# The ENDCaP-C Study REGISTRATION FORM

**Please complete paper form prior to registration. Once completed, please visit https://www.trials.bham.ac.uk/ENDCaPC OR if unavailable, call 0800 953 0274 (Mon-Fri, 9am-5pm)**

| **Part A: Identification details** | | | |
|---|---|---|---|
| Responsible Gastroenterologist | _____ | Hospital | _____ |
| Patient Surname | _____ | Patient Forename | _____ |
| Date of birth: | DD / MMM / YYYY | Hospital No | _____ |

Please tick the eligibility boxes below that apply. A tick in a shaded box means that the patient is ineligible.

| **Part B: Eligibility – Inclusion Criteria** | **Yes** | **No** |
|---|---|---|
| **Does the patient have a diagnosis of:** | | |
| > Chronic ulcerative colitis (UC) with symptoms for over 10 years | ☐ | ☐ |
| > Primary Sclerosing Cholangitis (PSC) | ☐ | ☐ |
| One of the above must be answered 'Yes' for the patient to be eligible | | |
| On the surveillance programme and undergoing a routine colonoscopy during the study period? | ☐ | ■ |
| Patient is willing to accept the possibility of an additional colonoscopy after 4-12 months? | ☐ | ■ |
| Is the patient at least 18 years old? | ☐ | ■ |
| Has written informed consent been obtained? | ☐ | ■ |

| **Part C: Eligibility – Exclusion Criteria** | | |
|---|---|---|
| Does the patient have a bowel obstruction? | ■ | ☐ |
| Is the patient unable to undergo complete colonoscopies? | ■ | ☐ |
| Are they a patient with proctitis only? | ■ | ☐ |
| Does the patient have a previous history of colorectal cancer? | ■ | ☐ |
| **If UC only indicated in Part B (not applicable if PSC or PSC & UC)** | | |
| Does the patient have fulminant colitis? | ■ | ☐ |
| Are they a Crohns colitis patient? | ■ | ☐ |
| Does the patient have unclassified IBD? | ■ | ☐ |
| Does the patient have microscopic colitis? | ■ | ☐ |

| **Part D: Eligibility** | |
|---|---|
| ENDCaP-C eligibility must be confirmed by a medically qualified doctor. By signing this form the named clinician confirms that the information provided on this document is true and this patient fulfils all necessary criteria for inclusion into the ENDCaP-C study. | |
| **Name of person confirming eligibility:** | |
| **Signed:** | **Date eligibility confirmed:** DD / MMM / YYYY |

| **Part E: Consent & Registration** | | |
|---|---|---|
| Name of person taking consent: | | Date consent was taken: DD / MMM / YYYY |
| Name of person registering the patient: | | Version of consent form: v ___.___ |
| Trial Number (to be completed once registered): | ☐☐☐☐ | Date of Registration: DD / MMM / YYYY |

| **Form completed by:** | | |
|---|---|---|
| Full name: | **(PRINT NAME)** | Date form completed: DD / MMM / YYYY |
| Signed: | | |

**FOR TRIALS OFFICE USE ONLY:**

| Received: | Date | Initials | Entered: | Date | Initials | Checked: | Date | Initials |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

**CONFIDENTIAL ONCE COMPLETED**

**Please post to: ENDCaP-C Study, FREEPOST RTGS-UHJJ-AUCB , Birmingham**
**Clinical Trials Unit, University of Birmingham, Edgbaston, Birmingham B15 2TT**



Version 6.0, 11th January 2017

# The ENDCaP-C Study

# COLONOSCOPY FORM

TNO ☐☐☐☐

*To be completed at the time of colonoscopy (either baseline or repeat)*

Hospital: _____ Clinician: _____

Hospital number: ☐☐☐☐ Month and Year of birth: MMM / YYYY

(last four digits only)

**This section to be completed at Baseline ONLY:**

Smoker No ☐ Yes ☐ → If **yes**, how many cigarettes per day? ☐☐☐

Family history of IBD: No ☐ Yes ☐

Diagnosis age ☐☐

**Colonoscopy:** Initial ☐ Repeat (4-12 months) ☐ **Performed by:** _____

Date of colonoscopy: DD / MMM / YYYY

Length of time colonoscopy: ☐☐ hours ☐☐ mins

Dye spray used?* No ☐ Yes ☐

* This must be **"Yes"** for repeat (reference standard colonoscopy) at 4-12 months

Any complications of colonoscopy? No ☐ Yes ☐

If **yes**, was the bowel perforated or injured during the colonoscopy? (If yes this should be reported as a serious adverse event) No ☐ Yes ☐

Any other complications during the colonoscopy? No ☐ Yes ☐

If **yes**, please give details: _____

## If UC, Please give the Montreal classification:

***(Macroscopic assessment of the disease)***

Distal (Recto-Sigmoid) ☐ Extensive (beyond splenic flexure) ☐

Left-sided (to splenic flexure) ☐ Other (please specify) _____

**Completed by:**

| Full Name: **(PRINT NAME)** | Date form completed: DD / MMM / YYYY |
|---|---|
| Signed: | |

**FOR TRIALS OFFICE USE ONLY:**

| Received: | Date | Initials | Entered: | Date | Initials | Checked: | Date | Initials |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

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Version 4.0, 11th January 2017

# The ENDCaP-C Study

# MEDICATION FORM

TNO ☐☐☐☐

*To be completed within 30 days of the colonoscopy (either baseline or repeat)*

Hospital: _____ Clinician: _____

Hospital number: ☐☐☐☐

(last four digits only)

Month and Year of birth: MMM / YYYY

**Colonoscopy:** Initial ☐ Repeat (4-12 months) ☐

**Please confirm all the drugs the patient is on at the time of the colonoscopy:**

| Categories | If yes, please specify: **Medication Name** | **Dose** | **Route** |
|---|---|---|---|
| Aminosalicylates (5-ASAs) No ☐ Yes ☐ | | | |
| | | | |
| | | | |
| Immunosuppressants No ☐ Yes ☐ | | | |
| | | | |
| | | | |
| Biologics No ☐ Yes ☐ | | | |
| | | | |
| | | | |

**Completed by:**

| Full Name: **(PRINT NAME)** | Date form completed: DD / MMM / YYYY |
|---|---|
| Signed: | |

**FOR TRIALS OFFICE USE ONLY:**

| Received: | Date | Initials | Entered: | Date | Initials | Checked: | Date | Initials |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

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Version 3.0, 11th January 2017

# The ENDCaP-C Study

# HISTOLOGY FORM

TNO ☐☐☐☐

Hospital: _____

Hospital number: (last four digits only) ☐☐☐☐

Time point : Baseline ☐ Repeat (4-12 months) ☐

Month and Year of birth: MMM / YYYY

## ENDCaP-C Biopsy Sample

| Biopsy Sample | **Full Block Number** (exactly as given on the block) | Site |
|---|---|---|
| 1 | | ☐ Left side ☐ Right side ☐ Rectum |
| 2 | | ☐ Left side ☐ Right side ☐ Rectum |
| 3 | | ☐ Left side ☐ Right side ☐ Rectum |
| 4 | | ☐ Left side ☐ Right side ☐ Rectum |
| 5 | | ☐ Left side ☐ Right side ☐ Rectum |

**Note:** As a minimum, we require 2 x double-bite biopsies from the left side of the colon, 2 x double-bite biopsies from the right side of the colon, and 1 x double-bite biopsy from the rectum.

**Note:** If additional biopsies are included please complete the section overleaf.

**Was dysplasia, adenocarcinoma or any other abnormalities detected in any of the ENDCaP-C biopsy samples?**

**Please complete the table below for each biopsy sample.**

| Biopsy Sample | No abnormalities present | Possible dysplasia. Uncertain | Low grade dysplasia | Mix low/high grade dysplasia | High grade dysplasia | Adenoma | Other | If other, specify |
|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |

**Inflammation is being assessed centrally so associated comments should NOT be reported above.**

**Was dysplasia detected in any other biopsy taken during this colonoscopy that has not been sent to the ENDCaP-C Study Office?** No ☐ Yes ☐

**If yes,** please complete the sections below :

| Block Number | Site |
|---|---|
| | ☐ Left side ☐ Right side ☐ Rectum |

| No abnormalities present | Possible dysplasia. Uncertain | Low grade dysplasia | Mix low/high grade dysplasia | High grade dysplasia | Adenoma | Other | If other, specify |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

**Note:** If dysplasia or other abnormalities are detected in more than one biopsy sample, please give details overleaf.

**Continued on next page.**

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V6.0, 11th January 2017

# The ENDCaP-C Study

# HISTOLOGY FORM

TNO ☐☐☐☐

**Additional biopsy material sent?** No ☐ Yes ☐

**If yes, please complete the following sections:**

| Biopsy Sample | Block Number | Site |
|---|---|---|
| 6 | | ☐ Left side ☐ Right side ☐ Rectum |
| 7 | | ☐ Left side ☐ Right side ☐ Rectum |
| 8 | | ☐ Left side ☐ Right side ☐ Rectum |
| 9 | | ☐ Left side ☐ Right side ☐ Rectum |
| 10 | | ☐ Left side ☐ Right side ☐ Rectum |

**Was dysplasia, adenocarcinoma or any other abnormalities detected in any of the additional biopsy samples?**

**Please complete the table below for each additional biopsy sample.**

| Biopsy Sample | No abnormalities present | Possible dysplasia. Uncertain | Low grade dysplasia | Mix low/high grade dysplasia | High grade dysplasia | Adenoma | Other | If other, specify |
|---|---|---|---|---|---|---|---|---|
| 6 | | | | | | | | |
| 7 | | | | | | | | |
| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |

**Inflammation is being assessed centrally so associated comments should NOT be reported above.**

**Histology Completed by:**

| Full Name: **(PRINT NAME)** | Date form completed: DD / MMM / YYYY |
|---|---|
| Signed: | |

**FOR TRIALS OFFICE USE ONLY:**

| Received: | Date | Initials | Entered: | Date | Initials | Checked: | Date | Initials |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |



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# The ENDCaP-C Study

## SURGERY FORM

TNO ☐☐☐☐

*To be completed as soon as possible following surgery*

Hospital: _____ Clinician: _____

Hospital number: ☐☐☐☐ (last four digits only)

Date of birth: DD / MMM / YYYY

**To be completed after surgery:**

Date of surgery: DD / MMM / YYYY

Performed by: _____

**Type of surgery:**

- EMR / Polypectomy ☐
- Total Colectomy ☐
- Sub Colectomy ☐
- Pan-proctocolectomy ☐
- Other ☐ *If other, please specify:* _____

**How was the surgery performed:**

- Endoscopy ☐
- Laparotomy ☐
- Laparoscopy ☐

**Complications at the time of surgery?**

No ☐ Yes ☐

If yes, please specify:

_____

_____

**Completed by:**

| Full Name: **(PRINT NAME)** | Date form completed: DD / MMM / YYYY |
|---|---|
| Signed: | |

**FOR TRIALS OFFICE USE ONLY:**

| Received: | Date | Initials | Entered: | Date | Initials | Checked: | Date | Initials |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

**CONFIDENTIAL ONCE COMPLETED. Please post to: ENDCaP-C Study, FREEPOST RTGS-UHJJ-AUCB , Birmingham Clinical Trials Unit, University of Birmingham, Edgbaston, Birmingham B15 2TT**

# Blood and Stool Sample Collection

**Participant Trial Number:** ☐☐☐☐ **Month & Year of Birth:** ☐☐☐ / ☐☐☐☐

**Site:**

**Date sample(s) sent:** ☐☐ / ☐☐☐ / ☐☐☐☐

**TYPE OF SPECIMEN**

Please indicate which samples you are including in this shipment (*tick all that apply)*:

☐ **Blood** → Date sample collected: ☐☐ / ☐☐☐ / ☐☐☐☐

☐ **Stool** → Date sample produced: ☐☐ / ☐☐☐ / ☐☐☐☐

*(approximately)*

If one or both of the above will not be sent, please provide a reason why below:

_____

_____

**SENDER'S CONTACT DETAILS**

Email address:

Phone number: Fax number:

**Form completed by (print name):** _____ *(Please note: your name must be on the trial delegation log)*

**Signature:** _____ **Date signed:** ☐☐ / ☐☐☐ / ☐☐☐☐

**INSTRUCTIONS:**

(1) **Please FAX this form to the ENDCaP-C Study Office at 0121 415 8871.** This will be forwarded to the sample collection lab to notify them of an impending arrival.

(2) **Please remember to write the participant's trial number, month & year of the participant's date of birth and the name of your site on each of the samples.**

(3) **Place the samples, in the associated SpeciSafe transport packaging, AND this form in the padded envelope pre-labelled with the freepost address and send to:**

**Valerie Pestinger / Jonathan James**
**RAICR store**
**Institute of Cancer & Genomic Sciences**
**FREEPOST RTUH–AAHZ–CSSH**
**University of Birmingham**
**Edgbaston**
**Birmingham**
**B15 2TT**

**Please contact the ENDCaP-C Study Office if you have any queries:**

0121 414 9012 ENDCaP-C@trials.bham.ac.uk

# SERIOUS ADVERSE EVENT FORM

**Please report within 24 hours any SERIOUS ADVERSE EVENTS (see protocol section 7.1 for definition and expected SAEs within the study) by completing all of the details below and faxing this form to the ENDCaP-C Study Office on +44 121 415 8871. *Causality MUST be assigned to the SAE – this can only be done by a clinician***

| **Identification details:** | Patient TNO | | |
|---|---|---|---|
| Hospital number (last 4 digits only): | | Hospital | _____ |
| Month and Year of Birth: | MMM / YYYY | Responsible Consultant | _____ |

## SAE description:

SAE: New Event ☐ Related to previous event ☐

Date event started DD / MMM / YYYY Date event ceased DD / MMM / YYYY

Outcome: Fatal ☐ Recovered ☐ Continuing ☐

Details of Adverse Event (including any diagnosis, tests and action taken. Please attach copies of relevant reports):

_____

_____

_____

_____

| | | | |
|---|---|---|---|
| Was the event life threatening? | No ☐ | Yes ☐ | |
| Was the event fatal? | No ☐ | Yes ☐ → | If **yes**, Date of Death DD / MMM / YYYY |
| Did the event require/prolong hospitalisation? | No ☐ | Yes ☐ → | If **yes**, for how many days? _____ days |
| Other reason for reporting? | No ☐ | ☐ → | If **yes**, please specify _____ |

_____

Do you consider the SAE to be:

Definitely related to the colonoscopy ☐ Probably related to colonoscopy ☐ Possibly related to the colonoscopy ☐

Probably not related to the colonoscopy ☐ Definitely not related to colonoscopy ☐

Please give reasons if you consider the event to be related to the colonoscopy

_____

_____

Form completed by: _____ Date form completed: DD / MMM / YYYY

Signed: _____ Position: _____

**(You must have signed the delegation log)** Telephone number_____

**Signature of Principal Investigator:** _____ Date: DD / MMM / YYYY

When you have faxed the form, please then send this form (with copies of any relevant reports) to:

ENDCaP-C Study Office, Birmingham Clinical Trials Unit, FREEPOST RTGS-UHJJ-AUCB, University of Birmingham, Birmingham B15 2TT

**FOR BCTU USE ONLY:** **SAE Reference Number:**

| Date reported to BCTU: | Date reported to CI: | Date due to be reported to MREC: |
|---|---|---|
| Date DD / MMM / YYYY Initials_____ | Date DD / MMM / YYYY Initials_____ | Date DD / MMM / YYYY Initials_____ |

**CI comments:**

_____

_____

# The ENDCaP-C Study

TNO ☐☐☐☐

## ADDITIONAL DATA FORM

Hospital: _____ Month and Year of birth: MMM / YYYY

Hospital number: (last four digits only) ☐☐☐☐ Date of first ENDCaP-C colonoscopy: DD / MMM / YYYY

NHS number: ☐☐☐☐☐☐☐☐☐☐

Patient sex: Male ☐ Female ☐

Year of first or earliest documented of symptoms: ☐☐☐☐ (e.g. 1995, 2004)

Year of histologically confirmed diagnosis: ☐☐☐☐ (e.g. 1995, 2004)

Family history of colorectal cancer: No ☐ Yes ☐ Unknown ☐

If **Yes**, please **provide family details if available** or state **"information unavailable"** if applicable:

_____

_____

Approximate number of colonoscopies prior to first ENDCaP-C colonoscopy: 1 ☐ 2-5 ☐ 6-10 ☐ >10 ☐

Routine surveillance schedule at the time of the first ENDCaP-C colonoscopy: 1 yearly ☐ 3 yearly ☐ 5 yearly ☐

Approximate date of next planned non-trial colonoscopy: MMM / YYYY

*Please estimate the date of the next planned non-trial colonoscopy based on last colonoscopy and surveillance schedule if there is nothing recorded in the patient notes/records.*

Number of outpatient visits within the last 12 months: 0-3 ☐ 4-6 ☐ 7+ ☐

Number of inpatient hospital episodes within the last 12 months: 0 ☐ 1-2 ☐ 3+ ☐

Has the patient taken steroid medication for the treatment of their UC in the 12 months prior to the baseline ENDCaP-C colonoscopy? No ☐ Yes ☐

Has the patient taken regular aspirin in the 12 months prior to the baseline colonoscopy? No ☐ Yes ☐ Unknown ☐

Has the patient taken statins in the 12 months prior to the baseline colonoscopy? No ☐ Yes ☐ Unknown ☐

*It is anticipated that data for some questions may not always be available and "Unknown" has been provided as an answer to these questions. However, if any other questions cannot be answered, please annotate the form next to the associated question to indicate this.*

**Completed by:**

Full Name: **(PRINT NAME)** Date form completed: DD / MMM / YYYY

Signature:

| Received: | Date | Initials | Entered: | Date | Initials | Checked: | Date | Initials |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

**Please post to: ENDCaP-C Study, FREEPOST RTGS-UHJJ-AUCB, Birmingham Clinical Trials Unit, University of Birmingham, Edgbaston, Birmingham B15 2TT**



CONFIDENTIAL ONCE COMPLETED

**Health Questionnaire**

***English version for the UK***
***(validated for Ireland)***

TO BE COMPLETED:

**PRIOR TO INITIAL COLONOSCOPY**

**ENDCaP-C Trial No: ……..……**

**Patient Initials: …….....**

**Date of Birth: ……..……/…….…….....…/……..……**
**DD MMM YYYY**

**Today's date: ……..……/…….…….....…/……..……**
**DD MMM YYYY**

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

**Mobility**

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

**Self-Care**

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

**Usual Activities** (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

**Pain/Discomfort**

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

**Anxiety/Depression**

I am not anxious or depressed ❑

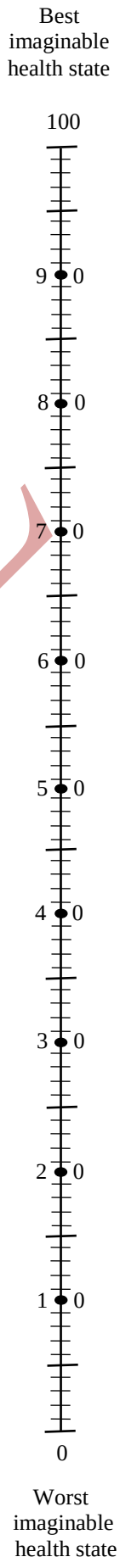
I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

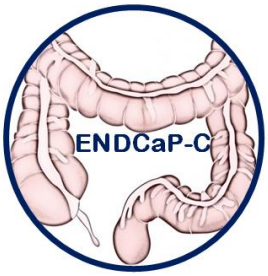
We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own health state today**



TO BE PRINTED ON TRUST HEADED PAPER

**GP Letter**




**Enhanced Neoplasia Detection and Cancer Prevention in Chronic Colitis (ENDCaP-C)**

Dear Dr .....

| | |
|---|---|
| Patient's Name: | DOB: |
| Address: | |
| Hospital No: | |

I am writing to inform you that the above named patient who is registered under your care who has been diagnosed with *ulcerative colitis or Primary Sclerosing Cholangitis*, has given their consent and subsequently been enrolled in the **ENDCaP-C** study.

The **ENDCaP-C** study is a multi-centre test accuracy cohort study which aims to prospectively evaluate the ability of a methylation assay to detect dysplasia missed by histology within a surveillance programme for colitis associated neoplasia (CAN).

Secondary issues to be explored include estimating the incremental accuracy of methylation testing over histology within a CAN surveillance programme and gain experience of its applicability in the clinical setting

Your patient has been provided with a Patient Information Sheet for the study (copy enclosed) which explains why he/she has been approached to take part in the study, and that his/her participation is entirely voluntary. The information sheet also explains what participation in the study will involve, the risks and benefits of taking part, and emphasises that your patient is free to withdraw from the study at any time without the need for justification and without prejudicing his/her future medical care.

The study is sponsored by The University of Birmingham and coordinated by the Birmingham Clinical Trials Unit (BCTU) at the University of Birmingham. **ENDCaP-C** was developed by the West Midlands Inflammatory Bowel Disease (IBD) Network and the University of Birmingham Clinical Trials Unit. The University of Birmingham Clinical Trials Unit are acting as coordinating centre. The study is funded by the NIHR Efficacy and Mechanism Evaluation (EME) Programme. The study has been approved by The South East Coast – Surrey Ethics Committee

Please note that follow-up data may be requested from you relating to your patients progress and survival status.

If you require any further information about the **ENDCaP-C study** in general, please contact the **ENDCaP-C** study office at the Birmingham Clinical Trials Unit. If you have any queries relating to your patient, please contact your patient's research team using the contact details listed below.

Please file this letter in the patient's notes. In addition the **ENDCaP-C** study office would appreciate being notified if they are no longer one of your patients.

Yours sincerely

……

**Name:**

**Job title:**

## Your patient's research team:

**Study doctor:** **Contact Number:**

**Research Nurse:** **Contact Number:**

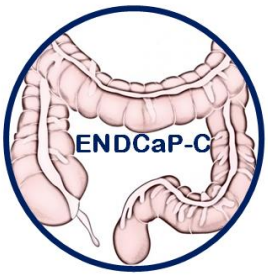
**ENDCaP-C Study Office, Birmingham Clinical Trials Unit (BCTU), School of Health and Population Sciences, Public Health Building, University of Birmingham, Edgbaston, B15 2TT.**

**Tel: 0121 415 9103 E-mail: ENDCaP-c@trials.bham.ac.uk**

TNO ☐☐☐☐

**DELETE THIS LINE AND PRINT ON TRUST HEADED PAPER**

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




## Patient Consent Form
## Version 5.0; 25th January 2017

**Sponsor Protocol Number: RG_12-074**

**Please initial each box to indicate your consent**

1. I confirm that I have read and understood the patient information sheet for the **ENDCaP-C** study 5.0 25th January 2017 and have had the opportunity to ask questions. ☐

2. I understand that I may have a repeat colonoscopy at 4-12 months after study entry ☐

3. I understand that my participation in this study is voluntary and that I may withdraw at any time, without giving a reason, and without my medical and legal rights being affected. ☐

4. I understand that information about me and my progress including long term follow up data will be supplied in confidence to the study coordinators at the University of Birmingham Clinical Trials Unit (BCTU) by my own doctors and by NHS registries for use in the **ENDCaP-C** study. This information may also be looked at by the Sponsor. I agree to information held and maintained by The Health and Social Care Information Centre, together with current and future UK NHS bodies, being used to help contact me or provide information about my long-term health status and healthcare. ☐

5. I agree to a copy of my consent form being sent to the central organisers of the **ENDCaP-C** study at the University of Birmingham CTU. ☐

6. In the unlikely event of a loss of my capacity the research team will retain personal data already collected and continue to use in for the purposes for which consent was sought. ☐

7. I understand that my relevant medical notes may be looked at by responsible individuals from the **ENDCaP-C** study office at the University of Birmingham CTU, or from regulatory authorities or the study sponsor or from the NHS trust, where it is relevant to my participation in this study. I give permission for these individuals to have access to my records. ☐

Continued on next page

TNO ☐☐☐☐

**Please initial each box to indicate your consent**

8. I understand that my GP will be informed of my participation in the study and may be contacted to provide information about my progress, in confidence, to the central organisers. ☐

9. I give permission for the collection and storage of biopsy samples taken from my bowel lining and for these samples to be sent to Queen Elizabeth Hospital Birmingham and The Birmingham United Molecular Pathology (BUMP) laboratory for tests, and for tissue to be stored after the study and used for future research projects approved by an Ethics Committee. ☐

10. I give permission for any remaining sample material at the end of the study to be stored at The Human Biomaterials Resource Centre at The University of Birmingham, a research tissue bank and for these samples to be made available for future research projects. ☐

11. I consent to the analysis of DNA extracted from my biopsy samples. ☐

12. I agree to take part in the **ENDCaP-C** study. ☐

**Optional consent:**

13. I agree to take part in the Blood and Stool Sample collection and understand that if have a repeat colonoscopy at 4-12 months I will be asked to provide a blood and stool sample. I give permission for these samples to be sent to University of Birmingham for testing, and to be stored after the study and used for future research projects approved by an Ethics Committee.

*(Please initial <u>one box only</u>. This will not affect your treatment).*

I agree ☐ I do not agree ☐

Name of Participant: ……

Signature: …… Date:……

Name of person taking consent: ……

Signature: …… Date:……


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

## Patient Information Sheet
## Version 5.0; 25th January 2017

## 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.

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

## Patient Information Sheet
## Version 5.0; 25th January 2017

**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).

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.

Depending on the results of the biopsy, you will either finish your participation in the study, no further action will be taken and your care will continue as usual. Or you may be invited to undergo another colonoscopy between 4 and 12 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. At this second colonoscopy, we will also request your permission to collect a stool sample and to take a small sample of blood. This blood and stool collection is optional and if you wish to take part in this, your consent will be taken. The samples will be sent on to the University of Birmingham. 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 4-12 month period and we will ask for your consent to do this when you enter the ENDCaP-C study. This will not involve return visits to the hospital, instead research staff involved in ENDCaP-C may, in the future, access electronic data from your central NHS records, for example through the Health and Social Care Information Centre (HSCIC). This will provide researchers with information that is routinely gathered and stored during your visits to primary care and hospital, and will allow researchers to find out about your health after the trial has ended. By using routinely collected data we will be able to do this without needing to contact you further. In order to do this, we would need to send your name, gender, date of birth and NHS number with any request for **information**.

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 may 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 4 and 12 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 and a registration form with your full date of birth and hospital number. 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, Institute of Applied Health Research, 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


**Full Title – ENDCaP-C Study: Enhanced Neoplasia Detection and Cancer Prevention in Chronic Colitis**

**Patient invitation letter**

Dear Sir/Madam,

We are writing to you because you are on the ulcerative colitis surveillance programme and will soon be returning to hospital for a routine colonoscopy.

We are running a study to try to find out if a new test used together with colonoscopy is better at detecting pre-cancer changes than just colonoscopy. We want to find out if this new test, which looks at changes in the structure of your DNA, can identify earlier than colonoscopy alone, which patients are at higher risk of developing cancer.

To try to investigate this, we are aiming to invite 1000 patients, from across the UK, with ulcerative colitis who are on the surveillance programme to participate in this study. This study has been developed by the West Midlands Inflammatory Bowel Disease (IBD) network and the University of Birmingham.

Enclosed is an information sheet which explains the study further and what it would involve for you as a participant.

We would like to invite you to meet the gastroenterologist 30 minutes before your next colonoscopy appointment to discuss this study further. Your doctor will be able to answer any questions you may have about the study.

Yours sincerely,

<insert consultant name>