<TO BE PRINTED ON TRUST HEADED PAPER>

Optimisation before Crohn's surgery using Exclusive Enteral Nutrition (OCEaN) Study

Participant Information Sheet

Including immunological sub-studies

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1. Invitation and brief summary

The OCEaN research team would like to invite you to take part in our research study. You are being invited because you are due to have an operation for Crohn's disease. This study aims to find out whether a special form of diet consisting of liquid food only (i.e. special nutritional drinks) before your operation improves your recovery and reduces your risk of complications such as infection and stoma formation. Whether you take part in the study or not is entirely up to you.

This participant information sheet is to help you decide whether you would like to be involved. A member of our research team can go through this with you and answer any questions. You will be given time to think about this and talk to others if you wish.

2. Purpose and background to the research

Crohn's disease causes inflammation, ulceration, bleeding and narrowing of the bowel (gut). People can have periods of good health ("*remission*") as well as times when symptoms are more active ("*flare ups*" or "*relapses*"). Medications can help keep it in remission, but at least one third of people will need surgery to remove part of their diseased gut at some stage.

Previous studies suggest that a special liquid diet might help improve recovery from surgery and reduce complications. This diet is called “exclusive enteral nutrition” (EEN) because it is the only form of food taken for a period of time. In active Crohn’s disease, we know that this special liquid diet can improve symptoms, reduce inflammation and heal the gut as effectively as steroids. In this study, we are looking at whether 6 weeks of the special liquid diet (EEN) before your operation might help you recover quicker and make the operation safer with less chance of complications. This special liquid diet will be your only source of food for 6 weeks. Previous studies on this were too small, not well-designed or not planned in advance to find out how well this special liquid diet works.

This study aims to answer these questions and potentially change the way clinicians treat people prior to Crohn’s surgery in the near future. We will recruit 618 patients from across the UK who are due to have surgery for Crohn’s disease to remove or repair part of their diseased gut.

3. Why have I been invited? Can I say no?

You are being invited to take part in this study because the doctors who are involved in your care are planning an operation to remove or repair part of your bowel which is affected by Crohn’s disease.

The decision to take part in this study is entirely your own choice. You do not have to take part if you do not want to and this will not affect the standard of care you receive. If you decide not to take part, you don’t have to give a reason why. Before you decide whether or not you wish to take part, please read the information provided below carefully and discuss it with your family, friends, GP or anyone else you choose to. Please take time to ask questions about the study, do not feel rushed or under any obligation to make a quick decision. If there is anything that is not clear, please speak to a member of the research team.

4. What would taking part involve?

If you do decide to take part, the local research team will ask for your consent and you will be given this information sheet and a copy of the consent form to keep.

Your consent form will stay on record in the study file and your medical records and be available for review by the trial monitors. With your permission, a copy of your signed consent form will also be sent to the OCEaN Study Office at the University of Birmingham. During the course of the study, you will be asked to confirm your willingness to continue.

How and why you are put into a group and what is the difference?

If you agree to take part, a computer will randomly assign you to either a special liquid diet (EEN) before your operation or staying on your usual diet. You have a 50:50 chance of either.

The researcher will let you know which group you have been put in to. Neither you, the researcher nor the clinical team can choose which group you will be in. This process ensures there is an equal chance of being placed in each of the groups and is the best way to make sure that there is a fair comparison between the two groups. It is also very important for the validity of the study findings.

Before your operation

For all those taking part (both groups):

- As far as possible, we will ensure that you do not come to hospital for any research visits. We will get the information we need during your usual visits or via telephone or video call.
- The information we will collect include your weight, height, blood and stool tests results. We will collect this at the start of the study and 5-6 weeks after starting either the special liquid diet or normal diet.
- You will be invited to fill out questionnaires at the start of the study and prior to your operation. This can be done online, on paper or over the phone with your research team – whichever you prefer. If you prefer to complete the questionnaires online you will receive a link via email or mobile, depending on your preference. If your preference is to complete on paper, the questionnaires will be sent to you in the post.
- We will look at your notes to get information about your medical history, what treatments you have already had and may ask you to clarify anything which isn't clear.
- You will be asked to provide a stool sample before you start on the study and 5-6 weeks after starting either the special diet or normal diet. We will send you a special kit to collect your stool sample and instructions on how to return it using a pre-addressed and postpaid envelope. Your stool sample will be sent directly to the University of Glasgow.

Special liquid diet group:

- If you are in the group taking the special liquid diet, you will be seen by the hospital dietitian. They will help you find a liquid diet that you can manage as the only source of food for six weeks, **no solid food is allowed**.
- If there isn't a hospital dietitian available, then the hospital may ask our dietitian/nutrition researchers based in Glasgow to contact you. They will discuss the different options available for the special liquid diet and then send you some taster samples to try at home. Once you've had a chance to try them, they will contact you to

find out which ones you like and then ask your GP and/or hospital consultant to write a prescription for the ones you like best.

- You should only start on your special liquid diet six weeks before your planned operation. If your operation is delayed by up to six weeks, we will support you continuing on the diet if you think you can manage it.
- There are a number of types of liquid diets available and so if you don't like one, there are other ones you can try.
- We will provide you with participant support sheets for the liquid diet.
- We have an online support website where you will be able to get information on managing the special liquid diet. You can also get support from others involved in the study. We understand that it can be difficult to stick to a liquid diet for six weeks so we want to offer you as much support as we can.
- Ourdietitian/nutrition researchers in Glasgow will contact you to check how you are managing with this diet. This will happen approximately twice. The first time will be 1-2 weeks after starting the diet and again 5-6 weeks after the start of the diet. This discussion will take around 15 minutes.
- Your local dietitian will support you during this study too.

Standard care / normal diet group:

- If you are in the normal diet group, you may still see a dietitian for advice if your clinical care team feels you need it. You should carry on eating and drinking whatever you would usually eat and drink for the six weeks before your operation. If your dietitian gives you any additional supplements you should take these.

Additional information regarding the online support website:

- If you are in the group taking the special liquid diet, you will be encouraged to access the online support website to help you with this.
- This website has been specially created to support participants of this research study, and only those taking part in the study and on the special liquid diet will have access to it. The website is not publicly accessible.
- The website has been created via a third party, (FutureLearn Ltd). In order for you to have access to the website we will need to share your name and e-mail address with FutureLearn Ltd, so that you can be sent a link to set up an account. We will ask for your permission to do this.
- There is a weekly automated email sent to participants.

During your hospital stay

At the time of your operation, we will ask your surgeon to provide information about your operation, such as whether you had a laparoscopic (keyhole) or an open operation. We will also ask them to measure and record how much bowel they removed. After the operation

we will collect information on how long you have stayed in hospital and whether you have had any complications. We will be using the *Quality of Recovery-15* questionnaire to collect some of this information. This questionnaire will take approximately 5 minutes to complete and can be completed on paper or over the telephone with the nurse.

After your discharge from hospital

After the operation, you will be followed up for 12 months as part of the study. During this time, you will be invited to fill in a number of questionnaires which can be done online or on paper. If your preference is to complete on paper, the questionnaires will be sent to you in the post.

- *CLIQ* - this questionnaire will be completed every two weeks until 12 weeks after your operation. Then it will be every month for another 3 months and then a final questionnaire at 12 months. This questionnaire will take approximately 10 minutes to complete.

- *EQ-5D-5L* – this questionnaire will be completed 6 weeks, 6 months and 12 months after your operation. This questionnaire will take approximately 5 minutes.

- *Health Resource Use* – this questionnaire will be completed 6 months and 12 months after your operation. This will take approximately 20 minutes to complete.

We will also look at your medical records to get the results of blood, stool tests and any colonoscopies or imaging that you have as part of your routine care and follow-up. This will be for up to one year after your operation. Your participation in the study ends 12 months after your operation.

To make it easier for you to keep track of what needs completing when, we have created two checklists – one for if you are assigned to the special liquid diet and another for if you are assigned to stay on your usual diet. The checklists can be found at the end of this document.

Stool sample collection

You will be asked to provide a stool sample at four timepoints: when you enter the study (baseline sample), 5-6 weeks after starting the special liquid diet or normal diet (pre-operative sample), 6 weeks after your operation and 6 months after your operation. We will send you a special kit to collect your stool sample and instructions on how to return it using a pre-addressed and postage paid envelope. Your stool sample will be sent directly to the University of Glasgow. As a thank you, you will receive a £25 shopping voucher for every stool sample that you complete as part of the study. Once the University of Glasgow has

confirmed receipt of your stool sample(s), you will receive the shopping voucher in the post or electronically (depending on your preferred method of contact).

Microbiome study

Your stool samples will be used to understand the effect of the special liquid diet on the bugs (bacteria) normally living in our gut using analysis of their genetic material (i.e. bacterial DNA). We will study if certain bacteria and the molecules they produce can tell us which patients with Crohn's disease will get better and who will not during treatment with the special liquid diet and after the operation. Analysis of samples will take place primarily at the University of Glasgow. Part of your stool samples will be sent to the University of Strathclyde and Czech University of Biological Sciences, Prague who specialise in the analysis of gut bacteria. Data from this analysis will also be shared with the Earlham Institute, Norwich UK. Samples will not bear any personal or identifiable information about you, nor will you be able to be identified by any type of analysis we will carry out. Samples will be stored at the University of Glasgow anonymously, bearing a unique participant identifier. Analysis of gut bacteria will be done for research purposes only and will have no implications or importance for your disease progression or the treatment you receive from your healthcare professionals. We will also ask for your permission to store and use your samples in future studies to explore the role of gut bacteria in Crohn's disease.

Optional extra studies

- ### Qualitative Research Interviews

We want to understand your experience of being involved in this study. The person talking to you about taking part in OCEaN will also ask if you are potentially interested in talking to a researcher based at the University of Birmingham about your experience of the study and also of the diet you have been on before your operation. This will provide really valuable information about the views of people who take part in OCEAN, about diets before the operation, and help us to improve the study going forward.

If you are interested you will be given the qualitative information sheet and will be asked to provide contact details so that the researcher can talk to you about it more.

Some people find that it is a really useful opportunity to talk about their views and experiences of the study with a researcher. All discussions are confidential and the findings from these research interviews are reported in a way that nobody will be able to identify you individually. Nothing you say will be directly reported back to those working on the study at your hospital, or the doctors involved in your treatment.

- ### Crohn's Optimisation and Surgical Timing (COAST) study

You may be invited to participate in an additional study which asks questions about your food intake and the psychosocial aspects of eating (food-related quality of life) before and after the operation. The COAST study will help us identify if diet and food-related quality of life change after the operation and whether a special liquid diet is helpful. If you are interested in taking part you will be given the COAST information sheet. If you agree to take part, you will be asked to complete the following questionnaires online (or on paper) when you start the study, and then 6 weeks and 12 months after your operation.

- *Food frequency questionnaire (FFQ)* - this questionnaire contains a list of foods for participants to tick their usual frequency of consumption of each food and some additional questions on the types of some commonly eaten foods.

- *Food-related quality of life in IBD (FRQOL)* – this is a questionnaire that measures the psychosocial aspects of eating.

- **Immunological sub-studies**

You may be invited to take part in the optional immunological studies, which will be looking at changes to your tissue and blood whilst being on the special liquid diet or normal diet. If you agree to take part in these additional studies then blood samples will be collected at the beginning of the study and at weeks 5-6 of your special diet or normal diet. You will be required to come in person to the hospital to have your blood collected at weeks 5-6 of your special diet or normal diet. Your blood samples will be sent to the University of Glasgow laboratory, study collaborators or other laboratories providing similar analysis within the UK/EU.

The tissue samples will be collected from your gut at the time of your operation and at your colonoscopy 6-12 months after your operation. All samples will be labelled with a unique participant identification number. Your tissue samples will be sent to the University of Birmingham laboratory for analysis.

5. What are the possible benefits of taking part?

Although the special liquid diet is an established treatment for active Crohn's disease in children, we cannot guarantee any specific benefit to you by taking part in this study. However, it may be helpful for future patients undergoing surgery for Crohn's disease. If this study shows this special liquid diet is helpful in improving recovery after surgery, the plan is for it to be offered to all Crohn's patients having surgery in the NHS.

6. What are the possible disadvantages and risks of taking part?

Taking part in this study means that you might have a different form of food. If you are allocated to receive the special liquid diet, this diet will provide you with all the energy and nutrients that your body needs. There is a small risk that if you are unable to manage the special liquid diet, you may not get all of the nutrients your body needs. If this happens, you need to discuss this with your dietitian so they can find you an alternative.

If you cannot manage any of the liquid diets available, you can come off the study at any stage and continue on your standard clinical care.

Some patients find a liquid only diet gives them looser or harder pale stool; this is normal and it is not a reason for concern. If a member of the research team thinks that you should withdraw from the study, he/she will explain the reasons and arrange for your clinical care to continue.

Listed below are some of the most common side effects of a liquid diet:

- Feeling Hungry
- Bloating/wind
- Looser stool or urgency to open bowels
- Headaches/irritability
- Weight changes

The unwanted side-effects often improve as your body adjusts to the liquid diet, but speak with your medical team if any side-effects continue or become troublesome.

7. Pregnancy and Breast-feeding

As EEN is a different (liquid) form of food, there are no known safety concerns for pregnant women or baby.

If you become pregnant during the study, please inform a member of the research team. Your research team will need to reassess your dietary requirements. Your need for an operation or other medical treatment will be reviewed by your medical team.

You will continue to be followed up in the study. Additionally, we would like to follow up on your pregnancy and will ask for your permission to collect follow-up information on your pregnancy and the health of your baby.

8. Who is organising and funding the research?

The research is being funded by the National Institute for Health Research (NIHR) Health Technology (HTA) Programme (which is part of the NHS) and is being sponsored by The University of Birmingham (UoB), which has certain legal and ethical responsibilities for the

study. This study is being coordinated by Birmingham Clinical Trials Unit (BCTU), which is part of UoB.

The study is being organised and developed by University Hospitals Birmingham, University of Glasgow, Kings College London and BCTU. The medical team at your hospital is not being paid for its role in the study i.e. there is no financial incentive for including you in this study.

9. How have patients and the public been involved in this study?

Patients with Crohn's disease have been key in designing this study. They led in decisions about what information we collect and which surveys were chosen for the study. They also helped in deciding how long we should use the special liquid diet and how often we ask you to complete questionnaires. These patients also helped design the participant support website for those taking the special liquid diet. A member of this group is also a co-applicant and will continue to be involved.

Patients were also involved in reviewing this Information Sheet. People with Crohn's disease will continue to be involved throughout the study until its completion.

10. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favourable opinion by the Seasonal Research Ethics Committee.

11. Will my taking part in this study be kept confidential?

If you decide to take part in the study, all information collected about you during the course of the study will be kept strictly confidential. Information about your Crohn's disease treatment and follow-up will be sent by your local team to the OCEaN study office at the University of Birmingham. It will be securely stored under the provisions of the 2018 Data Protection Act in the same way as all your other medical records. This will include an electronic copy of your consent form.

Any paper records will be kept in a locked filing cabinet, in a locked room in a University of Birmingham building with controlled access. Any electronic data will be stored securely on University of Birmingham servers that are password protected.

To help protect your confidentiality we will use your unique identification number and not your name.

If you consent in future research, staff may access electronic data from your central NHS records/NHS England. This will provide us with information that is routinely gathered and

stored during your visits to primary care and hospital, and will help us to find out about your health after the study has ended and the long-term effects of the liquid diet. By using routinely collected data we will be able to do this without needing to contact you further. We would need to send your name, gender, date of birth and NHS number with any request for information to the central NHS records. All individuals who have access to your information have a duty of confidentiality to you.

As this is a large important study it might be very helpful to use your data to answer other research questions in the future. Therefore, we may use your anonymized data for other ethically approved studies in the future. Your data will be stored and maybe shared with other researchers but only after the appropriate approvals have been granted.

12. Involvement of General Practitioner / other healthcare practitioner

With your permission, your General Practitioner (GP) will be informed you are taking part in this study. Any other relevant healthcare providers may also be informed. By consenting to taking part, you agree to us sharing your progress in the study with your GP, and other relevant healthcare providers, as needed for your clinical care.

Your GP may be asked to prescribe your special liquid diet.

13. How will we use information about you?

The University of Birmingham is the Sponsor for this study and is based in the United Kingdom. The University will use information from you and your medical records in order to undertake this study and will act as the data controller. This means that the University is responsible for looking after your information and using it properly. We consider the processing of your information to be necessary for the purpose of:

- Carrying out research, which is a task performed by the University in the public interest;
- Scientific or historical research purposes, statistical purposes or archiving purposes in the public interest;
- For compliance with a legal obligation to which the University is subject, for example, retention of records in accordance with good (clinical) practice, inspection or audit.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. More information on how the University processes personal data can be found on the University's website on the page 'Data Protection – How the University Uses Your Data' (http://www.birmingham.ac.uk/privacy/index.aspx).

Should you opt in to SMS communication your mobile number will be shared with a UK-based, GDPR compliant third-party SMS platform to send you text messages for completing the questionnaires. Your data will not be used by the third-party for any other purpose.

Not all of our research team are based in Birmingham. All members of the research team will have access to your data stored in Birmingham, for example, the research nutritionists in Glasgow and data will be shared as part of the study with collaborators in the University of Glasgow and Kings College London.

We will need to use information from you and your medical records for this research study. This information will include your:

- Name
- NHS number
- Contact details (including phone number and email address)
- Date of birth
- Sex
- Ethnicity

People will use this information to do the research or to check your records to make sure that the research is being done properly. They will make sure that relevant information is recorded for your care, and to oversee the quality of the study. Your hospital will pass these details to the University of Birmingham along with the information collected from you and your medical records. Individuals from the University of Birmingham and regulatory organisations may look at your medical and research records to check the accuracy of the research study. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. The only people who will have access to information that identifies you will be people who need to contact you to complete questionnaires or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. The University of Birmingham will keep all information about you safe and secure.

Your name and contact details will only be provided to the study team when essential, in most cases you will be identified by a unique participant identification number.

We may share data about you outside the UK for research related purposes to:

- Learn about the effects of the special liquid diet on the gut bacteria.
- Understand whether a special liquid diet improves recovery post surgery compared to a usual diet.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under

certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following organisation that works with our group:

- Czech University of Biological Sciences, Prague

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

14. What are your choices about how your information is used?

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

15. Where can I find out more about how my information is being used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- In the leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to dataprotection@contacts.bham.ac.uk, or
- By ringing us on 0121 414 3916

16. What if something goes wrong?

Taking part in the study will not affect your legal rights. In the event that something does go wrong and you are harmed during the trial there are no special compensation arrangements. If you are harmed then you may have grounds for legal action but you may have to pay your legal costs. The University of Birmingham has in place Clinical Trials indemnity coverage for this trial which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial.

With respect to the conduct of the trial at Site and other clinical care of the patient, responsibility remains with the NHS organisation responsible for the clinical site and is therefore indemnified through NHS Resolution. The NHS have a duty of care to participants whether or not the participant is taking part in a clinical trial and the normal NHS complaints mechanisms will still be available to you.

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, you should ask to speak to the researchers involved who will do their best to answer your questions (contact details are at the bottom of this form).

If you remain unhappy and wish to complain formally, you can do this through the normal National Health Service complaints mechanisms, this is usually the Patient Advisory and

Liaison Service (PALS) or your hospital complaints service. The contact details can be found on the end of this Patient Information Sheet or via this website: https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/

17. What if I do not want to take part?

If you do not want to be involved in this study or you change your mind at a later stage and want to withdraw, your care will continue with your local team as before. You will not be expected to take any further active part in the study. We will not collect any further data above but data already collected will be stored and analysed as already described.

18. Will my travel expenses be reimbursed?

The follow up visits in this study are routine clinic visits as part of your usual care and can be done remotely so you should not incur any additional travel expenses taking part in this study. Therefore, there is no travel or parking reimbursement available for our participants beyond that normally offered by the hospital.

19. What happens if new information becomes available?

If new information becomes available about diet before surgery during this study, a member of the research team will tell you and discuss whether you should continue in the study. If your research doctor is happy for you to continue, you will have the option to decide whether you wish to or not. A member of the research team may ask you to re-sign a consent form if you decide to continue.

20. What happens when the research study stops?

At the end of the study your usual consultant will continue to look after you.

21. What happens to my samples?

At the end of the study and with your permission, left over stool samples will be biobanked at the OCEaN dedicated freezer at the University of Glasgow, Glasgow Royal Infirmary for future research within ethically approved studies. Samples sent to the University of Strathclyde and Czech University of Biological Sciences will be destroyed once analysis has been completed.

If you have chosen to take part in the immunological studies, at the end of the study and with your permission, left over blood and tissue samples will be stored in freezers at the University of Birmingham and University of Glasgow for future research within ethically approved studies. Blood samples sent to other UK/EU laboratories will be destroyed once analysis has been completed.

22. What will happen to the results of the research study?

The findings of the study will be made public. We would like to publish our results in medical journals and present the findings at conferences, to help other doctors and medical staff learn from the findings and for patients to benefit. All findings will also be written as a formal research report and will be published in a freely accessible journal. No individual participants will be identifiable in any report or publication.

We will write reports on the results of this study and make them suitable for the general public. Our patient group will help us write reports and share on social media as well as patient support groups such as Crohn's & Colitis UK.

If EEN is shown to be effective and make surgery safer or easier to recover from, then widespread uptake can be anticipated across the NHS.

23. How will my personal data be kept secure?

The University of Birmingham takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

The University of Birmingham will keep all information about you safe and secure. In relation to this project, any paperwork containing identifiable data will be kept in an access-controlled and secured room inside a locked filing cabinet. Electronic data will be kept on secure, encrypted IT servers within the University of Birmingham.

24. How long will my personal data be kept?

Your data will be retained for 10 years after the publication of the research outcomes. If you withdraw from the project, we will keep the information we have already obtained but, to safeguard your rights, we will use the minimum personally-identifiable information possible.

25. Who can I contact for further information?

Thank you for taking the time to read this information sheet and for considering taking part in this study.

More information about being involved in research in Crohn's disease can be obtained from relevant charities such as Crohn's and Colitis UK at www.crohnsandcolitis.org.uk.

Should you require further information or would like to speak to someone about the study, or proceed to join the study, please contact a member of your local research team:

Name:	
Job Title:	
Contact Details:	

Alternatively, you can contact the OCEaN study team:

OCEaN study office
Birmingham Clinical Trials Unit
Public Health Building
University of Birmingham
Edgbaston
B15 2TT
Email: ocean@trials.bham.ac.uk.

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Randomised to the NORMAL DIET

Randomisation:

- ☐ Collect baseline data
- ☐ Collect stool sample
- ☐ Questionnaires to complete

Week 5-6 of diet:

- ☐ Collect stool sample
- ☐ Collect blood sample

Prior to surgery:

- ☐ Questionnaires to complete
- ☐ Interview with qualitative researchers *(optional)*

S U R G E R Y

Day 3-5 post surgery:

- ☐ Questionnaire to complete

Week 2 post surgery:

- ☐ Questionnaire to complete

Week 4 post surgery:

- ☐ Questionnaire to complete

Week 6 post surgery:

- ☐ Questionnaires to complete
- ☐ Collect stool sample

Week 8 post surgery:

- ☐ Questionnaire to complete

Week 10 post surgery:

- ☐ Questionnaire to complete

Week 12 post surgery:

- ☐ Questionnaire to complete
- ☐ Interview with qualitative researchers *(optional)*

4 months post surgery:

- ☐ Questionnaire to complete

5 months post surgery:

- ☐ Questionnaire to complete

6 months post surgery:

- ☐ Questionnaires to complete
- ☐ Collect stool sample

12 months post surgery:

- ☐ Questionnaires to complete

Randomised to the EEN DIET

Randomisation:

- ☐ Collect baseline data
- ☐ Collect stool sample
- ☐ Appointment with dietitian
- ☐ Questionnaires to complete

Week 1-2 of EEN diet:

- ☐ Phone call from dietitian

Week 5-6 of EEN diet:

- ☐ Collect stool sample
- ☐ Phone call from dietitian
- ☐ Collect blood sample

Prior to surgery:

- ☐ Questionnaires to complete
- ☐ Interview with qualitative researchers (optional)

Online tool available for support

S U R G E R Y

Day 3-5 post surgery:

- ☐ Questionnaire to complete

Week 2 post surgery:

- ☐ Questionnaire to complete

Week 4 post surgery:

- ☐ Questionnaire to complete

Week 6 post surgery:

- ☐ Questionnaires to complete
- ☐ Collect stool sample

Week 8 post surgery:

- ☐ Questionnaire to complete

Week 10 post surgery:

- ☐ Questionnaire to complete

Week 12 post surgery:

- ☐ Questionnaire to complete
- ☐ Interview with qualitative researchers (optional)

4 months post surgery:

- ☐ Questionnaire to complete

5 months post surgery:

- ☐ Questionnaire to complete

6 months post surgery:

- ☐ Questionnaires to complete
- ☐ Collect stool sample

12 months post surgery:

- ☐ Questionnaires to complete