

**PARTICIPANT INFORMATION SHEET: PART 1 and 2**

Management of diarrhoea in ulcerative colitis: multi-arm multi stage of low FODMAP diet, amitriptyline, ondansetron, or loperamide: MODULATE

You have been invited to take part in a research study called “MODULATE”.

This information sheet will tell you why we are doing the study and what will happen if you decide to take part.

This leaflet is in two parts: we suggest that you read Part One first, and if you are interested in taking part, continue to read Part Two.

Please read this information carefully, and feel free to discuss it with others, if you like.

There are more information leaflets about the treatments you may receive, which will be provided.

If you are interested in taking part, a research nurse will then contact you to talk about the study and answer any questions you may have.Part 1- I am considering taking part

Part 1 will tell you about the purpose of the study, and what will happen to you if you choose to take part.

Part 2- I want to know more

Part 2 will give you more detailed information about the conduct of the study and data protection.

Treatment Information Sheets

The Treatment Information Sheets will give you more details about the treatments available in this study, including dosage and potential side effects.

How to contact us:

If you have any questions about this study, please talk to the research team at

<< Enter research team contact details including phone number and email address>>

Thank you for taking the time to read this information sheet.



Disclaimer: This research is funded by the NIHR HTA 17/33/03. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

PART 1: I am considering taking part

What is MODULATE?

MODULATE (Management of diarrhoea in ulcerative colitis: multi-arm multi stage of low FODMAP diet, amitriptyline, ondansetron, or loperamide) is a clinical research study. MODULATE aims to identify effective treatments for ongoing diarrhoea in people with stable ulcerative colitis (UC).

What is the purpose of this study?

Ulcerative colitis is an inflammatory bowel disease. Some people with UC have difficult, chronic diarrhoea even when they have been told their disease is stable. This can have a huge physical and an emotional impact on people. However, we don’t currently know how best to treat these people.

A potential approach may be to use existing treatments that work in other conditions for example, irritable bowel syndrome (IBS). Many people with IBS also suffer with chronic diarrhoea and there are treatments available to help them. One of those treatments is a special diet known as the low FODMAP diet. Several drugs are also used to treat diarrhoea in IBS, including low-dose tricyclic antidepressants (TCAs), such as amitriptyline, the anti-sickness drug ondansetron, and the anti-diarrhoeal drug, loperamide. All of these treatments are known to slow down the flow of digested food down the gut, improving diarrhoea and other related symptoms.

The MODULATE study aims to find out if these treatments are effective in relieving diarrhoea symptoms in people with stable UC. This is the first study to explore this, and we hope that the results will lead to more effective treatments for this group of patients.

We want to be clear that we are not offering you these treatments because we think you have IBS. There are important differences between IBS and UC. However, it’s possible that some diarrhoea treatments may work for both conditions.

Why have I been invited to take part in this study?

You have been invited to take part because you have UC and you may still be suffering from diarrhoea, despite being on the correct treatment for your disease, and your UC being stable. By ‘stable’ we mean that there is no evidence of inflammation. Your local hospital has agreed to take part in this study. We are hoping to recruit 491 patients from around 26 hospitals across the UK.

What is the standard treatment?

There is currently no established standard treatment for diarrhoea in patients with stable UC. This is why this study is important, as it will provide key information on which treatments are effective in relieving symptoms of diarrhoea in people with UC who display no evidence of inflammatory activity.

What is a Low FODMAP diet?

FODMAP stands for fermentable oligo-, di-, mono-saccharides and polyols. These are types of carbohydrates found in foods. FODMAPs are known to trigger gut symptoms, such as tummy pain and diarrhoea in people with easily irritated guts, such as those with IBS. Food can be classed as high, medium, or low in FODMAPs, depending on the amount of FODMAPs each contains. The low FODMAP diet involves a process of restricting, reintroducing, and then personalising FODMAP intake in order to identify your own tolerance levels, as well as trigger foods. A Low FODMAP diet is recommended for the management of IBS and has been found to improve symptoms in 50% to 80% of people with IBS. We want to find out if this diet can help manage symptoms of diarrhoea in people with stable UC. Patients randomised to this treatment will be given sessions with a specialist dietitian, who has been trained to deliver this dietary approach.

What is amitriptyline?

Amitriptyline is a common drug that has been used for more than 50 years. At a low dose, we believe it helps manage diarrhoea in IBS because it slows down bowel activity. This is why we think it may also help relieve symptoms of diarrhoea in UC. Amitriptyline is sometimes used to treat depression. However, when being used for depression, it is given in much higher doses. This study will only be using small doses of amitriptyline, and the drug is being used because of its impact on bowel activity, rather than mood.

What is ondansetron?

Ondansetron is another common drug, which has been used to treat nausea for more than 25 years. Ondansetron has been tested in a small study in people with IBS and diarrhoea, and the results showed that it improved stool consistency, frequency, and urgency. In this study we want to test the effect of ondansetron in patients with UC with diarrhoea to see if it has the same benefits.

What is loperamide?

Loperamide is a medication that is used to decrease the frequency of diarrhoea. You can buy loperamide from pharmacies and supermarkets. We are testing this drug as we believe that some patients with UC would like to use this drug, but it is not clear whether it is of benefit, so they may receive conflicting advice from doctors.

Am I guaranteed to receive one of the treatments described above?

No, if you are eligible to enter the trial you are not guaranteed to receive the above described treatments. We are also including a group who will continue to receive their usual care (known as a control group). We need a control group so that we can monitor their symptoms and compare them to those people receiving study treatments

What is the control group in this study?

People allocated to the control group will receive a dietary advice sheet designed for people with IBS, containing suggestions that may help improve symptoms of diarrhoea. We will also be giving this sheet to the people in all of the other groups. We ask that you do not adjust or change your diet or medications for your UC in any other way, whilst you are taking part in the trial. This is to make sure that any differences we see in symptoms are due to the treatments people are receiving as part of the trial, and nothing else.

Do I have to take part?

No, your participation is entirely voluntary and it is up to you to decide whether or not to take part. If you decide to take part you will be given this information document and the treatment-specific information documents to keep. You will be asked to complete a consent form, but you are still free to withdraw at any time from the study, without giving a reason.

Your doctor will be happy to talk through alternative treatment options for your UC. Your treatment and care will not be affected in any way.

You may provide consent to take part either face-to-face during a clinic visit, remotely using a paper form that will be sent to you, or you may use an electronic form (e-Consent). If you decide to provide consent remotely, a researcher will send you study documentation and call you to talk through the study and the consent process. The study researchers will ask you to verify your name and date of birth before you give consent.

**Information you should know about consenting electronically (e-Consent)**

The e-Consent process is a bit different to completing a paper form. If you choose to use the e-Consent system, the investigator discussing the study with you will need to enter your details into the e-Consent system before you use it. Your details will include your email address, your date of birth, your initials and NHS number. These are needed so that you can be identified in the system (so that the investigator is looking at your record and not anyone else’s). Your email address is needed so that you can be sent a message inviting you to use the e-Consent system.

If you agree for these details to be added to the e-Consent system, they will also be visible to the team that is running the MODULATE study at the Clinical Trials Research Unit, University of Leeds.

Your details will be held securely and treated confidentially. Please see Section 2 below for more information about how this record of your consent will be stored, if you agree to take part.

If you agree to have your details added to the e-Consent system but you then decide you do not want to give consent to take part in the study, your details will be completely removed from the system and securely destroyed within 30 days of notification.

If you do not agree for these details to be added, you can still record your decision to take part, but you will need to use a paper form and not use e-Consent.

If I want to, will I definitely be able to take part?

Unfortunately, no. Although we think you might be suitable to take part, we still need to carry out some tests, and ask you some questions to make sure it is appropriate for you to take part. These are known as “eligibility screening tests” and are described below. If the eligibility screening tests show that it is not appropriate for you to take part in the study, your doctor can discuss alternative treatment options with you.

What do the eligibility screening tests involve?

If you decide you would like to take part in the study, you will have an initial telephone call with a member of the research team (a nurse) to find out more about you and your UC. Following this, if the nurse thinks you are suitable to take part, a member of your research team will discuss the study further with you and you will be asked if you wish to provide informed consent. If you consent to the study, you will be asked to provide stool and blood samples, and potentially to have a flexible sigmoidoscopy (more info below). If you consent to having your blood and stool samples analysed remotely (see section on “How will my information be used”), we will organise for a stool sample kit and blood sample collection kit to be sent to your home. You will be provided with instructions on how to provide the samples at home. Once you have collected your samples, you will be required to put these in a post-box where they will be sent to Exeter Clinical Laboratory, based at the Royal Devon and Exeter NHS Foundation Trust for analysis. If you would prefer to come into hospital for your bloods, we will post you a stool sample kit before you make a visit to hospital to provide your blood sample. These tests are for your safety, and are to ensure that your UC is stable. We need to make completely sure that your bowel symptoms are not caused by definite uncontrolled activity of your disease. If your gastroenterologist feels uncertain that your UC is classed as clinically stable, then you will have to have a flexible sigmoidoscopy to confirm this before you can take part.

A flexible sigmoidoscopy is a procedure where a flexible, narrow tube, with a tiny camera on one end, is used to look inside your rectum and lower bowel. The flexible sigmoidoscopy will be carried out following a phosphate enema (where fluid is used to gently clean out part of your bowel), so you won’t need oral bowel preparation (e.g. a laxative). We will only do a limited examination of the first 20 cm or so of your lower bowel. The procedure can be uncomfortable, and so you will have the option to have a painkilling injection and a sedative injection beforehand to ensure you are comfortable. These injections will make you feel drowsy and relaxed. This is not a general anaesthetic, and you will not be unconscious, but you may not remember much about the procedure afterwards. You will need to bring a friend or relative with you to help you get home if you choose to have painkiller and sedation. Prior to the appointment, you will be given a card to take with you. This will make it clear to the staff that you have a right to opt to choose painkiller and sedation if you want to do so.

During the sigmoidoscopy, a couple of biopsies (small samples of the lining of the bowel) will be taken using tiny biopsy forceps passed through the tube. These biopsies will be looked at under a microscope. The biopsy is usually painless, and is a routine procedure.

A flexible sigmoidoscopy carries only a very small risk of complications. The main risks are:

* Perforation (tearing) of the lining of the bowel wall (1 in every 15,000). An operation is sometimes required to repair the hole.
* Haemorrhage (bleeding) may occur at the biopsy site (1 in every 1000). This may stop on its own but may require further treatment and an operation may be required.

What will happen to me, if I am eligible and decide to take part?

If the screening eligibility tests show that you are eligible, and you decide to continue into the study, you will then be asked to complete either an online or a paper questionnaire. This will ask you for information about yourself, any past and current medications, how you are feeling, details about your UC symptoms, and how much of an impact your symptoms have on your daily life.

You will then be randomly allocated to one of the treatments listed above. In order to be able to compare the five treatments, we need to place you into one of five groups. The best way to find out which treatments are most effective is to use a randomised study design. This means you will be put into a treatment group by a computer, at random (as if by the roll of a dice); this is called randomisation. Neither you, your health care team, nor the research team will be able to choose which one you receive. For every 2 people who are allocated to the control group, 1 person will be allocated to amitriptyline, 1 person will be allocated to ondansetron, 1 person will be assigned to loperamide, and 1 person will be assigned to a low FODMAP diet.



Will I know what treatment I am receiving?

Yes, the research team will tell you which treatment you have been allocated to. As long as you are in the study, we ask you to stick to the treatment you are assigned to, and not begin any new treatments after you have been randomised. This will allow us to accurately work out how effective each treatment is.

You should refer to the treatment-specific information documents for further details on each of the treatments in this study.

How long will the treatments go on for?

Whichever treatment you are allocated to, we expect your treatment period to last 6 months.

* **Amitriptyline, ondansetron, or loperamide:** If you are allocated to one of our drug treatment arms, we will ask you take your study treatment for 6 months. You will not have to pay for the study drug prescriptions.
* **Low FODMAP diet:** If you are allocated to the low FODMAP diet, you will be asked to follow a low FODMAP diet for 2 months. If you respond to the diet positively for the remaining 4 months you will be asked to reintroduce foods back into your diet to work out which FODMAPs trigger symptoms, and which do not. You will be supported in this by a dietitian.
* **Standard dietary advice sheet:** If you are allocated to the ‘control’ arm, you will be asked to follow the dietary advice on the sheet, but not to make any other changes to your diet or medications for your UC for 6 months.

 What happens if I have a flare?

If you, your doctor, or your study team think you are having a flare, please contact us immediately. We will invite you to an urgent appointment to assess you and discuss your concerns further. At the visit, we will ask you some questions, and ask for blood and stool samples. If the results of your assessments show you may be having a flare, or if you are still concerned, then we will offer you an urgent flexi sigmoidoscopy.

If the sigmoidoscopy confirms a flare, you will be referred back to your own doctor urgently, so that your UC medications can be adjusted appropriately. You would also be withdrawn from the study at this point. The data you have provided up until this point will be kept in the trial.

If the sigmoidoscopy shows no change, then you will be able to stay in the study, if you wish. Your health and wellbeing are the most important things. We will never encourage you to stay in the study if you, or the team, do not believe it is the right thing for you.

Will I need extra hospital visits?

It may be possible for you to take part without visiting hospital. This will involve providing consent remotely and consenting to sharing your name, gender, date of birth and postal address with Exeter Clinical Laboratory at the Royal Devon and Exeter NHS Foundation Trust in order for them to post you your sample packs (see below “How will my information be used?”). If you are randomised to one of the study arms that involves a drug, this can be posted to your home. If you are randomised to the dietary arm of the study, then your appointments will likely take place remotely.

However, if your clinician is concerned that your disease is unstable, you will need to attend hospital for a flexible sigmoidoscopy appointment to prove that this is not the case. If you experience a flare, you may also be required to attend hospital.

What else does the study involve?

* **Phone calls** - during the study you will be contacted via telephone by a researcher about your participation in the study. The frequency and nature of these phone calls will depend on which treatment you are given.
* **Questionnaires -** you will be asked to complete an online or paper questionnaire three times (once before entering the study, once at 8 weeks, and once at 6 months after entering the study). These questionnaires will ask about you, your treatment and the types of food you eat. Please see the diagram below for further details. Some of the questionnaires used in this study will have the term “IBS” in them. This is because these questionnaires were developed for use in IBS and cannot be changed. However, this study is not looking at IBS.
* **Blood tests –** we would like to carry out a blood test before you enter the study (as part of the “eligibility screening tests” - see section 11) and another one after 6 months to monitor disease activity. We will not store the blood samples after testing is complete.
* **Health records-** We may collect information about you from electronic health records, for example previous test results.
* **Stool sample –** we would like to collect a stool sample before you enter the study (as part of the “eligibility screening tests”, see section 11) and another one after 6 months. A stool sample kit will be sent to you in the post for you to provide a stool sample for analysis.
* **Flexible sigmoidoscopy results –** We will collect information regarding the results of your flexible sigmoidoscopy and associated biopsy results, should you need to have this procedure performed.

**Figure 1**

The above diagram (Figure 1) shows your study journey if you are randomised to the dietary advice treatment ‘control’ arm. To see what your journey will look like if you are allocated to the other arms of the trial, please refer to the Treatment Specific Information documents.

Part 2 – I would like to know more

What are the possible disadvantages of taking part?

Taking part in the study will involve time commitments for seeing and talking to the research nurse and/or dietitian, and completing questionnaires. Although the drugs used in this study have been widely used for many years, all drugs can cause side effects. The side effects of these drugs are discussed in the treatment-specific information documents.

The study drugs might harm an unborn baby; therefore you should not agree to take part in this study if you are pregnant, or planning to become pregnant. You should not become pregnant during the study treatment period (this is the case for all study treatment options) or for a safety period of at least 7 days after taking your last study treatment tablet.

You must also agree to use a reliable form of effective contraception during this time. If you do become pregnant during the study, or you find out that you are pregnant within 3 months of finishing treatment, then you please tell the study research team at once.

What are the possible benefits of taking part?

We cannot promise that the study will help you, but you may have improvements in your UC symptoms, and the new knowledge we gain may help others with UC. If the study shows any of our treatments to be effective, they could become widely available to patients in the near future and end up helping many patients like yourself. Taking part in this study will also give you the opportunity to receive extra health checks, via the blood tests and other investigatory procedures. You will also have the opportunity to discuss your UC symptoms more frequently with healthcare professionals.

If you find that the treatment you are given as part of the study is helpful in relieving your symptoms, you may be able to continue on this treatment once the trial has finished. This will be at the discretion of your doctor, and you should therefore discuss this with them after the study.

What if relevant new information becomes available?

Sometimes during the course of a study, new relevant information may become available. For example, new information about the treatments. We will post updates on our trial website and will send you an email, text, or letter if there are any important changes to the study. If relevant, we will discuss with you whether you want to continue in the study. If you decide to continue you may be asked to sign an updated consent form. Occasionally, on receiving new information, your doctor may consider it to be in your best interest to withdraw you from further study treatment.

What will happen if I don’t want to carry on with the study?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. However, we would like to know the reason, if you are willing to provide this. Before deciding to stop, you should talk to your study doctor or nurse. They can advise you and may be able to deal with any concerns you may have. If you decide to stop taking part at any time it will not affect the standard of care you receive.

If you decide to stop taking your study treatment, you are likely to go back to receiving only your usual treatment for UC as per your local hospital practise. If you have extra appointments planned as part of the study and still wish to attend these, this can be arranged. Likewise, if you wish to continue completing any study questionnaires whilst you are no longer on the study treatment, then your answers will still be extremely valuable.

If you decide to stop your study visits or assessments, in order to make sure the research is still reliable, we will need to keep the information we have already collected about you, and include it in the study analysis

Unless you clearly tell us you don’t want us to, we will continue collecting information about your health from routine hospital visits, via your GP or through other contact between you and your hospital. This is to help ensure the results of the study are valid.

Who has organised, reviewed and funded the research and who will be supervising it?

The Chief Investigator is Professor Alexander Ford, based at the University of Leeds. The study is being sponsored by the University of Leeds, and is being organised on their behalf by the University of Leeds Clinical Trials Research Unit (CTRU). The National Institute of Health Research fund the research. All research is looked at by an independent committee of people called a Research Ethics Committee to protect your interests. The study has been reviewed and approved by Leeds West Research Ethics Committee.

What if there is a problem?

**Complaints:**

If you have a concern about any aspect of this study, you should ask to speak with your research nurse who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital or you can contact PALS (Patient Advice and Liaison Service) telephone << LOCAL PALS CONTACT >>

**Harm:**

Every care will be taken throughout this clinical study. However, in the unlikely event that you are injured as a result of the managing organisation (University of Leeds), compensation may be available and you may have to pay your related legal costs. Your hospital where you receive your treatment has a duty of care to you, whether or not you agree to participate in the study, and the University of Leeds accepts no liability for negligence on the part of your hospital. If you wish to complain about any aspect of the way you have been treated please contact your research nurse or doctor in the first instance.

Any claims will be subject to UK law and must be brought in the UK.

If you have private medical insurance, you should tell your insurer that you are taking part in research. They will let you know if it affects your policy.

How will my information be used?

Every effort will be made to ensure the information needed for study purposes will be collected on either online or paper forms and sent (usually using standard Royal Mail post but in some cases by fax or email) from the hospital to the CTRU. You will be allocated a study number, which will be used along with your date of birth and initials to identify you on each online or paper form. Your full name will be included on your consent form and a copy of this will be mailed to the CTRU, so that we can check you have definitely agreed to take part in the study.

Your name and address and email address are collected on a contact details form to enable the CTRU to send study questionnaires, newsletters and updates about the study to you. If you are happy to receive text or email reminders, these contact details are also collected. These details will be provided to CTRU on paper or electronically and stored securely.

If you consent to remote samples, your name, gender, date of birth, and postal address will be provided to Exeter Clinical Laboratory at the Royal Devon and Exeter NHS Foundation Trust, as Exeter Clinical Laboratory are the central laboratory for the MODULATE study and require this information to process your blood and stool samples. They will post packs to your home, for you to collect the samples on your own, which means you will not be required to attend hospital. These samples are required from you to ensure it is safe for you to enter the study. They will be collected again at 6 months, to see if there has been any change in the laboratory values. If you do not wish for Royal Devon and Exeter NHS Foundation Trust to have this information, you will be required to attend your local participating site to give a blood sample and to drop off a stool sample.

Every effort will be made to ensure that any further information about you that leaves the hospital will have your information removed so that you cannot be recognised from it; this information will usually be removed by a member of the study team at your hospital, but may also be removed by the CTRU upon receipt.

Your data will be entered onto a secure database held at the CTRU, and where required, Exeter Clinical Laboratory. Your healthcare records may be looked at by authorised individuals from the research team, the University of Leeds (the study Sponsor), or the regulatory authorities to check that the study is being carried out correctly.

All the information we collect for this study will be made available to other researchers at the end of the study for additional research, including information you have already provided if you stop taking part in the study. However, information will only be shared for worthwhile research projects with appropriate ethical approvals, only in such a way that no individual person can be identified, and only when we are sure the other researchers will manage your data correctly and securely.

As part of this study, we will use some of your information (your name, date of birth, and NHS number and address/postcode) to link to data about you in standard NHS patient registries held by NHS Digital, and NIHR Bioresource.

We will do this because it is a more efficient way to collect certain data about your health. By using data collected from routine health visits, we can reduce the burden (such as the number of hospital visits) on you and your hospital. When we do this linking, we will only use the data mentioned above to identify you, and we will follow strict rules when working with other organisations to maintain confidentiality and to protect your data.

You can find out more about the work of the NIHR Bioresource at <https://bioresource.nihr.ac.uk/>

The low FODMAP diet (which is the dietary intervention we are testing in this study) was developed by researchers at Monash University in Australia. As part of our research, we will be sharing the data from food frequency questionnaires with Monash University to calculate results for this study. No personal details will be shared with them and there is nothing in this information that could identify you. We will not send any other information about you to Monash University. The team at Monash will send us their results so we can use them in the main study. They may conduct further research using the data, but they will not be able to identify anyone from the data sent to them.

**Involvement of the General Practitioner/Family Doctor (GP):**

Your GP, and the other doctors involved in your healthcare, will be informed of your participation in this study.

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal and presented at scientific conferences. The data will be anonymous and none of the participants involved in the study will be identified in any report or publication. The results of the study will be available to you.

Future research

**Using your information for further research**

When you agree to take part in a research study, the information about your health and care, your initials, date of birth and NHS number 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 (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-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.

Information about data protection

University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Leeds will keep identifiable information about you for 25 years after the study has finished.

Your data may be passed to other organisations (possibly in other countries where the data protection standards and laws are different to the UK) to monitor the safety of the treatment(s) that you are receiving; this data will have your name removed.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.

You can find out more about how we use your information at [https://ctru.leeds.ac.uk/privacy/](https://ctru.leeds.ac.uk/privacy/%20.%20)

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that if you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO).

Our Data Protection Officer can be contacted using the following details:

• Email: DPO@leeds.ac.uk

• General postal address: University of Leeds, Leeds LS2 9JT, UK

• Postal address for data protection issues: University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT

• Telephone number: +44 (0)113 243 1751

* Website: https://ctru.leeds.ac.uk/modulate/

**Delete this line, then print on trust headed paper**

|  |  |
| --- | --- |
| Participant ID:  | Initials:  |
| Date of Birth:  | NHS number:  |
| EudraCT Number: 2019-003220-21ISRCTN: 16086699 | Principal Investigator: |

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**PARTICIPANT CONSENT FORM**

***Please initial each box***

1. I confirm that I have read and understand the information sheet dated 08 November 2021 (version 7.0) and all treatment-specific information documents listed below (dated) for the MODULATE study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.

|  |  |
| --- | --- |
| **Title** | **Version and Date**  |
| MODULATE Treatment Information Sheet\_Amitriptyline  |  |
| MODULATE Treatment Information Sheet - Ondansetron |  |
| MODULATE Treatment Information Sheet - Loperamide |  |
| MODULATE Treatment Information Sheet – Low FODMAP |  |
| MODULATE Treatment Information Sheet - REDCap |  |

1. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the above study, the data and samples collected from me will be used in analysing the results of the study and, in some cases, further information about any unwanted effects of my treatment may need to be collected by the study team.
2. I agree to my data (including identifiable data and contact details) being collected and used by the CTRU. I understand they will hold this data confidentially and securely.
3. I give permission to allow the research team and the CTRU to contact me at various time points throughout the study via telephone, text message, email, or post.
4. I understand that relevant sections of my medical records and data collected in the study, may be looked at by authorised individuals from the research study team, from regulatory authorities, and from the study Sponsor, where it is relevant to my taking part in the study. I give permission for these individuals to have access to my records. This may also include anonymised data being sent outside of the EU.
5. I agree for the CTRU to collect information on the outcome of any pregnancy that is recorded whilst I am in the study.
6. I agree for the CTRU to check my address with my GP.
7. I agree for my personal details (which will include my initials, date of birth, and NHS number) to be shared with providers of Electronic Health Records so that information about my healthcare use can be obtained, for future research linked to the MODULATE study, or for other research projects, subject to ethical approval.

1. I agree to a copy of this Consent Form being sent to the CTRU.
2. I agree to my GP being informed of my participation in this study and being provided with a copy of this consent form.
3. I agree to take part in the study.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Study samples**

**I will provide samples (please tick one option)**

 **At hospital Remotely, via Exeter Clinical Laboratory**

**The following point must be initialled if using remote samples via Exeter Clinical Laboratory**

1. I agree to sharing my name, gender, date of birth, and home postal address with Exeter Clinical Laboratory based at the Royal Devon and Exeter NHS Foundation Trust for the purpose of posting out sample collection packs to my home for remote analysis of my blood and stool samples.

**My preferred questionnaires (please tick one option):**

 **Online Paper**

**Patient:**

Signature…………………………………………………………………………………

Name (block capitals)……………………………………………….……………………

Date………………………………………………….………………

**Investigator:**

Signature………………………………….…………………………………………………

Name (block capitals)……………………………………………….……………………

Date………………………………………………….…………………