ENDCaP-C Study: Enhanced Neoplasia Detection and Cancer Prevention in Chronic Colitis

Patient Information Sheet
Version 3.0; 28th July 2015

Summary of an Invitation to take part in a research study called ENDCaP-C.

- Ulcerative colitis (UC) affects over 30,000 patients in the UK and we know that patients with long-term UC are at an increased risk of developing colorectal cancer.
- Timely recognition of pre-cancer cells is vital in order to improve outcome for patients.
- Currently in the UK, patients undergo regular and thorough surveillance of the colon to look for pre-cancer changes. This involves repeated colonoscopy and biopsy at 1, 3, or 5 yearly intervals.
- We have identified genes which are potentially important in the development and progression of cancer and a new test has been developed which is based on detecting changes in structure of DNA. This test is performed on biopsies collected routinely during your colonoscopy. We will also explore the possibility of detecting these same changes in blood and stool samples.
- This hospital is taking part in a national study called **ENDCaP-C**, which aims to test how well this new test detects pre-cancer changes and if this is better than just colonoscopy alone.
- Detecting changes earlier means treatment can also be given earlier.
- We do not know how accurate this new test will be at detecting pre-cancer changes and that is why we are undertaking this research study.
- We are inviting you to take part in **ENDCaP-C** but you do not have to and if you decide not to this will not affect the quality of your care.
- Please take time to think about whether you want to take part in the **ENDCaP-C** study. More details are provided below and your medical team will be happy to answer any questions.

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An invitation to take part in a research study called ENDCaP-C

*We would like to invite you to take part in a research study called **ENDCaP-C**. Before you decide whether or not you wish to take part in **ENDCaP-C**, you need to understand why the research is being done and what it will involve for you.*

- *Part 1 below tells you the purpose of this study and what will happen to you if you take part.*
- *Part 2 gives more detailed information about the conduct of the study.*

Please take time to read this information carefully and ask us if there is anything which is unclear or on which you would like more information. Take your time to decide whether or not you wish to take part.

Part 1

Why am I being invited to take part in ENDCaP-C?

Your consultant will have invited you to take part in **ENDCaP-C** as you have Ulcerative Colitis and you are due to have a routine check colonoscopy. Your consultant has invited you to take part in the study as they believe the study asks an important question. The **ENDCaP-C** study is trying to find out the accuracy of a new test to be used with colonoscopy and biopsy to better detect pre-cancer changes earlier and thereby allowing earlier and better treatment. The **ENDCaP-C** study aims to include 1000 people like you from hospitals throughout the UK.

Do I have to take part?

No. Taking part in research is voluntary. If you decide to take part you will be given this information sheet to keep and later asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason. If you decide not to take part, then you don't have to give any reason. Your care will not be affected in any way and you will receive the standard care you would otherwise be given at this hospital. Your doctor will be happy to talk through any questions you may have regarding **ENDCaP-C**.

What will happen if I agree to take part?

If you agree to take part in the **ENDCaP-C** study, we will go through the study information with you, giving you the chance to ask any questions. You will need to sign a consent form if you agree to take part. Your details, including a copy of the signed consent form, will then be passed to the **ENDCaP-C** study office at the

Birmingham Clinical Trials Unit (BCTU). There is an optional quality of life study which will involve the completion of a short questionnaire about your current state of health. If you wish to take part in this your consent will be taken and the questionnaire can be completed prior to your first colonoscopy as part of the study.

Most of the treatment you receive will be the same as you would receive even if you were not in the study. At your planned colonoscopy appointment, you will have a standard colonoscopy and routine biopsies (samples taken from your bowel lining)will be taken. This procedure may cause slight discomfort but is not painful. These biopsies will be sent for analysis.

If the biopsy results are normal, you will finish your participation in the study. No further action will be taken and your care will continue as usual. Oryou may be invited to undergo another colonoscopy between 6 and 9 months later. There is only approximately a 1 in 10 chance that you will be asked to come back for a second colonoscopy. At this colonoscopy, the bowel lining would be examined by spraying it with a harmless non-permanent dye and biopsies would be taken depending on the appearance of the bowel lining. We may also request your permission to collect a stool sample and to take a small sample of blood. After this second colonoscopy, you will continue on the surveillance programme at your hospital as normal.

We would like to continue to collect follow-up data after this 6 month period, but this will not involve return visits to the hospital, instead we will collect data from standard NHS registries. We will ask for your consent to do this when you enter the ENDCaP-C study.

Your recommended follow-up treatment on the basis of results from the colonoscopy will follow standard medical care. You may be offered an endoscopic resection (a procedure to remove any abnormal tissue from your colon, performed with a long, narrow tube equipped with a light, and video camera), or you may be offered surgery.

We will need to collect information about the colonoscopy, any subsequent operation, any complications and any clinical outcomes. All information collected will be strictly confidential in the same way as your medical records.

What will happen to my samples?

The biopsies taken from your bowel lining will firstly be examined under a microscope at the local laboratory to look for any abnormalities. All samples will undergo central review at a pathology lab at the Queen Elizabeth Hospital Birmingham. DNA will be extracted from your biopsies and then they will be transferred to The Birmingham United Molecular Pathology (BUMP) laboratory at Birmingham Women's Hospital. The DNA extracted from your biopsies will be examined for evidence of any changes in its structure that would make it more likely that you might go on to develop colon cancer in the future. In addition, if you have a second colonoscopy, we will also apply the same tests to the stool and blood

sample. If we are able to detect changes in stool and/or blood this would make the test much easier to use in day to day practice. Tissue samples will be identified by study number and one other identifier and any information generated will be entered into a secure study database.

At the end of the study, any remaining material will be stored at The Human Biomaterials Resource Centre at The University of Birmingham. This is a research tissue bank and that samples will be made available for future research projects.

What are the alternatives for diagnosis or treatment?

If you decide not to participate, this will not affect your clinical treatment in any way. You would continue in the scheduled colonoscopy surveillance programme at your hospital.

What are the possible disadvantages and risks of taking part?

The study may involve an extra colonoscopy between 6 and 9 months after entry into the study. This will involve standard bowel preparation (including laxatives or an enema). A sedative and pain killers may also be given during the colonoscopy. The procedure will be of roughly the same duration as the initial colonoscopy. There is a very small risk (a 1 in 1000 chance) with colonoscopy of bowel perforation or bleeding. If this happened, an operation would be required to repair the hole. At the second colonoscopy you will also be asked to provide a stool sample and to collect a small blood sample.

What are the possible benefits of taking part?

There may be no benefit in taking part in this study, however, we hope that any pre-cancer changes will be detected early which would ensure that treatments could be started earlier. It has been shown that starting treatment earlier is often more effective.

Also, the information we get from this study may in the future help us better treat patients with longstanding ulcerative colitis.

Part 2

What if relevant new information becomes available?

Sometimes we get new information about the treatment or procedure being studied. If this happens, your study doctor will discuss how this affects your care and your participation in **ENDCaP-C**. Your research doctor might consider whether you should continue in the study or withdraw. Either way, he/she will explain the reasons and arrange for your care to continue. If you decide to continue in the study he may ask you to sign an updated consent form. If the study is stopped for any other reason, your doctor would, again, tell you and arrange your continuing care.

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

You can decide not to continue with study follow-up at any time and you don't have to give any reason. Your care will not be affected in any way and you will receive the standard care you would otherwise be given at this hospital. If you do decide not to continue, we would still like your data to remain on file and be included in the final study analysis unless you request that they should not be.

What if something goes wrong?

Taking part in the study would not affect your legal rights. If you are harmed by taking part in this research project, The University of Birmingham will be liable if harm was due to the research and not the underlying clinical care. If the harm is due to someone's negligence, then you may have grounds for a legal action but you may have to pay for this. Whether or not you take part in the study, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should ask to speak to the researchers involved in the study who will do their best to answer your questions (contact details are at the bottom of this form). If you remain unhappy and wish to complain formally, you can do this through the normal National Health Service complaints mechanisms, this is usually the Patient Advisory and Liaison Service (PALS).

Will my taking part be kept confidential?

If you decide to take part in **ENDCaP-C**, all information collected about you during the course of the study will be kept strictly confidential in the same way as all of your other medical records. Information about your colonoscopy and follow-up will be sent by your doctors to the **ENDCaP-C** study office at the University of Birmingham Clinical Trials Unit (BCTU), on paper and electronically, where it will be securely stored under the provisions of the 1998 Data Protection Act. This will include a signed copy of your consent form, including your full name. Your GP and the other doctors involved in your clinical care will be notified of your participation in the **ENDCaP-C** study and kept informed of your progress. We may use national records to track your progress, but otherwise all information about you and your treatment will remain confidential.

With your permission, your relevant medical notes may be inspected by authorised individuals from the BCTU. They may also be looked at by regulatory authorities and by the Sponsor. The purpose of this is to check that the study is being carried out correctly.

What will happen to the results of the study?

Once **ENDCaP-C** has finished we will publish the results in a medical journal so that others can benefit. We will also publicise the results on the study's website. No individual patients will be identified in any publications. A copy of the published results of the study will be sent to all patients who have participated in **ENDCaP-C** upon request. In line with clinical study guidelines, at the end of the study, the data will need

to be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made. Should you withdraw consent for your data to be used, it will then be confidentially destroyed.

Who is organising and funding the research?

The **ENDCaP-C** study was developed by the West Midlands Inflammatory Bowel Disease (IBD) network and the Birmingham Clinical Trails Unit. The study is coordinated by the **ENDCaP-C** study office at University of Birmingham Clinical Trials Unit and is sponsored by the University of Birmingham. The research has been approved and reviewed by all of these organisations. The study is being funded by the National Institute for Health Research (NIHR) Efficacy and Mechanism Evaluation (EME) Programme.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people called the Research Ethics Committee to ensure your safety, rights, wellbeing and dignity. This study has been reviewed by the South East Coast – Surrey Research Ethics Committee.

Where can I get further information?

If you have any further questions about your colonoscopy or this clinical study, please discuss them with your surgeon or the local study investigator.

Details of local study investigator/ person to contact:

Name.....

Job title.....

Contact Details.....

The **ENDCaP-C** study office is located at:

Birmingham Clinical Trials Unit
School of Health and Population Sciences
Public Health Building
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Web address: www.birmingham.ac.uk/ENDCaPC;

e-mail: ENDCaP-C@trials.bham.ac.uk