**PATIENT INFORMATION LEAFLET AND INFORMED CONSENT FORM**

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| Study N°: | **08-62 (Version 5) 15/10/25** |
| Study Title: | **Bowel Disease Bio-resource Development : Identification of Potential Biomarkers for Bowel Disease** |

**STUDY CONTACTS**

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| Principal Investigators: | **Dr Niamh McCawley and Professor Jochen Prehn** |
| Hospital Name and Address: | **Beaumont Hospital** |

***If you have any questions concerning this study, or if any problems arise during the study, you can contact the following people during normal office hours.***

Study Doctor: Dr Niamh McCawley
Telephone no: 01-809 3092

***For questions about your rights or if you wish to make a complaint while taking part in this study, call the following:***
Clinical Trials Office

**Data Controller's/Joint Data Controllers Identity:** Beaumont Hospital/RCSI

**Data Protection Officer's Identiy:** Mark Graham

**Data Protection Officers Contact Details:** Data Protection Office, Beaumont Hospital: 01-8092162

**What is this Patient Information Leaflet about?**

You are being invited to take part in a research study being carried out with Beaumont Hospital and RCSI, to develop a bowel tissue resource ( biobank ) for future research into bowel disease.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

If you choose to participate in this study, you can change your mind any time you like by simply contacting the principal investigators at the above address. You don't have to give a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

**Do I have to take part?**

No, taking part is entirely voluntary. It is up to you to decide whether or not to take part. If, after considering all of the information in this leaflet and after discussion with your study doctor/study team, and once all of your questions have been answered, you do decide to take part, you will be asked to sign the attached informed consent form. This process is known as 'informed consent'. You will be given a copy of this information leaflet and the signed informed consent form to keep.

If you decide not to take part in the study, this will not affect the standard of care that you receive. If you decide to take part but later change your mind, before or after the study starts, you are free to discontinue without having to give a reason. This will not affect the standard of care you receive or affect any of your legal rights. Your study doctor may decide to discontinue your participation in the study with or without your agreement if it is in your best interest. Possible reasons for this will be explained to you by your study doctor prior to commencement of the study and are detailed later in this leaflet in the section: *Can anyone else stop me from being in the study?*

Thank you for considering taking part in the study and for reading this Patient Information Leaflet.

**Who is organising and funding the study?**

This study is organised through collaboration between the Department of Surgery , Beaumont Hospital as well as the Department of Physiology & Medical Physics in the Royal College of Surgeons in Ireland.

**What is the purpose of the study?**

Research into bowel disease is ongoing within Beaumont Hospital, and as part of that research, you are being asked to allow some of the diseased tissue that is normally removed, as part of your diagnosis or treatment, to be used for current and unspecified future research, subject to approval by an independent body, the Beaumont Hospital Ethics (Medical Research) Committee.

To undertake studies of the biology of bowel disease, it is vital to have access to large series of samples of tissue and corresponding clinical data. Although considerable progress has been made in the treatment of bowel disease, future advances are likely to be made through a greater understanding of the underlying biology.

This study may include genetic testing of your diseased tissue. To establish whether this is as a result of inherited genetic defects (genetic changes that are passed on in families), which may not only apply to you but also to your family members, and that can predispose some people to develop cancer, we would need to perform germline testing of normal tissue. This will not be carried out under the umbrella of this current study and further consent would be required if we were to ascertain such data or information.

**How many people will take part in the study?**

We anticipate the Biobank will eventually include samples from up to 5000 patients

**How long would I be in the study?**

If you decide to take part, you would be in the study for about 7 years.

## What will happen to me if I decide to take part in the study and what will I have to do?

**INFORMED CONSENT:**

If you decide to take part in the study, you will be asked to sign the consent form at the end of this Patient Information Leaflet.

As you are aware, you about to undergo (or will have had) a procedure, either a camera test (colonoscopy) or an operation to possibly diagnose or treat bowel disease. During the procedure samples will be taken and then studied in the Histopathology Laboratory in Beaumont Hospital to obtain information about your bowel disease. This information helps plan your future treatment. If you participate in this study, small pieces of the tissue not required by the lab will be taken and stored in the pathology department in Beaumont Hospital to be used for future research into bowel disease. The corresponding clinical information about you and your condition will also be required to be collected. Your tissue and clinical data will be kept indefinitely to ensure optimum use from your donated sample. No further personal involvement is necessary as you will not be required to return to give blood samples or have follow up visits for research purposes, as may be the case in other research studies.

In order to allow the greatest amount of research to be performed on this tissue and learn the greatest amount possible about colorectal cancer, the biobank may share your tissue and deidentified (pseudonymised /anonymise sed) medical information with other scientists and researchers at other universities, governments, hospitals, health related companies or research institutes either in Ireland or internationally. These individual research institutions must apply for specific ethical approval to use fresh or preserved tissue and data from this invaluable resource or have data agreements in place with Beaumont Hospital or RCSI if working in collaboration with them.

## What are the risks related to the sample collection procedures?

There are no specific risks involved in being included in this study.

## Where and how long will my samples be stored?

Your samples will be kept indefinitely. Samples will be stored at the local hospital and at the Royal College of Surgeons in Ireland in a laboratory freezer at -80°C.

If you discontinue or are discontinued from the study, the biological samples collected from you as part of the study will be removed . If the researchers did any testing of your biological samples before you withdrew your permission, the researchers will remove your data from the study.

**Who will have access to my samples?**

Researchers for this study from the Royal College of Surgeons and their collaborators will have access to the samples for the specific research indicated in this Patient Information Leaflet.

In order to allow the greatest amount of research to be performed on the sample you donate and learn the greatest amount possible, researchers involved in this study may share your sample and coded medical information with other scientists and researchers at other universities, hospitals, health-related companies or research institutes. If you consent to your coded biological samples being used for other scientific purposes in addition to the study, you have the right to object to that use at a later stage. If you wish to object to such use, please contact your study doctor.

Research performed with your sample and coded medical information could result in the discovery and development of new drugs, tests or products. There is no financial benefit in you taking part in this study, even in the event that new products, tests or treatments are developed or discovered. The biological samples which are taken as part of this study will be coded and your name, address, or hospital number will never appear on the sample. This is called 'coding'. Therefore, researchers will be unable to identify you from the sample.

**Will I be paid for my samples?**

You will not receive financial payment or any other payment in kind for participating in this study

**What do the study tests involve and what are the risks?**

All tests you will have are part of the routine care and the risks of these tests will be explained to you by the study doctor/study team in advance of any test being carried out.

You can ask your study doctor or study team any questions you may have about the risks and possible side effects of the study tests.

**What are the possible benefits of taking part in the study?**

You will not benefit directly from taking part in this study but the information we will obtain will provide further knowledge of bowel disease biology and ultimately assist in better understanding and improved treatment. You will not receive any information relating to the tissue provided to the biobank. If you agree to take part in this study you will have the satisfaction of knowing that your

participation may improve the future treatment and clinical care given to people diagnosed with bowel disease.

**Information about Confidentiality and Data Protection**

This section explains how your personal data including information derived from your biological samples and data about your health will be collected, used, shared and protected for the study. It also describes your rights in relation to your personal data. Your agreement with this collection, use and sharing of your personal data is part of your participation in the study. If you do not agree with the collection, use or sharing of your personal data, you will not be able to participate in the study.

- Personal data are protected by European Union (EU) data protection law (General Data Protection Regulation ("GDPR")).
- The study doctor and study team, and any other researchers working on this study must comply with this law.
- Any information that could directly identify you (such as your name, address, medical record number, contact information) will be replaced with a code by the study doctor and clinical study team before transferring your data to the research team. This means that the research team cannot identify you using only the data it receives. This is called 'coded data'.
- The Royal College of Surgeons in Ireland is the data controller of the data for this study as it is responsible for deciding what data will be collected and how it will be used.

The use of your personal data has the following legal basis under aticle 9.2(j) GDPR;

- 'Processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

**What personal data will be collected?**

To answer the research questions, the study doctor and clinical study team will collect personal data about you. This data will come from your medical records and questionnaires and the National Cancer Registry. The following data about you will be collected for this study:

- Date of Birth
- Results of examinations and tests such as laboratory blood tests, medical imaging such as x-ray, CT scan, MRI, genetic tests, tissue or sample tests.

- Information about your health and medical history, health conditions, previous and current treatments and medical procedures.

**How will my data be used?**

Your data will be reviewed, collected and used for the study as follows:

- to determine if you can participate in this study
- to manage the administrative processes of the study
- to learn more about the disease being assessed in the study

- to manage the study in accordance with best practice for research studies

Your coded data and biological samples collected for this study may also be used in future scientific research studies, the specific details of which may not be known at present. They could include:

- identification of new medical uses of the treatment for collorectal disease
- further examination of the disease or conditions being assessed in the study

The use of your personal data for future scientific research projects has the following legal basis under article 6 (e) of GDPR: Beaumont hospital wishes to use data relating to your health and care when you agree to take part in a research study due to its mission in the public interest to improve health outcomes and the lives of patients.

Under Article 9 of GDPR Genetic Data and Data concerning health will be included as part of future studies.

You can indicate your choices on the Informed Consent Form under 'Optional Decisions' at the end of this document as follows:

- whether you wish to consent to your samples to be part of any possible future research
- whether you wish to be contacted by your study doctor/team and asked whether you consent prior to any possible future research being conducted for which your samples may be eligible Any proposed research will be submitted to an appropriate research ethics committee to seek prior approval. Neither you nor your study doctor/team will be given reports or other information about any research that is done using your samples.

Choosing not to take part or not to be contacted will not affect your participation in the study and your current or future medical care.

As a research participant, you will have no ownership rights to discoveries arising from use of your clinical data and results of scientific research conducted on your tissue samples and no payment will be made to you even if research on your samples results in the development of new medical products or diagnostic tests.

**Who will receive my personal data?**

- The study doctor and study team will provide your coded data to the research team at the Royal College of Surgeons Ireland for the study.
- The research team may share your coded data with research partners at other universities, hospitals, health-related companies, drug development companies, or research institutes.
- The study doctor and study team may share your data with regulatory authorities in countries and with the ethics committees responsible for oversight of this study. These bodies are responsible for ensuring that the research is being conducted properly, in accordance with laws and ethical requirements, and

ensuring the protection of the rights, safety, and well-being of study participants, and they may use your data in order to fulfil their duties.

- The results of this study may be published in study reports or scientific presentations. They may also be used for research related to the development of pharmaceutical products, diagnostics or medical aids. Information that directly identifies you will not be included in any publication.
- Some of your coded genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

**What are the risks related to the use of my personal data?**

There is a risk that someone could get access to the personal data in your medical records at the hospital or your coded data that the research team at the Royal College of Surgeons Ireland has collected and stored.

Every effort will be taken to maintain participants' confidentiality; however, a low risk has been identified of confidentiality being compromised. All staff have undertaken additional training to reduce this risk to the lowest possible level.

**How will my personal data be protected?**

The study doctor and study team will store your coded data collected for the study in a secure storage area to which only authorised study staff have access. Representatives of the following groups may be provided with access to your medical records and your coded data stored at the study site to verify that the study is being conducted properly and that the study data are being reported correctly.

- The Royal College of Surgeons, Ireland
- Beaumont Ethics Committee

Both the study doctor and study team and all persons who are given access to your data are required to protect the confidentiality of your identity and your data and to use and disclose it only as described in this leaflet for the study.

- The Royal College of Surgeons Ireland will store the coded data provided by the study doctor and study team in a secure central database to which access is limited to only authorised staff who require them to manage, analyse and report on the study and has security measures in place to prevent unauthorised individuals from accessing coded data.
- The Royal College of Surgeons Ireland will only use your data for the purposes described in this leaflet. Research partners and authorised organisations of the Royal College of Surgeons Ireland are required to sign a written agreement to protect your coded data and use it only for the purposes described in this leaflet before your data is shared.

- The study doctor and The Royal College of Surgeons Ireland will retain your coded data for as long as is required by EU or local laws and regulations, consistent with best practice for conducting research studies.

The study site where the study is being conducted will retain your medical records for as long as required by law.

For this study, the research team will retain the coded data for 7 years after the submission of the final report or publication.

The research team may share your coded data with research partners located outside the EU where data protection laws may offer less protection than in the EU. Transfer of coded data to research partners outside the EU is covered by a Material and Data Transfer Agreement and can take place only if there are adequate data protection laws in the country or if there is an agreement in place to ensure the sharing of your coded data is in line with EU data protection laws. You may request a copy of the safeguards in place. Please ask the study doctor in the first place.

**What are my rights regarding my personal data that have been collected for the study?**

You may ask the study doctor to have access to the personal data that have been collected about you. If you believe that any of the data are incorrect, you may ask your study doctor in writing if it can be rectified or erased. According to the EU data protection law you have the following rights in relation to your personal data in certain circumstances: deletion, restriction of processing, objection to processing as well as the right to data portability (allows individuals to obtain and reuse their personal data for their own purposes across different services). However, your rights are limited in order for the research to be reliable and accurate.

As mentioned earlier in this leaflet, you have the right to withdraw your consent to participation in the study at any time without having to give a reason. If you discontinue or are discontinued from the study, the study doctor and study team will stop collecting and sharing new data from you for the study .If you discontinue from the study, the information about you that was already obtained will be removed from the study.

If you consent to your coded data being used for other scientific purposes in addition to the study, you have the right to object to that use at a later stage. If you wish to object to such use, please contact your study doctor.

**Consent to Future Uses**

Tissue samples and coded data collected through the study will only be used in future research to learn about, prevent, detect, or treat colorectal cancer. As part of this consent, permission is only granted for storage of your data/biological material for use as part of this current ongoing research. You may decide

you wish to be contacted and re-consented regarding possible future uses of your stored data/biological material . You also have the option to grant permission for this stored data/

biological material to be used in future research without the requirement of you granting consent on each occasion.

Future research may involve other Primary Investigators from RCSI or Beaumont hospital. Before any research is conducted the study will undergo thorough review by the Beaumont Hospital Research and Ethics group. Similar to the ongoing study, future research endeavours will relate to cancer research. More specifically the search for characteristics within tumours that may help diagnosis and treat this disease. For example; a future study may look to see if a novel protein relating to a resistance to a cancer treatment was present in your tumour sample. However your data/ biological material will never be used in studies outside the remit of cancer research.

Coded data pertaining to personal information provided by consenting individuals will be maintained in a secure central database to which access is limited to only authorised staff who require them to manage, analyse and report on the study and has security measures in place to prevent unauthorised individuals from accessing coded data.
Biological material will be maintained within the RCSI biobank. Material will be coded and will only be identifiable by authorised staff who have been granted permission to access coded data. Stored biological material includes resected tumour samples that were removed during the surgical process. Samples are usually fixed in formalin and embedded is paraffin for the purpose of preservation.

At present cancer research is funded by Research charities such as the 'Irish Cancer Society' and there is no commercial involvement. Should future research involve commercial groups, such involvement will be reviewed in advance by the Beaumont Research and Ethics group before initiation and contracts will be put in place to ensure your data is protected.

**Who can I contact for more information about the use of my data in this study?**

If you have any questions about how your coded personal data will be collected, used and shared in the study, please contact your study doctor and/or study team (see the **Study Contacts** on the first page).

If you wish to raise a complaint on how The Royal College of Surgeons Ireland has handled your data, you can contact RCSI's Data Protection Officer as follows:
email: dataprotection@rcsi.ie

The Data Protection Officer will investigate the matter. If you are not satisfied with the response or believe The Royal College of Surgeons Ireland has processed your data unlawfully you can make a complaint to the

supervisory authority as the main data protection authority for The Royal College of Surgeons Ireland as follows:

Data Protection Commission, Canal House, Station Road, Portarlington, Co. Laois, Ireland
Tel. +353 (0)57 868 4800 or Lo-Call: 1890 25 22 31 | e-mail: info@dataprotection.ie

**Can I stop being in the study?**

Yes, you can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

**Can anyone else stop me from being in the study?**

The study doctor may stop you from taking part in this study with or without your agreement at any time if:

- it is in the best interest for your health
- you do not follow your responsibilities for taking part in the study
- it is discovered at a later time that you do not meet the study participation requirements
- the study is stopped by the sponsor
- the sponsor stops enrolling new patients for any reason
- administrative reasons require your discontinuation

**What happens if I am injured because I took part in this study?**

It is important to note that nothing said in this consent form alters your legal rights to seek to recover damages should you suffer injury as a result of participation in this study.
Every reasonable precaution will be taken to ensure your safety during the course of the study.

Participation in this study is covered by the State Claims Agency. The amount of any compensation paid may, however, be reduced if you have not complied with the instructions issued for this study. In addition, the medical practitioners involved in this study have current medical malpractice insurance coverage and coverage under the Clinical Indemnity Scheme managed by the State Claims Agency.

It is important that you tell your study doctor if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or telephone the number listed in the **Study Contacts** on the first page.

**What are the costs of taking part in the study?**

There will be no extra costs for any tests when you are taking part in this study. Your travel expenses will not be reimbursed. Also, you will not be paid for your participation in this study.

**Who has reviewed and approved this study?**

This study has been reviewed and approved by Beaumont Hospital Ethics Committee.

**What will happen to the results of the study?**

Once all patients have completed their participation in the study, the information obtained will be analysed. Results of the study are likely to be published in medical journals and used for scientific presentations. You will not be identified in any reports or publications resulting from the study. Your study doctor will be informed of the overall study results when they are known. If you would also like to know the results of the study, the study team will be able to give this information to you when it becomes available. Results from the research specifically on your donated tissue samples will not be returned to you or your study doctor.

**INFORMED CONSENT FORM**

| | |
|---|---|
| Study N°/ Title: | Bowel Disease Bio-resource Development : Identification of Potential Biomarkers for Bowel Disease; Tissue retention and destruction. |
| Study Doctor name: | Dr Niamh McCawley |
| Hospital name: | Beaumont Hospital, Dublin |

| | Please read through the following numbered points and initial the boxes on the right hand side to confirm acceptance of each point | Please initial box |
|---|---|---|
| 1. | I have read the Patient Information Leaflet about this research study or it has been read to me. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction. | |
| 2. | I understand that my participation in the study is voluntary and that I am free to discontinue at any time without having to give a reason and without my medical care or legal rights being affected. | |
| 3. | I am aware of the potential risks and benefits of taking part in this study. | |
| 4. | I give my permission for my medical records to be looked at by the study team, Beaumont Hospital Ethics Committee, and the other organisations named in the Patient Information Leaflet and/or their designated representatives who have a duty of confidentiality not to disclose my identity, to confirm that the study is being conducted correctly and that the information collected is accurate. | |
| 5. | I give explicit informed consent for my personal data including data about my health, where a code replaces my name, to be collected, processed and analysed as is required for the study.<br>I consent to the transfer of my data outside of the European Union/European Economic Area which may have a lower level of protection than in Europe. I understand that without my agreement to the processing of my personal data I cannot take part in the study. | |
| 6. | I understand that if I agree to take part in the study that my samples including data derived from my samples may be used for research as described. I understand that I will have no direct benefit from this research and have no ownership rights to discoveries arising from the use of my data and I will receive no payment nor be entitled to a share of any profits if research on my samples results in the development of new medical products or diagnostic tests. | |

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|---|---|---|
| 7. | I understand that if I withdraw my consent for the participation in the study, I may request that all my tissue samples are disposed of in a lawful and respectful manner and remaining diagnostic tissue is returned to the hospital. | |

| | **Optional Decisions** | **Tick YES or NO below** |
|---|---|---|
| | **Please read the following points and tick either the Yes or No box on the right hand side** | |
| 1. | I give permission for my tissue samples and coded data collected through the study to be used in possible future research to learn about, prevent, detect, or treat colorectal disease.<br>If YES please tick the appropriate box according to your wishes<br>☐ I give my full consent and do not want to be further contacted.<br>**or**<br>☐ I want to be re-contacted by my study doctor/team for my additional consent before my samples are used. | ☐ Yes ☐ No |
| | | |
| **I consent to take part in this study. I am not giving up any of my legal rights by signing this form.** | | ☐ Yes ☐ No |

| Patient | | |
|---|---|---|
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| Name (Print) | Signature | Date |

| *Legally Acceptable Representative (if applicable) | | |
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| | | |
| Name (Print) | Signature | Date |
| **Write the patient name above in addition to the Legally Acceptable Representative* | | |

| Witness (if applicable) | | |
|---|---|---|
| | | |

| Name (Print) | Signature | Date |
|---|---|---|

| Study doctor (investigator) | | |
|---|---|---|
| | | |
| Name (Print) | Signature | Date |

| Consenting Professional* | | |
|---|---|---|
| | | |
| Name (Print) | Signature | Date |

**Principal Investigator/Sub-investigator/Research Nurse/Translational Research Coordinator/Other Healthcare Professional who is permitted to obtain consent, has received appropriate training and is delegated by the Principal Investigator.*

**Informed Consent**

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|---|---|
| Study N$^{o}$/ Title: | Bowel Disease Bio-resource Development : Identification of Potential Biomarkers for Bowel Disease; Genetic analysis |
| Study Doctor name: | Dr Niamh McCawley |
| Hospital name: | Beaumont Hospital, Dublin |

| | **Please read through the following numbered points and initial the boxes on the right hand side to confirm acceptance of each point** | **Tick YES or NO below** |
|---|---|---|
| 1. | I have read the Patient Information Leaflet about this research study or it has been read to me. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction. | ☐ Yes ☐ No |
| 2. | I understand that my participation in the study is voluntary and that I am free to discontinue at any time without having to give a reason and without my medical care or legal rights being affected. | ☐ Yes ☐ No |
| 3. | I am aware of the potential risks and benefits of taking part in this study. | ☐ Yes ☐ No |

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|---|---|---|
| 4. | I give my permission for my medical records to be looked at by the study team, Beaumont Hospital Ethics Committee, and the other organisations named in the Patient Information Leaflet and/or their designated representatives who have a duty of confidentiality not to disclose my identity, to confirm that the study is being conducted correctly and that the information collected is accurate. | ☐ Yes ☐ No |
| 5. | I give explicit informed consent for my personal data, including genetic data and data about my health, where a code replaces my name, to be collected, processed and analysed as is required for the study.<br><br>I consent to the transfer of my data outside of the European Union/European Economic Area which may have a lower level of protection than in Europe. I understand that without my agreement to the processing of my personal data I cannot take part in studies that involve analysis of genetic material. | ☐ Yes ☐ No |
| | **Please read through the following numbered points and initial the boxes on the right hand side to confirm acceptance of each point** | **Tick YES or NO below** |
| 6. | I understand that if I agree to take part in the study that my samples including data derived from my samples may be used for research as described. I understand that I will have no direct benefit from this research and have no ownership rights to discoveries arising from the use of my data and I will receive no payment nor be entitled to a share of any profits if research on my samples results in the development of new medical products or diagnostic tests. | ☐ Yes ☐ No |
| 7. | I understand that if I withdraw my consent for the participation in the study, I may request that all my tissue samples are disposed of in a lawful and respectful manner and remaining diagnostic tissue is returned to the hospital. | ☐ Yes ☐ No |

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| | **Optional Decisions**<br>**Please read the following points and tick either the Yes or No box on the right hand side** | **Tick YES or NO below** |

| | | |
|---|---|---|
| 1. | I give permission for my tissue samples and coded data collected through the study to be used in possible future research to learn about, prevent, detect, or treat colorectal disease.<br>If YES please tick the appropriate box according to your wishes<br>☐ I give my full consent and do not want to be further contacted. **or**<br>☐ I want to be re-contacted by my study doctor/team for my additional consent before my samples are used. | ☐ Yes ☐ No |
| 2. | I give permission for my tissue samples and coded data collected through the study to be used in possible future research unrelated to the current study.<br>If YES please tick the appropriate box according to your wishes<br>☐ I give my full consent and do not want to be further contacted.<br>**or**<br>☐ I want to be re-contacted by my study doctor/team for my additional consent before my samples are used. | ☐ Yes ☐ No |
| | | |
| | | |
| **I consent to take part in this study. I am not giving up any of my legal rights by signing this form.** | | ☐ Yes ☐ No |

| Patient | | |
|---|---|---|
| | | |
| Name (Print) | Signature | Date |

| *Legally Acceptable Representative (if applicable) | | |
|---|---|---|
| | | |
| Name (Print) | Signature | Date |
| **Write the patient name above in addition to the Legally Acceptable Representative* | | |

| Witness (if applicable) |
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| | | |
|---|---|---|
| | | |
| Name (Print) | Signature | Date |

| Study doctor (investigator) | | |
|---|---|---|
| | | |
| Name (Print) | Signature | Date |

| Consenting Professional* | | |
|---|---|---|
| | | |
| Name (Print) | Signature | Date |

**Principal Investigator/Sub-investigator/Research Nurse/Translational Research Coordinator/Other Healthcare Professional who is permitted to obtain consent, has received appropriate training and is delegated by the Principal Investigator.*

*2 copies to be made: 1 for patient, 1 for hospital records; original to Investigator Site File*