Delete this line, then print first page of Information Sheet and Consent Form on Trust/Hospital headed paper

FOxTROT 2
Personalising neo-adjuvant chemotherapy in locally advanced but operable colon cancer

Funded by Yorkshire Cancer Research

Is earlier Chemotherapy treatment better for bowel cancer patients over 70 and for those with other medical conditions?

PATIENT INFORMATION AND INFORMED CONSENT FORM (PIS 2)

(A large-print version of this form is available)

We invite you to take part in the international FOxTROT 2 research study. Before you decide, it is important that you know why we are doing the research and what is involved.

Why are we doing this research and why should I consider taking part?

You have been invited to take part in FOXTROT 2 as you have been diagnosed with cancer of the bowel (colon) that your surgeon thinks can be removed by an operation.

The standard treatment approach for your bowel cancer is to have surgery to remove your tumour(s) and then followed by, if necessary, chemotherapy to kill off any undetectable remaining cancer cells. However giving chemotherapy ahead of surgery is the standard approach in the treatment in some other types of cancer as it produces better results for patients.

Our international FOxTROT 1 research, completed in 2020, showed that having some chemotherapy first, before surgery was better for patients who were young and fit. We want to find out if this approach will also benefit patients like yourself.

If I take part what will happen?

After we have answered your questions, you will need to complete a 'consent' form. You will then have the normal tests and some additional ones to make sure that this research is suitable for you. A computer system will then automatically place you into one of two groups by chance (randomly). One group (containing two-thirds of the patients) will start the usual chemotherapy drugs very quickly and before surgery. The second group will have the standard treatment approach of surgery first. The advantages and disadvantages of being in either group and much more information are described on the following pages.

With your help, and by comparing how the two groups get on, we will be able to see whether providing earlier chemotherapy is better for all future patients.

Contents

Part 1 – More detailed information about FOxTROT

There is a considerable amount of information provided over the remaining pages of this document and whilst we have tried to make it as complete and understandable as possible, there may be parts which are unclear. Whether you have questions or simply want to check your understanding, to assist you in keeping a note of these as you read through this document, we have incorporated a 'Patient's Questions Sheet' for your use on page 22. You can then raise these matters with our research staff who will be please to answer them.

What is the purpose of the research?

The standard treatment for bowel cancer is surgery to remove the cancer tumour, usually followed by a course of anti-cancer drugs (called chemotherapy) to reduce the chance of cancer returning in the future by treating any remaining cancer cells.

Bowel cancer becomes more common the older we get (the average age at diagnosis is 71). Such patients may not receive chemotherapy due to other existing medical conditions. They therefore tend to have poorer outcomes.

Our recent international research (FOxTROT 1) showed that receiving some chemotherapy before surgery was both safe and reduced the chance of cancer coming back. However, patients participating in this research were mostly younger and fitter with few other medical problems. Importantly, the older patients that did participate in FOxTROT 1 did tolerate the side effects of chemotherapy taken before surgery better than after surgery.

The main benefit from FOxTROT 2 will be that the information gained from the research will help improve the treatment of future patients in a similar position to yourself.

If you decide not to take part in FOxTROT 2, your Doctor will talk through with you alternative treatment options. Your treatment and care will not be affected in any way by your decision not to participate in FOxTROT 2.

Allocation to Participant Groups

FOxTROT 2 is a randomised research study, which means that participants are put into one of two groups at random. This is the best way to be sure that results from clinical research are correct and a fair comparison can be made between the different treatments. A computer will allocate you randomly (as if by the roll of dice) to one of two groups of participants. All participants in one group will receive the standard treatment (an operation first). Participants in the other group will receive some chemotherapy before their surgery. Both groups will be seen by an oncologist after surgery to decide whether they need any more chemotherapy.

Allocated to the New Treatment Group (Chemotherapy first)

There is a 2 in 3 chance of you being allocated to the new treatment group, i.e. the group receiving chemotherapy before surgery. We are running the FOxTROT 2 research because we hope that chemotherapy prior to surgery may give better results than standard treatment. However, we cannot be sure in advance whether this is the case – that is the reason for doing this research.

Description of the treatment and any additional tests

Participants allocated to this group will receive chemotherapy drugs called oxaliplatin and fluoropyrimidine for 6 weeks. These are the same chemotherapy drugs that are normally given after surgery. The difference is WHEN they are given on your treatment plan. These drugs are either are either given by infusion (drip) 2 weekly ("OxMdG") or by a combination of an infusion and tablets 3-weekly (OxCap); your oncologist will discuss these options with you.

After finishing the chemotherapy you will have a 3 to 4 week rest period, to allow the chemotherapy to have its full effect and for any side effects to settle. You will have a CT scan at this time to allow the research team to look at the effect of earlier chemotherapy. This CT is in additional test that you would not have as part of standard care. Then the operation to remove the tumour will take place. Following your operation there will be a 4 to 8 week recuperation period to allow you to recover before seeing the oncologist to discuss whether any further chemotherapy is needed. The decision of whether to have further chemotherapy after the operation will be made by you and your oncologist. We will however collect information on any such treatment.

Potential Advantages to you

A. Participants receiving chemotherapy prior to surgery should usually start treatment shortly after entering the research study.
B. You may be more likely to have chemotherapy as part of your cancer treatment if you have it before surgery, rather than after surgery (current usual treatment). This was the case for participants in the FOxTROT 1 trial. FOxTROT 1 also showed that participants tended to have less complications after the operation if they had chemotherapy first.
C. Your progress will be carefully monitored throughout the research.

Potential Risks to you

- There is a small risk that the tumour may continue to grow whilst receiving the chemotherapy and you may have need to have an emergency operation or stent.
- There is a risk that you may have severe side effects from the chemotherapy that mean that your operation is delayed, or that you may not be fit enough for an operation.
- Chemotherapy can have life threatening complications (very small risk) whether given before or after surgery.

Exposure to Ionising Radiation

If you take part in this study, you will have a number of CT scans you would receive whether or not you participate in the study. These will assess the tumour when you are first diagnosed and later at regular intervals after your surgery including after 3 years. We will access the results from these scans to allow us to ensure that you remain disease free and to assess how colon (bowel) tumours behave.

As part of this trial one additional scan may be requested by your doctor to reassess the tumour in the period following chemotherapy and before surgery. This is an optional scan and it will not be performed on all participants in the trial. These CT scans use ionising radiation to form images of your body and to provide your doctor with information about the tumour. Ionising radiation from the scan may cause cancer many years or decades after the exposure. The chances of this happening to you as a consequence of taking part in this study are very low and about 0.5% or 1 in 200 cases. For comparison, the natural lifetime cancer incidence in the general population is about 50% and a patient with colorectal cancer not taking part in the study would have CT scans leading to a risk of 0.4% or 1 in 250 cases.

Allocated to the 'Standard Treatment' Group (Surgery First)

There is a 1 in 3 chance of you being allocated to the 'standard treatment' group. This means that you will have an operation to remove your tumour first. Following that, there will be a 4 to 8 week recuperation period after surgery to allow you to recover before seeing the oncologist to discuss any further chemotherapy. The decision of whether to have further chemotherapy after the operation will be made by you and your oncologist, but we will collect information on this treatment.

Potential Advantages to you

A. The 'surgery first' group is the standard treatment and has been experienced by thousands of patients before you.
B. You will have fewer research tests but your progress will be carefully monitored throughout the research.
C. Your involvement in this research study may help future patients understand which of the two treatment approaches is the best for patients similar to you.

Potential Risks to you

The potential risks are the same as undergoing surgery followed by chemotherapy in standard care outside of this research.

Exposure to Ionising Radiation

If you take part in this study, you will have a number of CT scans you would receive whether or not you participate in the study. These will assess the tumour when you are first diagnosed and later at regular intervals after your surgery including after 3 years. We will access the results from these scans to allow us to ensure that you remain disease free and to assess how colon (bowel) tumours behave.

Activity summary table – research tests for both groups

The table below describes the additional tests and questionnaires for participants to complete as part of this research. We will look to organise as many of these activities on the same day (as far as possible) in order to minimise the travel to your local hospital and the impact on your time. We regret that we are unable to cover any additional costs that you may incur from participating in this research.

Activity	**All participants in the research**	**Before starting neoadjuvant (before surgery) chemotherapy** (Only for those in the new treatment group)	**Before each cycle of neoadjuvant (before surgery) chemotherapy** (Only for those in the new treatment group)	**After neoadjuvant (before surgery) chemotherapy** (Only for those in the new treatment group**)**	**Before starting chemotherapy after the operation**	**1 year after you are allocated to a group**	**3 years after you are allocated to a group**
1. Giving Consent *	X						
2. Medical history	X						
3. Having a CT scan (chest/abdomen/pelvis)				X *			
4. Having a stored tumour sample (sent for MMR testing –see What happens if I decide to take part?)	X						
5. Request permission for additional tests on stored tumour for future research (optional)*	X						
6. Routine blood tests to make sure it is safe for you to have chemotherapy	X	X	X		x		
7. Giving a blood sample (optional) – to look at the level of cancer cells in your blood *	X		X	X	X		
8. Completing a Questionnaire about your quality of life. This should take about 30 minutes to complete and will be completed during a standard hospital visit *	X			X	X	X – this will be posted to you by your research team	X
9. Pregnancy test (only if you are female and pregnancy is a possibility)	X						

An * means that this test is additional to what would usually happen to you in standard care.
An X in the table means this test will be performed at this time.

Your options

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

Unfortunately, no. Although your doctor thinks you might be suitable to take part, they will still need to carry out some medical tests and ask you some questions to make sure it is suitable for you. These are known as “eligibility screening tests” and are described below. If the eligibility screening tests show that it is not suitable for you to take part in FOxTROT 2, your doctor will discuss your alternative treatment options with you.

Do I have to take part?

No, your participation in FOxTROT 2 is entirely voluntary and you may stop at any time, without giving us a reason.

If you decide to take part, you will be given this information document to keep. You will be asked to sign a consent form, but you are still free to stop at any time and without giving a reason.

If you decide not to take part or you initially agree to take part but later change your mind, your Doctor will be happy to talk through alternative treatment options, for example the standard treatment of surgery followed by consideration of chemotherapy (to lessen the chance of your cancer coming back). Your treatment and care will not be affected in any way.

What happens if I decide to take part?

If you decide to take part, you will be given this information document to keep. Once you have had any questions answered and have gone through the consent form with your doctor, arrangements will be made for you to enter the research. You will be asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason.

There are some further tests to check if you are eligible to be allocated to one of the two groups. All the things that you will do as part of the study are shown in the Activity Summary Table on page 6 of this document. Firstly, you will need to have all the eligibility screening tests done which include:

- Blood tests
- An assessment of your medical history
- A physical examination
- A CT scan of your chest/ abdomen/ pelvis
- A biopsy
- Completion of quality of life questionnaire

- A pregnancy test (only if you are female and pregnancy is a possibility)

You would need to have some of these tests done even if you were not going to take part in this study, and some of them may already have been done as part of the investigations of your cancer. Your medical team will check the results of these investigations and your medical history to make sure that the research is suitable for you. If the eligibility screening tests show that this research is not suitable for you to take part, your doctor will discuss your alternative treatment options with you.

You may take some of the chemotherapy drugs as tablets. You will be given a diary to record the number of tablets you take during this research and you should take this with you when you see your research team. This will help your research team keep records of any missed tablets.

In FOxTROT 1 we saw that tumours in different parts of the bowel respond differently to chemotherapy before an operation. We also found that a laboratory test on your tumour could help us predict if your cancer would not respond to chemotherapy. This is called mismatch repair (MMR) testing. This was most important for participants with a tumour in the right side of their colon. We will test this in all participants' tumours in the FOxTROT laboratory. We will test a tumour sample already taken from you – no further tests are needed.

If you have bowel cancer on the right side of your body and your MMR test indicates that your tumour will not respond to chemotherapy, it will not be in your best interests to take part in the research. If your tumour is unlikely to respond to chemotherapy then you should have an operation first and your normal hospital doctor will discuss this with you.

Participants with bowel cancer on the left side of the colon can also have their MMR status checked via the FOxTROT laboratory, but you will still be allowed to take part in this research.

For all participants taking part in FOxTROT 2 we need a sample of your tumour taken out at the operation. This is sent to the FOxTROT laboratory at the University of Leeds. This is important so we can understand:

- How well the chemotherapy has worked.
- So that the FOxTROT trial pathologists can look at your tumour. This makes sure that the same tests are done for all tumours regardless of what hospital you were treated in.

Your trial CT scans will be sent electronically to the FOxTROT team at the University of Leeds so that the FOxTROT doctors can make sure that all scans are treated the same in the trial.

How will my condition be monitored?

For participants having chemotherapy first:

For the group of participants receiving chemotherapy before surgery:
a) You will be asked about any side effects you have experienced and will have a blood test at each treatment visit (for safety and research purposes). Participants in this treatment group may have an additional CT scan (on your chest/abdomen/pelvis) at the end of the neoadjuvant chemotherapy. This will be around 2-4 weeks after finishing this treatment. Your doctor will tell you if you will have this scan.
b) You will be asked to complete a questionnaire about your quality of life after completing neoadjuvant chemotherapy.

For all participants:

You will of course be carefully monitored throughout your operation. Your surgeon will send the removed cancer for examination in the hospital's pathology laboratory, and will discuss the result of the operation with you.
After you have recovered from the operation, you will be assessed by the oncologist and, when sufficiently fit, you will discuss whether you would benefit from further chemotherapy. You will be monitored throughout this time for any side effects or other problems.

Regardless of whether or not you have chemotherapy after the operation, there will be a period of follow up, during which you will be asked to attend the clinic regularly for check-ups with occasional blood tests to assess your progress. These clinic visits will take place when you would usually be seen as part of your standard treatment, so you won't have to go to hospital more than usual. All participants will have a CT scan 3 years after starting the research study to assess your progress. All participants will be asked to complete a questionnaire about your quality of life following your surgery and at 1 and 3 years after starting to participate in the research. After the 3 year CT scan and questionnaire, there will be no further research activities. The trial team will request a yearly update of your condition from your hospital notes whilst the trial is still open.

Pregnancy and contraception

If you are pregnant, think you may be pregnant, are planning on becoming pregnant, or planning to father a child you **must not** take part in this study. You must also not take part if you are breast feeding.
The drugs under investigation in this study may be harmful to an unborn child.
To prevent pregnancy, a highly effective method of contraception (with a failure rate of <1% per year) must be used by all women who can have children during treatment, and for six months after stopping your treatment.
Male participants who can father a child must use a highly effective method of contraception (with a failure rate of less than 1% per year) for the duration of the study and for 90 days after stopping treatment.
Please talk to your doctor if you have any questions. If you become pregnant during the treatment you must tell your doctor immediately and your study treatment will be stopped. If your partner becomes pregnant you should tell your doctor immediately. Your doctor will be able to advise you on the risks to your unborn child and discuss the pregnancy with you.

It is important to tell your clinical care team if you are pregnant or become pregnant as this may affect your care. If you or your partner do become pregnant during your participation in the study, we will be obliged by law to request some basic information about the outcome of the pregnancy. This is so that organisations that monitor how medicines are used (such as the Medicines and Healthcare products Regulatory Agency [MHRA]) have the most up-to-date information about the effects of treatment.

What if there is a problem?

If a medical emergency related to your treatment in this research occurs while you are at home, you should contact the hospital where you received your treatment or you should go to the Accident and Emergency (A&E) department of your local hospital. You can also dial 999 as with any medical emergency. If the problem is not an emergency and you are unable to get to the hospital you should contact your GP.

Will my taking part be kept confidential?

If you decide to take part in FOxTROT 2, the information collected about you during the course of the research will be kept strictly confidential in the same way as all of your other medical records. Information about your disease and progress will be sent by your doctors to the FOxTROT 2 Research Office at the University of Leeds Clinical Trials Research Unit electronically or via post, where it will be handled confidentially and strictly in accordance with relevant data protection laws, including the Data Protection Act 2018. You will be allocated a study number, which will be used along with your date of birth and initials to identify you on each data form. Please refer to Part 2 and Part 3 for further details.

If you take part in the research, your relevant medical records may be inspected by authorised individuals from the research team, the University of Leeds (the study Sponsor) and by Yorkshire Cancer Research (who are funding the research). They may also be looked at by the regulatory authorities. The purpose of this is to check that the research is being carried out correctly.

The CT scans performed during the course of the research will be anonymised and stored electronically within the NHS and at the University of Leeds. They will be evaluated by the FOxTROT radiology research team based at Leeds Teaching Hospital Trust and authorised individuals from the research team.

In line with Good Clinical Practice guidelines, at the end of the research, your data will be securely archived for a minimum of 25 years. This is a requirement of clinical research and means that data can be checked at a later date if necessary. Arrangements for destruction of your confidential data will then be made.

Additional research

We would like to ask FOXTROT 2 participants for permission to carry out genetic testing on additional samples of your blood (these will be taken at the same time as your normal blood

tests wherever possible) along with unused tissue from your tumour biopsy or unused tissue removed during your surgery. This will be used in additional research to learn more about bowel cancer and to see if it is possible to predict which patients will benefit most from each type of treatment and to test new ways of monitoring your condition after surgery.

We would like to ask FOXTROT 2 participants permission to use the stored CT scans and associated reports taken during the course of the research for future additional research to learn more about how earlier chemotherapy affects bowel cancer.

These samples and scans will be identified only by a code number, not your name, and neither you nor your relatives will be identified or contacted and the results will not be added to your medical records.

These studies will not affect your treatment in any way, and you are free to withhold this permission without affecting your participation in FOxTROT 2 or your relationship with your doctor.

What will happen to any samples I give?

Blood and tissue samples you agree to have taken or collected for the research will be sent to laboratories outside your hospital contracted by the sponsor. These will be labelled with your research study number and a local laboratory number, they will not contain your name and address. These samples will be used to inform our understanding of which patients respond to therapy and the underlying mechanisms of response to treatment.

All samples will be sent to the laboratories using your hospital's standard processes or by a courier. When your samples are sent to the laboratories for further tests, there may be some of your samples left over once all the tests have been done. We will ask your permission to keep any of these left over samples in storage so that they may be used for future cancer research. Any future research projects using your samples will need to be approved by an ethics committee. If you do not consent to your samples being stored and used for future research, blood samples will be destroyed at the end of this research. Your cancer tissue samples will be sent back to your local hospital for storage.

What will happen to the results of the research?

The findings from the research will be used to help improve care for people with bowel cancer. When the research is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please ask your doctor.

Meet the team

Our highly experienced and friendly research team at *(insert site name)* will look after you as part of this research. Here are some of the team members that you may see during your visits.

Insert site specific photos of clinicians that the participants are likely to see/interact with and their names/roles. If individual sites are not comfortable in providing this then please delete this part of the PIS.

If you have any questions please talk to <<Enter PI, nurse name >> at << Contact details for site>>

Contact information

Contact details:

Urgent contact details

Non-urgent contact details

Part 2 – more about this study

What will happen if I don't want to carry on with the research?

You can stop taking part in all of this research, 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 say, as this will help us understand if there are common reasons for participants to stop taking part in research. Before deciding to stop, you should talk to your research doctor or nurse. They can advise you and they 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 research treatment (neoadjuvant chemotherapy – only applicable to new treatment arm), you are likely to proceed to an operation after a period of recovery. Research follow up visits and assessments can still go ahead, if you agree to this.
- If you tell us that you want to stop completing quality of life questionnaires, we will stop asking you to complete them. You can still take part in the research if you stop these, and you can change your mind later and start completing them again, if you want.
- If you decide to stop research follow up visits or assessments, 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 research 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 research are valid.

An important aim of the research is to find out how many participants complete their treatment and how people get on if they withdraw from treatment. For this reason, your data and samples would remain on file and be included in the final research analysis.

Finally, we may be legally required to collect information about any side-effects you have following your research treatment, even if you have told us you did not want to provide further data for the research.

Involvement of your General Practitioner/Family Doctor (GP)

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

Who has organised, reviewed and funded the research?

The **FOxTROT 2** research was developed by the National Cancer Research Institute's Colorectal Cancer Clinical Studies Group, and is funded by the medical charity, Yorkshire Cancer Research.

University of Leeds is the sponsor and has reviewed and approved this research and will be responsible for the management and conduct of the whole research. The day-to-day running of this research will be carried out by the Clinical Trials Research Unit (CTRU) at the University of Leeds.

The research has been reviewed and approved by all of these organisations.
All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This research has been reviewed and given a favourable opinion by a Research Ethics Committee. The project has also received approval by the Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency (MHRA).

The Chief Investigator is Dr Jenny Seligmann (Consultant Medical Oncologist) who is based at St James's University Hospital, Leeds. The Co-Chief Investigator is Prof Dion Morton (Professor of Surgery) who is based at the University of Birmingham.

What will happen if I lose mental capacity during the research period?

There is no reason at all to suspect that you will lose your mental capacity as a result of taking part in this research. A head injury, for instance, could happen to anybody whether or not they are taking part in this research and should this happen to you, you could continue with your research treatment unless your doctor and your family or carer did not think this was in your best interests.

What if I have a concern or complaint?

Every care will be taken in the course of this research. However, in the unlikely event that you are injured as a result of the design of the study or 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 research and the University of Leeds accepts no liability for negligence on the part of your hospital's employees. If you wish to complain about any aspect of the way you have been treated please contact your research 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.

If you wish to complain or have concerns about any aspect of the way you have been approached or treated during the course of this research study, the normal National Health Service complaints mechanisms are available to you. Your healthcare team will give you further information if necessary. If you are unhappy about anything to do with this research and wish to complain formally, you can do this at the Patient Advice and Liaison Service (PALS). You can find your nearest PALS office on the NHS Choices website: http://www.nhs.uk/Service-Search/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363. You can also ask your GP surgery, hospital, or phone NHS 111 for details of your nearest PALS.

Part 3 – Extra information about data protection

General information

The University of Leeds is the sponsor for this research based in the United Kingdom. We will be using information from you and your medical records in order to undertake this research and will act as the data controller for this research. 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 at least 25 years after the research has finished.

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 research, 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/

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 when you agree to take part in research, we will use your data in the ways needed to conduct the research and analyse the findings.

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

How will my information be used?

Your research doctor, nurse or other hospital staff will enter most of the information needed for the research directly into a secure research database held at the CTRU. You will be allocated a research study number, which will be used along with your date of birth and initials to identify you on each form. Your full name will be included on your consent form and a copy of this will be sent to the CTRU by fax or email so that we can check you have definitely agreed to take part in the research. If you completed a previous consent form to agree that some of your cancer sample could be sent to the central laboratory, this will also be sent to CTRU so that we can check this part of the consent.

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

Your healthcare records may be looked at by authorised individuals from the research team, the University of Leeds (the research Sponsor) or the regulatory authorities to check that the research is being carried out correctly.

We would also like your permission to obtain information held within your electronic health records, including any hospital attendances and admissions and your health conditions from your GP and hospital records. We may use this for future research linked to this study, or for other research projects. We would only do this once any future projects had received ethical approval. To obtain your health record data, we would need to send a limited amount of your identifiable data (for example, initials, data of birth, and NHS number) to the relevant data provider to obtain the correct information from these records. Other research teams may be

involved in this future research but they will not be able to identify you from the information provided to them.

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.

Unless you clearly tell us you don't want us to, we will continue to obtain data about you if you stop taking research treatment or stop attending research visits. This is to help ensure the results of the study are valid.

CT scans and pathology blocks will be sent for central review to ensure that results / reports are consistent across hospitals. Pathology blocks will be sent via standard hospital processes (such as Royal Mail or courier). CT scans will be sent electronically via secure electronic transfer. Wherever possible, this data will be anonymised and your name removed.

Your NHS hospital will use your name, NHS number and contact details to contact you about the research, and make sure that relevant information about the research is recorded for your care, and to oversee the quality of the research. Individuals from the University of Leeds and regulatory organisations may look at your medical and research records to check the accuracy of the research. Your NHS hospital will pass these details to the University of Leeds along with the information collected from you and your medical records. The only people in the University of Leeds who will have access to information that identifies you will be people who 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 Leeds (the research Sponsor) will collect information about you for this research study from your medical team. This information will include your name, date of birth and health information, which is regarded as a special category of information. We will use this information to monitor your progress.
Your NHS hospital will keep identifiable information about you from this research for at least 25 years after the research has finished.

Using your information for further research

When you agree to take part in research, the information about your health and care may be provided to researchers running other research programmes 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.

Delete this line, then print on Trust/Hospital headed paper

Patient ID:	Initials:
Date of Birth:	NHS/Hospital Number:
EudraCT Number: 2021-002216-31	Principal Investigator:

FOxTROT 2 Personalising neo-adjuvant chemotherapy in locally advanced but operable colon cancer

Funded by Yorkshire Cancer Research

PATIENT CONSENT FORM FOR RANDOMISATION INTO THE MAIN RESEARCH

Please initial each box

1. I confirm that I have read and understand the information sheet for the above research and have had the opportunity to ask questions. ☐

2. I understand that my participation in this research 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 research, the data and samples collected from me will be used in analysing the results of the research and in some cases further information about any unwanted effects of my treatment may need to be collected by the research team. ☐

3. I understand that my healthcare records may be looked at by authorised individuals from the research team, regulatory bodies or Sponsor in order to check that the research is being carried out correctly. ☐

4. I agree to a copy of this Consent Form being sent to the CTRU, along with a copy of my previous consent form (for sending cancer tissue to central laboratory) if applicable. ☐

5. I agree that my GP, or any other doctor treating me, will be notified of my participation in this research. ☐

6. I agree to take part in the research. ☐

The following points are OPTIONAL

Please tick ✓

Even if you agree to take part in this research, you do not have to agree to this.

	Yes	No
I give permission for surplus samples from my cancer sent to the FOxTROT study laboratories at the Universities of Leeds and Birmingham to be stored and used for future cancer research that is subject to ethical approval. I understand that my name will not be included on the samples, but they will be labelled with a unique reference number that will allow the sample to be linked back to data collected through the main research in future, for research purposes. I understand that my tissue samples are a 'gift' from me and may be shared on a collaborative basis with researchers in the UK and possibly abroad, including outside the European Economic Area. This may include commercial organisations. I understand that my tissue samples may be used for genetic research. I understand that data collected about me will also be shared so that the results of the research can be interpreted properly.	☐	☐
I give permission for an extra blood sample to be taken to look at the level of cancer cells in my blood. I agree to these samples being stored and used for additional research investigations that form part of this research. I understand that strict confidentiality will be maintained at all times and that my name and individual details will not be stored with my samples (i.e. they will be anonymised). However, a unique reference number will be allocated to the samples which may allow them to be linked back to me in future for research purposes.	☐	☐
I give permission for my CT scans and the associated CT reports to be stored and used for future cancer research that is subject to ethical approval. I understand that my name will not be included on the scan/report, but they will be labelled with a unique reference number that will allow the scan/report to be linked back to data collected through the main research in future, for research purposes.	☐	☐

Patient:

Signature……

Name (block capitals)……

Date……

Investigator:

I have explained the research to the above named patient and he/she has indicated his/her willingness to participate.

Signature……

Name (block capitals)……

Date……

(If used)Translator:

Signature……

Name (block capitals)……

Date……

Witness:

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

Signature……

Name (block capitals)……

Date……

(1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)

Patient Question Sheet (for your use)

No.	My Question/Notes	PIS Page No.	Answer Received
1.			
2.			
3.			
4.			
5			
6.			