MANCHESTER 1824

Central Manchester University Hospitals NHS

The University of Manchester

BOLT
Biomarkers of Lynch Tumours

Dear Lynch syndrome UK member,

Thank you for taking the time to read this document.

My name is Dr Neil Ryan. I am a gynaecologist in Manchester, who has been awarded funding from the Medical Research Council to explore the ways Lynch syndrome causes womb cancer. Specifically, what makes it different from womb cancers that arise in non-Lynch syndrome women? It is our hope to be able to use this information to **devise more accurate and straight forward ways of diagnosing Lynch syndrome** from womb cancers, enabling a move to a more **universal screening system in the UK**- that is we hope that one day as many women with womb cancer will be tested for Lynch syndrome as possible. With an earlier diagnosis more women will be offered potentially lifesaving colonoscopy.

We can only do this research if we have **womb cancer samples from women with known Lynch syndrome**. That is where you come in.

If **you have had womb cancer/endometrial cancer and have had a biopsy or hysterectomy** we would like your samples.

We do not need any further samples from you. We will use the **historical tissue** that is stored as a matter of course by the hospital in which you had your surgery.

All we will need you to do is read the patient information sheet attached to end of this document. If you agree to take part in email me on neilryan@nhs.net. I will ask you to complete a consent form (a copy of which is at after the patient information sheet below) and also give me some details regarding your surgery; namely when and where it took place along with your date of birth.

Thank you again for your anticipated help.

My warmest of regards

Neil

Patient Information Sheet

Biomarkers of Lynch syndrome Tumours (BOLT study)

INVITATION

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. This information should take about 15 minutes to read through. You can contact the research team should you not find any of the information clear and they will be happy to answer any questions.

WHAT IS THE PURPOSE OF THE STUDY?

We are a team of researchers interested in why womb cancer in people with Lynch syndrome is unique. We hope to find new ways to prevent, diagnose and treat womb cancer in women with Lynch syndrome. In addition we hope to understand how womb cancer develops in women with Lynch syndrome and those who do not have Lynch syndrome. We will do this by examining the womb cancers of people with Lynch syndrome and comparing them with the tumours of people without Lynch syndrome.

You have been contacted because you had a hysterectomy (removal of the womb) for womb cancer and because you have proven or suspected Lynch syndrome.

Your tissues are archived in the pathology department in the hospital where you had your surgery (this is normal clinical practice). We would like to retrieve your sample and use them for research as to better understand womb cancer and Lynch syndrome. This research will also contribute to Dr Neil Ryan's PhD.

WHY HAVE I BEEN CHOSEN?

You have been chosen because you have Lynch syndrome or your family has the mutation for Lynch syndrome and have had a hysterectomy in the past for endometrial cancer.

DO I HAVE TO TAKE PART?

It is completely up to you to decide if you wish to join the study. If you do not want to take part, this will not affect the quality of the medical care you receive.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

We will give you an information sheet to read. If you would like to take part we will ask for your written consent.

We will **perform tests on the tumour sample taken from your womb**. These tests will be done on tumour material collected as part of your routine clinical care. You will NOT need another biopsy to take part in this study. We will only use tumour samples that are left over after all the tests for your clinical care have been done.
We will access your medical records for information about the treatment you received for womb cancer and the follow up care you was given.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

You will need to put aside 15 minutes to read this document, sign the consent form and return it to us.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Patients taking part in this study will not benefit personally but will contribute to an improved understanding womb cancer and Lynch syndrome

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

When the study stops no further action will be required from you. Your medical treatment and follow up will continue as usual. You can, if you wish, be kept informed of the findings of the study.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON IN THE STUDY?

You are free to withdraw from this study at any time without your medical care being affected. If you withdraw from the study, we would like to keep all of your samples and to use the data collected up to the point of your withdrawal. However, if you wish, any stored tissue samples already collected will be destroyed.

WHAT IF THERE IS A PROBLEM?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (0161 701 6942). If you remain unhappy and wish to complain formally, you can do this by contacting the patient advice and liaison service (PALS) at the Central Manchester University Hospitals NHS Foundation Trust on 0161 276 8686 or by emailing pals@cmft.nhs.uk. In the event that something does go wrong:

Complaints:

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (0161 701 6942). If you remain unhappy and wish to complain formally, you can do this by contacting the University of Manchester's Research Practice and Governance Co-ordinator on 0161 275 8093 or by email to research.complaints@manchester.ac.uk. Alternatively, you may contact the patient advice and liaison service (PALS) at the Central Manchester University Hospitals NHS Foundation Trust on 0161 276 8686 or by emailing pals@cmft.nhs.uk.

Harm:

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or Central Manchester NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your participation in this study is confidential and a record of your participation will be kept with your hospital records. Only the study team at the St Mary's Hospital and other healthcare professionals who require access to your medical records will know of your participation. Healthcare professionals and scientists with whom we may collaborate outside St Mary's Hospital will not be able to identify you from the data we share.

Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to access the data collected during the study to make sure the research is being carried out appropriately. With your permission, they may access your personal data while conducting audits or monitoring visits. All individuals accessing the data will have a duty of confidentiality to you as a research participant.

WILL ANY GENETIC RESEARCH BE DONE?

We want to look at your DNA and RNA (the genetic code that is stored inside your tissues otherwise known as your genes) for mutations, sequence variation and gene expression differences to explore different aspects of you womb cancer.

WHAT WILL HAPPEN TO ANY SAMPLES I DONATE?

During your participation in the study, we ask that you donate your tissue samples for future research. This means that any tissue left over after the study has been completed may be used in future research without us needing to ask you again for permission to do so.

All research samples will be collected, processed and stored in the routine clinical laboratories and the Gynaecological Oncology Research Laboratory at St Mary's Hospital (Custodian: Dr Emma Crosbie) and will be linked to data from your clinical records. Only the study team at St Mary's Hospital will have knowledge of your identity linked to your clinical record and laboratory samples/data. The study will use donated samples to improve our understanding of the biology of womb cancer. The results of these investigations are unlikely to have any implications for you personally.

In the future, we would like to keep your samples in a tissue bank linked to your clinical data, for possible use in future studies. Where we intend to share samples with researchers at other institutes, including researchers working for commercial companies, for future studies that cannot yet be specified, the data will be anonymised. The use of data/tissue samples in future studies will be subject to additional Research Ethics Committee approval where appropriate.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?

We aim to widely publish the results of this study at international meetings and in medical journals.

WHO IS ORGANISING AND FUNDING THIS STUDY?

Dr Emma Crosbie, Senior Clinical Lecturer in Gynaecological Oncology is the chief investigator. Co-investigators include: Gareth Evans, Professor of Medical Genetics at St Mary's Hospital; Henry Kitchener, Professor of Gynaecological Oncology at St Mary's Hospital; Dr Neil Ryan, Clinical Research Fellow at St Mary's Hospital; Dr Abigail Derbyshire, Clinical Research Fellow at St Mary's Hospital; and Dr Sarah Kitson, Clinical Research Fellow at St Mary's Hospital.

The Medical Research Council (MRC) funds the study. None of the research team or supervisors will receive payment for their involvement. The study is being sponsored by the University of Manchester. If you have concerns about the conduct of the study you may wish to contact the University Research Office (0161 275 5436) or St Mary's Patient Advice & Liaison Service (0161 276 8686).

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favorable opinion. In addition the University of Manchester's governance team has reviewed this study.

CONTACT FOR FURTHER INFORMATION?

Dr Emma Crosbie (emma.crosbie@manchester.ac.uk) at 0161 701 6942.

Many thanks for considering taking part in this study.
Yours sincerely,

Dr Emma Crosbie, Senior Clinical Lecturer in Gynaecological Oncology, Institute of Cancer Sciences, St Mary's Hospital, Oxford Road, Manchester M13 9WL. Phone. 0161 701 6942. Email. emma.crosbie@manchester.ac.uk

MANCHESTER 1824

The University of Manchester

Central Manchester University Hospitals NHS
NHS Foundation Trust

CONSENT FORM

BOLT
Biomarkers of Lynch Tumours

Title: Biomarkers in Lynch syndrome Tumours (BOLT)

Patient ID for this study:

Principal Investigator: Dr Emma Crosbie
Senior Lecturer in Gynaecological Oncology
Institute of Cancer Sciences
University of Manchester
St Mary's Hospital
Tel: 0161 701 6942

Thank you for reading Patient Information Sheet (version 2, 27/11/2015) about our research project:

If you would like to take part, please read and sign this form ***and initial in the boxes***

1. I have read the attached information sheets on this project (listed above), and have been given a copy to keep. ☐
2. I give permission for my hysterectomy specimens to be used for research. I am free to withdraw my approval for use of my samples at any time without giving a reason and without my medical treatment or legal rights being affected. ☐
3. I give permission for someone from the research team to look at my medical records and get information on my clinical history, investigations and outcome, where relevant to my participation in this study. I understand that the information will be kept confidential. ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the NHS trust or regulatory authorities, where it is relevant to my taking part in this research. I give my permission for these individuals to have access to my records, and for them to contact me by telephone/post. ☐
5. I understand that I will not benefit financially if this research leads to the development of a new medical test. ☐
6. Where appropriate, I give permission for my hysterectomy sample, taken at another hospital, to be transferred to the Gynaecological Oncology Research Laboratory at St Mary's Hospital and used for research. ☐
7. **Consent for storage and use in possible future research projects**
I agree that the samples I have given and the information gathered about me can be stored in the Gynaecological Oncology Research Laboratory at St Mary's Hospital for possible use in future projects. I understand that some of these projects may be carried out by researchers other than those who ran the first project. I understand that I will not be identifiable from any of the stored samples or from the clinical information collected about me, which will be fully anonymised. ☐

8. **Consent for research**

I consent to take part in this study. I understand that this project, and future research, will use the samples I give to increase the understanding of womb cancer development, but that the results of these investigations may not have any implications for me personally. ☐

Name of Patient	**Date**	**Signature**
Name of Person Taking Consent (if different to researcher)	**Date**	**Signature**
Name of Researcher	**Date**	**Signature**

Would you like to be sent information about the overall progress of the study? ☐ Yes ☐ No

Thank you for agreeing to participate in this research