis

- We will collect stool samples and blood samples every three months for the first year and you will be given health questionnaires to complete.
- We will repeat the above every six months for the second year.
- You will have a follow up colonoscopy after one year to check on the health of your bowel.

Taking part in the study will not impact the treatment you receive, however if you are diagnosed with Crohn's or Colitis you may have access to more frequent check-ups and enhanced access to your dedicated Crohn's and Colitis team than if you didn't take part.

How much time does it take to be involved?

Each study visit will take approximately 30 minutes. Wherever possible these visits will be done on the same day as your routine trips to the hospital to minimise inconvenience. Other study activities, such as collection of a stool sample and completion of some questionnaires can take place at home in your own time. Visits involving a colonoscopy procedure are likely to take longer.

What are the benefits of taking part?

This study has been designed with the help of patient advisors living with Crohn's and Colitis from across the UK. They, as well as our group of researchers believe that participating in the Open-IBD research study has some immediate benefits for you if you are diagnosed with Crohn's or Colitis.

By taking part in this study you will have regular face to face reviews with experts highly experienced in the management of Crohn's and Colitis. Dedicated research clinics and/or clinic appointments for this research may mean you will be seen and reach a diagnosis faster than in standard NHS practice. These study reviews can provide you with access to support, knowledge and expertise at regular time points following diagnosis. Regular catch-ups with the research team can provide a level of reassurance and may provide more frequent opportunities to ask questions about your condition then would be routinely experienced in standard care.

In addition, if diagnosed with Crohn's or Colitis, the implementation of regular tests which form part of the research study will provide information about how you are responding to any treatments and potentially identify problems early. This includes a colonoscopy assessment at 12 months after diagnosis to check on the health of your intestine, to check that you are responding to treatment and decide if any further changes to your treatment should be made.

The longer-term benefits of the Open-IBD study are for the wider Crohn's and Colitis community rather than you personally. This study will improve our understanding of the links between gut microbes, genes, diet and Crohn's and Colitis. It also aims to identify how these factors influence an individual's response to treatment. Currently, it can take time to find the right treatment for patients, with medication changing multiple times in a trial-and-error approach. This study seeks to identify, at the time of diagnosis, which patients are likely to develop more complicated forms of the disease and to provide them with the most effective treatments early on. If successful our patient advisors think this could be transformative to the future care of patients following study completion.

What are the possible disadvantages and risks of taking part?

The study involves collection of blood and tissue samples. As with any medical procedure these carry small risks, but we minimise these by having them carried out by qualified and trained hospital staff. These procedures are standard practice whether you decide to join the study or not.

Blood sampling can cause discomfort and may cause a small bruise. Tissue samples (biopsies) are taken as part of your routine clinical care and at the same time some additional samples would be taken and used for the study. When a biopsy is taken, there is a small risk of bleeding (1 in 150 chance) and there is a very small risk that the procedure could create a hole in the bowel (perforation) (1 in 1500 chance).

All risks will be discussed with you before any samples are taken in line with standard NHS procedures.

Where does the study take place?

Study visits will take place at the local hospital where you receive your Crohn's and Colitis care, however lots of the data can be collected at home using online or paper questionnaires.

Do I have to take part?

No, it is up to you to decide whether you want to take part in this study. If you choose not to take part, you will still receive the usual care you would expect to receive from the clinical team at your hospital.

By signing a consent form, this means that you fully understand what taking part in the study means for you. That's why it is really important that you take as much time as you want to read this information sheet and ask any questions.

Will I be paid to do this study?

As a thank you for taking part, you will receive a £50 high street shopping voucher for completing the first study visit questionnaires. If you have a confirmed diagnosis of Crohn's or Colitis you will also receive £25 vouchers after completing your study questionnaires at each of the 3, 6, 9, 18 and 24 month visits, as well as an additional £50 voucher on completion of the 12 months study questionnaires.

Up to £60 in travel costs will be reimbursed during study participation. The total value over 2 years is up to £285.

Who can take part?

In order to take part in the study:

- You must be aged 16 or over.
- You must have tests and/or symptoms consistent with suspected Crohn's or Colitis based on review of your patient record by the research or clinical team.
- You must not have had a Crohn's or Colitis diagnosis confirmed previously.
- You must not have been treated previously for Crohn's or Colitis.

Why are we doing the Open-IBD study?

Around 25,000 people are diagnosed with Crohn's and Colitis each year in the UK. This is likely to rise in the coming years. Around 1 in 100 people overall will live with Crohn's or Colitis.

A group of treatments called 'advanced therapies' are often used to help manage Crohn's and Colitis. There are a number of different ones, all of which can work very well. However,

1. They do not work for everyone
2. They may become less effective over time
3. Later treatments may work less well after poor response to initial treatments

This can make life difficult as it may take time to find the right treatment for you and it may mean changing treatment multiple times. During this period, patients may experience uncontrolled symptoms and unnecessary side effects which can negatively impact their quality of life.

Many studies in Crohn's and Colitis focus on people who have had the condition for some time, usually many years, and have already received some treatment. The features responsible for the disease beginning and which treatments are best suited to each person may be harder to identify so long after diagnosis. Therefore, we crucially need to understand what factors are involved when people are first diagnosed and how this influences their disease behaviour and response to treatment over time.

In order to do this, we need to collect information about your health and your lifestyle by doing questionnaires, checking your medical notes, collecting samples and analysing biological markers in your blood, stool and biopsy tissue.

We aim to collect this information and samples from 1,000 people with Crohn's and Colitis. We will also use the information collected at the beginning from those patients who enter the study but don't go on to be diagnosed with Crohn's or Colitis (approximately 1,000), and will collect further information from medical records after 3, 12, 24, 36 and 48 months. Comparisons between people with and without Crohn's or Colitis may help us in future to predict who could go on to develop Crohn's or Colitis or other related conditions.

What does taking part in the study involve?

If you agree to take part, you will be asked to sign a consent form either before or during your first clinic visit. This can be done remotely on an electronic device or can be completed on a paper form. We will therefore ask you to provide your email address.

Alongside the standard procedures that will be undertaken to assess your symptoms and whether you have Crohn's or Colitis or not, we will collect some information for research purposes. This will include information about your health and medical history and some questionnaires looking at your symptoms, physical activity and diet. We will collect a blood sample and provide you with a kit to collect a stool sample at home and post it directly to our lab. Additionally, when you undergo a colonoscopy procedure, some tissue samples (biopsies) will be collected, and we would like to take some additional samples for research purposes.

If after this initial visit you are diagnosed with Crohn's or Colitis, you will be invited to attend 6 clinic visits over the next 2 years where you will be asked to complete similar questionnaires and provide further blood and stool samples as shown in diagram (**Figure 1**) below. You will be asked to have a follow up colonoscopy after 12 months, with biopsy samples taken. All visits will be carried out under the care of the clinical team at your hospital who are involved in this research study. You will therefore receive regular check-ups from a dedicated team of specialists throughout your involvement in the study.

If you are not diagnosed with Crohn's or Colitis after the initial visit, you will not need to provide any further information or samples directly. However, we would like to collect valuable information about any Crohn's and Colitis symptoms or subsequent related conditions from your medical records after 3, 12, 24, 36 and 48 months. Please note, whilst not being diagnosed with Crohn's or Colitis would mean you are no longer actively take part in the study, you would be fully supported in the usual way from your healthcare team with whatever follow on care or investigation is needed.

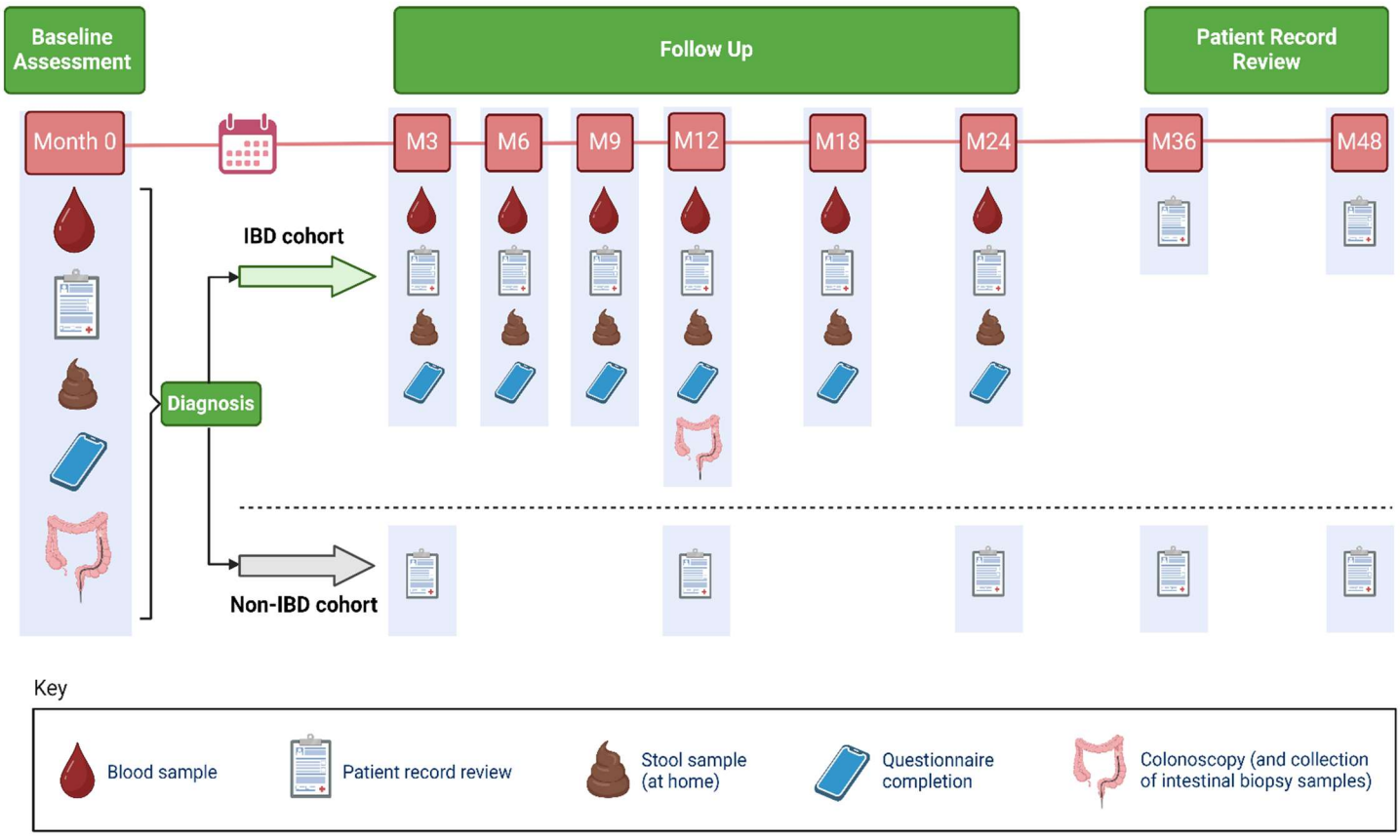

Figure 1. Timeline of Open-IBD study activities

More detail about what information and samples will be collected at each visit is provided below. This applies to all patients at the baseline (pre-diagnosis) visit. If you are then confirmed to have Crohn's or Colitis, you will be asked to attend at 3, 6, 9, 12, 18 and 24 months after the first visit. At each of these time points the following activities will take place:

- **Collection of health and demographic information**

We will collect some information from your medical notes including relevant medical history, current and previous medications and lifestyle details such as smoking habits, employment, education or training details. We will also collect the first part of your current postcode. These details will be collected by the team at your local hospital using your medical notes, however you may be asked to confirm answers to questions the research team are unsure about.

Information from your medical notes regarding related conditions, symptoms and treatments will also be collected at 3 and 4 years after the initial visit for those diagnosed with Crohn's and Colitis. People not diagnosed with Crohn's or Colitis will have this information collected from their medical notes at 3, 12, 24, 36 and 48 months. This will involve the research team at your hospital remotely accessing your medical record and you will not be required to visit the hospital or answer any questions.

- **Questionnaires**

We will ask you to complete a series of questionnaires. There are 10 in total, and they include questionnaires about symptoms, fatigue, stool consistency, as well as the impact that your condition is having on your quality of life. Additionally, we will also ask questions about your physical activity levels and how often you eat certain foods.

Most of these questionnaires can be completed very quickly. The questionnaire about your diet can take approximately 30 minutes to complete, however this one will be collected every 6 months in year 1 and annually in year 2 rather than at every visit. If English is not your primary language, some questionnaires may be available in additional languages.

If you do not complete all of the questionnaires during your study visit, they can be completed from home either on your own mobile device, on paper, or by giving answers over the phone to a member of the research team. You will receive reminders by email as a prompt if you have uncompleted questionnaires after your visit.

- **Blood Samples**

You will be asked to provide a blood sample at each visit. We will collect approximately 20 ml of blood (approximately 4 teaspoons), which will be sent by the study team at your hospital to the Open-IBD team at the Wellcome Sanger Institute labs in Cambridge. Your samples will be labelled with a unique study ID number, meaning that no personally identifiable information is associated with your sample. Researchers at the Wellcome Sanger Institute will look at the genetic information in the cells within your blood sample. The remaining blood (including plasma, the liquid part of blood that carries the cells) will be stored for further analysis and then sent to Newcastle University for biobanking (storing for future research use).

- **Stool Samples**

You will be asked to provide stool samples at each time point using a home collection kit provided by the study team at your hospital. The kit may be given to you when you are at the hospital or it may be sent to you by post. The kit will contain all you need to collect a stool sample at home, including

instructions. You will be asked to collect stool from one bowel movement and transfer a small amount into 3 different tubes using the equipment provided.

The kit will contain pre-addressed, freepost return packaging that you can use to post your stool sample to the Newcastle University research laboratory using a regular post box. The samples will be analysed to look at inflammation levels and gut microbes then biobanked (stored for future research use).

- **Biopsy samples**

One of the tests you will undergo when under investigation for suspected Crohn's or Colitis is a procedure using a camera to examine the bowel called a colonoscopy. Samples of tissue are already routinely taken during these procedures as part of standard NHS care, but if you agree to take part in this study, we will ask for additional biopsy samples to be collected. We will ask to collect up to 16 additional samples in total from the parts of your bowel affected by suspected Crohn's or Colitis. While the colonoscopy test can be uncomfortable, the process of taking biopsies is painless to the patient.

If it is confirmed that you have Crohn's or Colitis and you are still taking part in the study, you will be asked to have this same procedure 12 months after your first visit, where further biopsy samples will be collected. Although having a colonoscopy at 12 months after diagnosis is not currently standard practice, it is considered to be a feature of high-quality care and will give more accurate information about the activity of your disease.

Biopsy samples will be sent to the Wellcome Sanger Institute and Newcastle University for analysis. Any remaining biopsy tissue will be anonymously stored at Newcastle University for use in potential future research (biobanked).

If you are booked in for a colonoscopy at the same time as your study visit, we will ask you to collect your stool samples and complete the questionnaires before your colonoscopy. This is because the bowel preparation/cleansing that you need to take for the procedure may have an impact on your gut microbes. In some cases your clinical team may choose to do a shorter camera test than a colonoscopy, called a flexible sigmoidoscopy which only goes part way round your bowel. Research biopsies can be collected during this test instead.

- **Study updates and feedback**

We would like to keep you updated with study progress and key milestones, as well as results and outcomes. We may also want to ask you for feedback on your experiences of taking part in Open-IBD. This is optional and will not affect your participation if you do not wish to take part in this aspect of the study.

What else do I need to know about taking part?

- **Scans and endoscopy images/recordings**

If you agree to take part in the study, we will ask your permission to access and store images or video recordings from scans (e.g. MRI, CT or ultrasound) or endoscopy procedures (e.g. colonoscopy, flexible sigmoidoscopy, gastroscopy, enteroscopy or capsule endoscopy) performed prior to, or during the study. These images/video recordings will be stored securely and used for research purposes only.

- **Pregnancy**

If you are pregnant or become pregnant while taking part in the study, you can still take part. You will be asked to let the study team know that you are pregnant, and to let us know about any changes that may be made to your medications during or after pregnancy.

- **Surgery**

If you undergo any IBD-related surgery while taking part in the study, we will ask your local study team for information about this operation.

- **Hospital admissions**

If you are admitted to hospital on account of your symptoms you may still be eligible to take part in the study even if you have already received some treatment or had an endoscopy test.

Will my GP be informed of my participation in the study?

If you agree to take part, with your consent we will send your GP a letter informing them that you are participating. This is so that your medical records at your GP practice and in the hospital contain documentation that you are taking part in a research study. Any clinical test results from taking part in the study will be added to your medical notes at the hospital.

We may also collect further information from your GP medical records after 3, 6, 9, 12, 18, 24, 36 and 48 months if not available from your medical notes at the local hospital.

What will happen to me when the study ends?

You will continue to receive standard care in line with any other patient with your condition, under the care of your doctors and specialist nurses. For most study participants this will be at the same hospital and with the same clinical team.

What if I change my mind?

Even if you agree to take part, you can change your mind and withdraw from the study at any time by getting in touch with your site team. Your treatment will not be affected, and you will continue to receive the usual care you would expect from your Crohn's and Colitis team. You do not need to explain the reasons, but it is helpful to the study if you do. If you do withdraw from the study, we will keep the information and samples collected from you up to the point of withdrawal. We will ask for your consent to continue to collect data recorded in your NHS medical records until the study ends. This is because this information is still very useful to us.

What if something goes wrong?

If you have a concern about any aspect of this study, you can speak to a member of the Open-IBD study team at your hospital, who will do their best to answer your questions. Further contact details are included at the end of this information sheet.

If you are still unhappy and wish to raise your concerns with someone who is not directly involved in your care and you are based in England or Wales, you can contact your local Patient Advice and Liaison Service (PALS). You can find your nearest PALS office on the NHS website, or ask your GP surgery, hospital or phone NHS 111 for details of your nearest PALS. If you live in Scotland, you can contact the Patient Advice & Support Service (PASS), website www.pass-scotland.org.uk or phone 0800 917 2127.

In the unlikely event that you are harmed during the study and this is due to someone's negligence (they were careless) you may have grounds for legal action and compensation, but you may need to meet your own legal costs.

The Newcastle Clinical Trials Unit, part of Newcastle University, are managing the study on behalf of The Newcastle upon Tyne Hospitals NHS Foundation Trust. Newcastle University also has insurance arrangements in place to cover Newcastle University staff involved in designing and managing the study.

What will happen to the results of the research study?

The results will be analysed and written up in medical journals and presented in meetings to other doctors, nurses, researchers and patients. A report will also be written for the study funders. Individual feedback will not be able to be provided at the end of the study, however a summary of the study findings will be completed and available to all participants. All study data that is published will be anonymous so your identity will always be protected. An easy to understand summary of our findings will be published on our website at https://www.open-ibd.org/.

While you and your care team may be able to access some of the results of assessments carried out during the study, Open-IBD will not routinely provide feedback on individual genetic, or other results from samples taken for research purposes. The research analyses we undertake in this study can take many years to complete. They are not designed to make clinical diagnoses or influence your care. In the unlikely event that an abnormality is identified through analyses carried out on your samples or questionnaires during the study or later, which the study team believes is important for your Crohn's or Colitis management, or that indicates you may be at increased risk of a disease relevant to your future health, your clinical care team or GP may be notified. You may then be asked to provide further information or additional samples to be sent to an accredited NHS diagnostic laboratory to seek confirmation of the result discovered on your research sample.

How will my samples be used?

We want to know how your human cells in blood and in the gut and how gut microbes and other components of stool influence the behaviour of Crohn's and Colitis and other gut conditions. We want to know how these factors influence the start of disease, how well you respond to different treatments and to see if this knowledge can help develop new treatments. As your genes, immune system, microbes, the environment you live in and the foods you eat may all be important, it is crucial to look at the whole picture, and in a large number of people.

Genes are made up of DNA codes which we can find in your body's cells. RNA, a molecule similar to DNA, converts this code to control how cells behave. When you give us a blood, stool or biopsy sample, we separate out the DNA and RNA from the samples, analyse it, and store this information

safely. This allows us to identify genes in human and microbe cells that may be important in determining how you respond to a treatment.

We may also look for other things in your blood, stool and biopsy samples now or in future using stored samples. Examples of other research includes looking at:

- Different types of cells such as those involved in the immune system and stem cells
- Proteins such as antibodies
- Metabolites (molecules that form from chemical reactions in your body)

We may also grow some cells from your biopsies, called organoids. Organoids are 3D models of cells that grow from the cells present in biopsy samples collected during colonoscopy, they imitate the environment inside of the gut. These may be used to study how different cells of the intestine behave and interact with one another and/or other microbes, metabolites, medications or food. Future research with organoids could help us to better understand the causes of Crohn's and Colitis and how to develop or test new treatments. Studying organoid models also helps avoid the use of animals for medical research.

Could any of my other samples be used in the study?

We may contact your local site team and local NHS archives to access biopsy or surgical samples, including digital images, that have previously been taken or are taken as part of your standard care during the study period. We will follow all the required processes set up by the NHS archive and ensure your samples are treated with care.

What happens to my samples and data after the study?

Samples will mostly be analysed by the Open-IBD team at Newcastle University, the Wellcome Sanger Institute, Cambridge, plus other universities and hospitals around the UK, in London, Exeter, Cambridge and Edinburgh. Other centres in the UK or abroad will also analyse and be able to apply to work with study data or samples. These centres include research institutions like universities and hospitals and commercial institutions like pharmaceutical companies. Use of study samples will be overseen by a study sample access committee. The committee will include researchers and Patient and Public Involvement and Engagement (PPIE) group members who will review and approve applications to use samples.

At the end of the study all remaining samples will be transferred to the Newcastle Biobank for long term storage. The samples will be anonymised and any information regarding your identity will be removed. Organoid samples will also be kept and used for future research at the Wellcome Sanger Institute following completion of the study. Samples will be registered on the appropriate national directories and stored indefinitely.

Samples within the Newcastle Biobank or the Wellcome Sanger Institute will mostly be used by research teams in the UK. In some cases, researchers located overseas may wish to use these samples. The samples may be used by commercial partners. Any benefits from these will be used to directly improve patient care or enable us to conduct further research. Under UK law, sample donors are not entitled to a share of any profits which may result from this activity. Samples collected from this study will not be used for any animal testing or animal research.

Could the study period be extended?

We hope this study will provide valuable information about how Crohn's and Colitis behaves over time. Therefore, if at the end of the current study period, further funding can be obtained we may apply to extend the study period, perhaps for at least 10 years. If this occurs, we will continue to have access to your medical records, scans, endoscopy images and to any biopsy or surgical samples taken as part of your routine care. You would not need to be involved in further research sampling or questionnaires.

Will my taking part in this study be kept confidential?

Yes. You will not be named in any results, reports or on websites.

All the information that you provide during the course of this study will be securely stored. Paper copies of your study information will be stored in locked files or rooms at your local hospital. Electronic copies of your study information will be stored on a secure, password-protected computer database provided by Ennov. Only authorised members of the study team at the hospital and Newcastle Clinical Trials Unit will be granted access to the database.

Some parts of your medical records and the data collected for the study will be looked at by authorised persons from the Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle University and/or the Newcastle Clinical Trials Unit to check that the study is being conducted to the correct standards. All will have a duty of confidentiality to you as a research participant.

The study team at your hospital will have access to your information during the study to organise planned visits as well as for ongoing safety. Very occasionally, information might be given during the study that we would have a legal obligation to pass on to others, for instance information which suggested you or others were at risk of harm. In this case, confidentiality would be broken so that we could pass this information to the relevant people. You would be informed of this.

At the end of the study, all study information will be kept in a secure storage area (this is called archiving) for at least 5 years. This makes sure any queries about the running of the study have been answered. All information will be held securely to make sure we protect your confidentiality, after which it will be safely destroyed. Anonymised data and samples from this study may be stored indefinitely to answer additional research questions and to benefit future research studies.

Who has access to my data?

Data about you e.g. personal details and information about your health, will be stored in secure electronic databases. You will be given a unique study ID code, which will be used to identify your samples and data without using any personal details. Any information from analysis (genetic and other tests) will be stored separately from your personal details using the unique study ID. Access to your personal details will be available to authorised members of the local study team (for example, your treating clinician and research nurses at site).

Data collected to confirm your consent to participate will be stored in a secure electronic database called REDCap. Data collected as part of the study itself will be stored in a secure electronic database called Ennov, using your unique study ID. The staff responsible for managing the REDCap database at The Newcastle upon Tyne NHS Foundation Trust and the Ennov database at Newcastle Clinical

Trials Unit will also have access to some parts of your personal details. Paper copies of questionnaires (if used) will only include your unique study ID and never any personal details.

One of the health questionnaires used in this study asks you to record your current level of anxiety/depression. Should you record being severely or extremely anxious/depressed, staff within the Newcastle Clinical Trials Unit will notify the Principal Investigator at your hospital site, using your unique study ID in order to support you. These investigators have access to the data collected, however this notification is to ensure this is brought to their attention swiftly.

The data collected during the study (which cannot be linked to you personally) will be transferred to Open Targets study partners periodically during the study. These partners include research institutions including universities and hospitals and commercial institutions including pharmaceutical companies. This may include transferring data to partners based in other countries. UK data protection regulations will be adhered to at all times during this process.

Data may also be requested by external researchers during or after the study. Before any of your anonymised data is given to external researchers, the request will need to be considered by the study oversight committee. Under no circumstances will information that identifies you personally, be disclosed.

Every few months and at the end of the study, anonymised study data, including genetic sequencing data, will be uploaded to a public online archiving platform to allow researchers to access anonymised data for any future research and so help the scientific and clinical community to benefit as many people as possible using the data from Open-IBD. Online archiving is considered best practice by funding bodies and research journals.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- In our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to the Sponsor Data Protection Officer at nuth.dpo@nhs.net

Who is organising and funding the study?

- **Chief Investigator**

The doctor in charge of the study is Professor Chris Lamb, a Consultant Gastroenterologist and Clinician Scientist. He works for the Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University.

- **Study Sponsor**

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the study Sponsor and has responsibility for the study. The study is managed by the Newcastle Clinical Trials Unit, Newcastle University, on behalf of the Sponsor.

- **Study Funder**

The study is funded by Open Targets (https://www.opentargets.org/), a public-private partnership that includes funding from charities and pharmaceutical companies. Open Targets aims to use genetic data to identify targets for new drugs with the goal of discovering new medicines.

- **Open-IBD team**

The Open-IBD study team includes doctors, nurses and scientists from hospitals, universities across the UK and other research institutions, like the Wellcome Sanger Institute. We will work closely with our funder, Open Targets and the scientists who work at Open Targets partners (https://www.opentargets.org/) so the research undertaken in Open-IBD has the greatest chance of benefiting patients in the future.

Who has reviewed this study?

The study has been reviewed by an NHS Research Ethics Committee and the Health Research Authority (HRA). They need to be satisfied that your rights will be respected, that any risks are balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision to take part or not. The committee agreed that it is ethical to proceed.

The Newcastle Upon Tyne Hospitals NHS Foundation Trust has reviewed all the study documentation and assessed the risks of this study as part of their responsibility as study Sponsor.

Further information and contact details

If you have any further questions or would like any more information about the study or the rights of participants, please find your local contact details below:

[Please ask your local Open-IBD hospital site for contact details]

Thank you for reading this information sheet