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Yorkshire Bowel Cancer Improvement Programme (YCR BCIP)

Research investigating the improvement of outcomes in bowel cancer

1. We would like to invite you to take part in a study

We are inviting you to take part in the Yorkshire Cancer Research YCRBCIP study. Before you decide we would like you to understand why the research is being done and what it involves.

The research nurse or member of your clinical team will go through the information sheet with you and answer any questions you have. This will take about 10 minutes. Please take the information sheet away with you and you can talk to your friends, family or GP about the study if you wish. Take time to make your mind up.

We understand this invitation comes at a time when you have a lot to deal with already, but we want to find out how you are before your treatment starts, if possible, so we can find out how your health and well-being may change.

This study will involve a large group of patients from Yorkshire and the Humber who have had a diagnosis of bowel cancer. We will be asking patients to complete questionnaires to find out more about what life is like for people in the first year following a bowel cancer diagnosis and to give their permission to collect samples of their cancer tissue surplus to diagnostic needs.

2. What is the purpose of this study?

Over 3,000 people a year are diagnosed with bowel cancer in Yorkshire and the Humber.

Advances in screening, diagnosis and treatment have resulted in more people living with and beyond bowel cancer. Many people recover well. Other people, however, experience physical, emotional and social changes which may impact on their everyday lives making it more difficult to return to life as it was before their diagnosis. There is not enough information from patients themselves about the challenges they face.

No two bowel cancers are exactly the same. Over recent years researchers have found out more about types of bowel cancer by investigating the molecular make-up of the cancer cells. New tests are coming in which can provide doctors with more detailed molecular information which may help them decide on the best treatment. This is still at early days but already there are some tests that

are not done routinely that would provide more information. As new knowledge is gained more tests will become available.

While great improvements in bowel cancer survival have been made over the years, there is room for further improvement. During this project we would like to recruit patients, diagnosed with bowel cancer, from throughout the Yorkshire and Humber region. The aim is to collect information from the patients themselves, from tissue collected at surgery and to link this information with treatment data collected routinely as part of patient care. This information will be used to find ways to improve bowel cancer treatment across Yorkshire and the Humber and reduce the number of bowel cancer-related deaths. If successful, we hope to extend the approach across the country.

3. Why have I been asked to take part?

You have been asked to take part as you have recently been diagnosed with bowel cancer.

4. What would I have to do?

After you have read the information sheet and have had your questions answered, you will be asked whether you are happy to take part in the study.

If you want to take part you will asked to fill in and sign a consent form.

Then you will be asked to complete a questionnaire at up to three time points, one before your treatment starts, one 12 months later, and a further questionnaire approximately 3 years after diagnosis.

At the first time point you can complete questionnaires during your hospital visit or at home.

You can complete the questionnaires on paper and hand it back to the nurse or post it back to the research team in a pre-paid envelope. After 12 months, and again at around 3 years after your diagnosis we will get in touch via letter and ask you to complete the questionnaires again. We will send a paper copy with a pre-paid envelope.

If we do not receive your completed questionnaires within three weeks we will contact you to remind you. If after another three weeks we have not received your completed questionnaires we will send out another reminder and a copy of the questionnaire.

We currently have funding to run this study until 2025. The Leeds research team will keep your data securely for 5 years after the end of the study. This will enable us to follow-up outcomes using

data that that is routinely collected as part of your NHS care. If we are able to obtain further funding and you have consented that you would be willing for us to contact you, we may ask you if you would be willing to complete additional questionnaires.

One of the aims of this study is to test surplus tissue taken from biopsies or during surgery. By tissue we mean material your surgeon removes when taking a biopsy or during surgery. You will not have any extra tissue removed solely for the purposes of this study; we will be using tissue already removed for your clinical care and left over after clinical needs have been met. This tissue would ordinarily be stored in a tissue archive, where it is rarely accessed again unless required for further testing in the future. We will leave enough tissue in the archives for this purpose where possible, and your doctors will always be able to request the tissue back from the researchers if required.

We are continually learning more about bowel cancer, which leads to further research questions. The generous donation of surplus tissue for this project will form an invaluable resource which we would like to be able to continue using beyond this project in other NHS Ethics Committee approved research projects to improve our understanding of bowel cancer. The tissue will not be used up so tissue always remains in case new clinical tests become available. You will be asked to consent to the storage and use of your tissue in future approved research. If you would prefer not to have your tissue stored for future research, you can opt out of this via the consent form or at any point afterwards.

We will also ask your permission to:

- access information from your hospital medical records such as pathology and scan reports and other information which relate to your diagnosis and treatment for bowel cancer
- link the information you give with other information that is collected by the NHS routinely. This includes clinical and treatment details collected from your medical records that is already stored by the Public Health England National Cancer Registration and Analysis Service and NHS Digital. For further information about cancer registration please go to www.ndrs.nhs.uk

To make sure that the information we collect in the questionnaires and from the tissue is linked with your information collected routinely we will ask you to give us your name, date of birth and NHS number. We will use a study identification number as the 'common' link.

5. Do I have to take part?

No, it is up to you to decide whether to join the study. You may want to talk to your family and friends about it before you decide.

Your decision will not affect your treatment and care in any way.

6. What will happen if I join and then don't want to carry on with the study?

If you agree to take part and then later decide you want to stop being in the study that is OK. You don't have to give a reason for your decision.

You can withdraw from the study by telephoning us on 0113 3430344. Monday to Friday in working hours or by emailing us on E.Connearn@leeds.ac.uk .

We will use the questionnaire information collected from you up to the time of your withdrawal unless you state otherwise. If you do not want us to use your information we can remove it for up to two weeks following the completion of the first questionnaires.

Your tissue samples will be returned to your local hospital archives (or destroyed if appropriate). This is not always possible if researchers have already used the tissue, however we will make every effort to recall all the donated tissue or samples possible. Recalled tissue will be returned to your local hospital if they are still in a usable format, otherwise they will be disposed of by us as detailed in Leeds Teaching Hospitals NHS Trust policies on the disposal of human tissue.

7. Will my taking part in the study be kept confidential?

Yes. It is very important to us to respect your information and keep it confidential. We work within strict rules covering data protection and confidentiality.

On the front of the consent form and questionnaire you will see a unique study ID number. The purpose if this ID number is to protect your identity.

All Consent Forms will be held securely by the research team from the Trust to whom you gave consent.

Each site research co-ordinator will transfer a list of your details (name, address, date of birth, NHS number, gender, and study identification number) of all patients who consented to the study to the Leeds research team using a University of Leeds secure electronic transfer system. We need this information to be able to send you the questionnaires and request your surplus tissue samples from the hospital that is treating you for bowel cancer.

The Leeds research team will store this information in a secure encrypted research environment which has access limited to only those people who need to see this information. Access to this file will be limited to designated members of the research team; this will include the Project Manager, the Deputy Project Manager and the Research Tissue Co-ordinator. Members of the University of Leeds LIDA Data Analysis Team will have access to enable them to transfer your data securely into the file from the hospital sites and to transfer it to the National Cancer Registration and Analysis Service (NCRAS). Access will be granted to the a data manager at the NCRAS who has been designated as the person who will link study participants with the data held by NCRAS.

We follow all data protection law in safeguarding your information please see our General Data Protection Regulation (GDPR) Transparency Statement at the bottom of this document. We have a privacy statement on our website that provide you with further information if you would like to know more; https://ycrbcip.leeds.ac.uk/privacy-notice/

The paper questionnaires will be sent to the Leeds research team and kept completely separately to any information which could identify you. They will be stored securely and will only be accessible to authorised members of the Leeds research team. They will enter your questionnaire responses on to a secure computer system.

The Leeds research team will contact you about completing further questionnaires at 12 months and then around 3 years. The questionnaires will not include any identifiable information about you.

The research team in Leeds will enter your follow-up questionnaire responses on to a secure computer system. The responses will be marked with your study identification number only.

Questionnaire and tissue data will be kept separately and securely from your contact details.

All tissues collected will be marked with your study identification number. All other identifiable information will be removed (linked anonymised). This is to anonymise the samples to the

researchers to protect the privacy of the donor and their family but still allow the samples to be traced back to you should this be necessary. This is all in compliance with the Human Tissue Act 2006 and relevant codes of practice. All information about you is confidential and is protected by the Data Protection Act.

All tissue samples will be stored in a secure, access-restricted University of Leeds building. All digital data will be stored on secure, password-protected, restricted-access University of Leeds servers.

The Leeds research team will securely share your study and hospital number with the National Cancer Registration and Analysis Service (NCRAS) who have approvals to work with cancer patient data. In order to fully analyse and interpret the results, NCRAS will provide us with information held about you in existing NHS databases. This information will then be securely passed back to the University of Leeds research team using only your study number as an identifier. The study analysts will then link this medical information with the questionnaire and tissue sample information you have provided.

The analysis team for the research program will receive anonymised disease and treatment information linked to your survey responses and only identified by your unique study number.

No-one will ever be able to identify you personally from anything that we present or publish about the research.

The only situation in which we might need to share information about you with others would be either:

- if the researchers see or hear anything that causes very serious concern about your health, safety or well-being. If this happens the researchers have a duty to inform an appropriate professional in your hospital clinical team. We would make every effort to explain why we need to share this information before doing so or;
- if the researchers found characteristics of your cancer from the testing of your tissue which could influence decisions made about your future treatment by you and your clinical team. They may also identify hereditary factors which may impact on the future health of you and your family. You will be asked to consent to researchers reporting back any clinically relevant findings to your clinical team.

Your medical team will not see your responses to the questionnaires.

The Leeds research team will keep your data securely for 5 years after the end of the study this is to enable us to follow-up outcomes.

8. What will happen to the results of the study?

When the study is complete, we will present the results at scientific conferences, publish them in journals, and present them to clinical teams and to patients.

Each hospital who is part of this research programme will be given information about their services based on the analysis that has taken place using the data, tissue and survey responses to help them improve their services for bowel cancer patients.

The information collected will be available to other researchers to use for research and educational purposes. This will be completely anonymous and you will not be able to be identified. Researchers wanting to use the questionnaire data will have to make a formal application to the research team.

Please inform us if you would like to know the results of this work and we will be very happy to provide them. Up to date information about the study can be found on our website www.ycrbcip.leeds.ac.uk

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

Completing the questionnaires will take a bit of time. This is the only disadvantage we anticipate.

10. What are the possible benefits of taking part?

There are unlikely to be any direct benefits in taking part in the study. Sometimes people feel pleased to be able to contribute to research which may benefit future patients.

For a small number of patients there may be direct benefits:

- if they are found to have a particular type of bowel cancer that would mean they would be eligible to take part in a clinical trial testing new targeted treatments.
- if they are found to have a hereditary condition which might influence the treatment they get and also be important for their family members to know about.

11. Who is funding and organising the research study?

The study is funded by Yorkshire Cancer Research. The Chief Investigator for the research grant is Professor Philip Quirke from the University of Leeds.

12. Who has reviewed the study?

The quality of our proposed research has been reviewed and approved by Yorkshire Cancer Research.

Research projects using human tissue samples must have prior approval from an NHS Research Ethics Committee. There are several of these committees around the UK. They are comprised of medical experts, legal representatives, local Health Authority representatives and lay people. Their job is to examine proposals submitted by researchers. These proposals outline what they want to do, how they want to do it and what they want to achieve. The committee then decides if this can be done, is it legal, is it the right thing to do and does it have the best chance of success. This is what is meant by 'ethical'.

Informed consent must be obtained for all human tissue samples that are used for research. If consent is not given then tissues will not be collected or used for research under any circumstances. The rules and regulations regarding consent and donation are governed by the Human Tissue Authority and the Human Tissue Act with very stiff penalties if anybody is found to have contravened them.

All research connected with the NHS is reviewed by a Research Ethics Committee, to protect the safety, rights, well-being and dignity of those taking part. This study has been reviewed and approved by the West Midlands - Solihull Research Ethics Committee.

We have a small group of patients who have advised us and reviewed the documents for this study.

13. What if something goes wrong?

If you are unhappy or dissatisfied with any aspect of your part in the study please let us know.

If you remain unhappy and wish to complain formally you can do this via the Leeds Teaching Hospitals NHS Trust Patient Advice and Liaison Service (PALS) and Complaints:

Telephone: (0113) 2066261 - Available during normal working hours only.

E mail: patientexperience.leedsth@nhs.net

Or through your local PALS office

Add local site contact details for PALS

Add local PI name and contact details here

14. Further information and contact details

- If you require information about this research project that hasn't been covered in this information sheet please contact:

 University of Leeds YCR BCIP Project Manager Hannah Rossington 0113 3430337 or

YCR BCIP Deputy Project Manager, Emily Connearn 0113 3430344

 Your hospital add name and contact details of the local site PI.

Yorkshire Cancer Research Bowel Cancer Improvement Programme

University of Leeds

Leeds Institute for Data and Analytics, Level 11, Worsley Building

University of Leeds, Clarendon Road

Leeds, LS2 9NL

Telephone 0113 3430337 / 0113 3430344

This information sheet is for you to keep. If you decide to participate you will be asked to sign a consent form and given a copy of this to keep for your records.

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

General Data Protection Regulation Transparency Statement for

Yorkshire Cancer Research Bowel Cancer Improvement Programme

The 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 5 years after the study 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 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 URL
https://ycrbcip.leeds.ac.uk/privacy-notice/

and/or by contacting the Project Manager, Hannah Rossington H.L.Rossington@leeds.ac.uk or via Yorkshire Cancer Research Bowel Cancer Improvement Programme, LIDA, 11th Floor Worsley Building, University of Leeds, LS2 9NL.

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 a research study, we will use your data in the ways needed to conduct and analyse the research study. 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.

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).

You can contact the University of Leeds Data Protection Office via: Email: dpo@leeds.ac.uk Postal address: The Secretariat, University of Leeds, E C Stoner Building 11.72, Leeds LS2 9JT, UK.