Title of Study: Microchip-based Lab-on-Chip system for detection of genetic biomarkers of colorectal cancer in blood or stool
IRAS Project ID: 291551 **Chief Investigator:** Dr Constantinos Simillis

Patient Information Sheet

Brief Summary

Our study will test a blood sample and a faeces ('poo') sample on a microchip to see how good the microchip is at detecting genetic (DNA) markers specific to colorectal (bowel) cancer.

It is important to us that people diagnosed with colorectal cancer are willing to provide a blood and faeces sample to test with this new microchip.

If you think that you might be interested in helping our research, please read the information below.

Why is the study being done?

Colorectal cancer is the third most common cancer worldwide, and the second leading cause of cancer death globally. Detecting colorectal cancer early is key to improving patient outcomes, and the outcomes of treatment are much better when the cancer is found earlier. Also, identifying specific genetic markers (DNA) can guide and improve treatment of patients with colorectal cancer.

To test for colorectal cancer, patients need to have a colonoscopy (passing a camera into the bowel), which is accurate in detecting colorectal cancer, but it is invasive, requires bowel preparation, is associated with risks, and may cause patient discomfort and anxiety.

Colorectal cancer releases genetic markers (DNA) in the faeces or blood, and we have developed an innovative microchip-based Lab-on-Chip system which can detect these markers, and therefore, may be able to detect whether or not someone has colorectal cancer. In addition, such genetic markers can guide personalised patient treatment and improve patient outcomes.

This microchip-based test is designed to be fast, safe, reliable, non-invasive, lab-free, and easy-to-use. It is designed as a point-of-care test for genetic markers specific to colorectal cancer in blood and stools.

We need blood and faecal samples from patients who have been diagnosed with colorectal cancer. The blood and faecal samples will be tested with the microchip-based test to assess the ability of the microchip-based test in identifying genetic markers specific to colorectal cancer.

Why have I been asked to take part?

You have been given this information sheet because you have unfortunately been diagnosed with colorectal cancer.

Do I have to take part?

No, you do not have to take part. It is completely up to you, and you can always change your mind at any time. Your care will not be affected in any way.

When do I have to decide?

Ideally, you will decide once you have read and understood this information sheet and the hospital doctor/nurse/researcher has answered all your questions. However, it is OK if you wish to take the information away and discuss it with your family and friends. You will need to make another appointment with the research team if you do want to take part.

What is involved?

Once you have read this information sheet and the research team has answered any questions you may have, you will be asked to sign a consent form. This form lists the different things you will be asked to consent to, some of which will be optional.

Providing a faeces sample – You will be asked to provide a faeces sample. You will be able to collect a faeces sample in your own privacy at home or at the hospital. You will be provided faecal collection kits by post or provided when you attend hospital for any reason. You will be asked to place a small amount of faeces in a tube according to instructions within each test kit. You will be able to send the sample by post to our research laboratory with a form containing your information, or we can collect it from you in person when you attend hospital for any reason.

Providing a blood sample – You will be asked to provide a blood sample. This blood sample can be done at any time during the day, and you do not need to be fasted. The blood sample can be collected when you attend the hospital for any reason. This is a simple routine venepuncture (blood collection with a needle) to collect a small amount of blood. This will be done by a qualified healthcare professional or a phlebotomist (person taking routine blood tests).

Questionnaire or Interview (optional) – You will be asked to fill in a questionnaire regarding your views, opinions, and experience in having this new test. The questionnaire can be filled-in electronically or on paper. You may be also asked to have an interview with a member of the research team by telephone or in person, at a convenient time for you. There is no pressure to agree to fill-in the questionnaire or perform the interviews – you can agree to only providing the blood and faeces samples and decline the questionnaire or interview part and that would be OK with us.

What will happen if I do not want to carry on with the study?

Participation is voluntary, and no reason needs to be given if you wish to withdraw. By not providing blood and faecal samples, we will assume that you have changed your mind, and we will record on our database that you no longer wish to take part. If you have already provided a faeces or blood samples and wish to withdraw at that stage, we will continue to store and later analyse the samples unless you expressly tell us that you would like the samples to be destroyed. You can do this by contacting the study manager or chief investigator (see end page for contact details).

Please try to let us know if you have changed your mind about being interviewed by emailing c.simillis@nhs.net and we can remove you from our list of people to make contact with to arrange interviews. You can also let us know when we contact you to arrange the interview if you want to change your mind. You are not under any obligation to continue if you do not want to.

What are the possible benefits of taking part?

There are no benefits for you directly, although there may be in the future for you and many others. The results of the combined blood and faeces sample analyses will not be provided to your GP/consultant or you as a patient as they are not yet proven to work in predicting colorectal cancer. That is why we are doing this study.

What are the possible risks of taking part?

There is no actual research intervention (i.e. no medications or any active treatment given), and therefore, there is no significant risk of harm to patients participating in the study. You may experience slight bruising where the blood sample is taken, this is normal for some people who have blood tests, but if you are concerned, you should discuss this with the research team.

What if new information comes along?

Sometimes during research, we get new information about the treatment being studied. If this happens, we will tell you about it and discuss whether you want to continue in the study.

What information will you collect?

We will collect participant details, including name, surname, date of birth, age, hospital number, NHS number, address, phone number and/or email address. This information is needed so that NHS research staff can find your medical records to look for your clinical information and diagnosis, and to be able to contact you. Furthermore, we will collect any information regarding investigations of your bowel, including the result of your colonoscopy, or any other bowel tests(if performed), such as biopsy tests, genetic tests, blood tests or faeces tests, or radiological tests. No other information will be looked at. You will be allocated a unique key study number, and the main dataset will contain no personal identifiers, and the laboratory research staff performing the tests with the microchip will have no access to the NHS system to identify you.

How will my information be kept confidential?

Any details about you will remain strictly confidential. Participant anonymity will be protected and maintained. Participants' identities will be protected from any unauthorised parties. Information with regards to the trial will be kept confidential and managed in accordance with the Data Protection Act 2018, the General Data Protection Regulation 2016 (GDPR), NHS Caldicott Guardian, The Research Governance Framework for Health and Social Care and Research Ethics Committee Approval.

A unique study number for each study participant will be assigned as each individual enters the study. Faeces and blood samples that are collected for the study will be sent to the laboratory for processing and testing with the microchip device anonymously (no personal identifiers) using the unique study number linked to each study participant. Results from the samples will only refer to that unique study number (not your name or any other personal identifiers) and the results will be recorded alongside your unique study number by the study research team. Similarly, your questionnaire or interview will be assigned a unique study number and any identifiable information such as names and places will be coded and removed.

Appropriate access controls will be in place to ensure that access to confidential research information is restricted to those who need access. Your personal information will be retained at the Cambridge University Hospitals NHS Foundation Trust (CUH) in a secure environment until the study has ended. CUH is the sponsor for this study based in the United Kingdom. CUH will be using information from your medical records in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly. CUH will keep any identifiable information about you for five years after the study has finished.

In accordance with the General Data Protection Regulations (GDPR) guidelines, your right to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at https://www.hra.nhs.uk/information-about-patients/

CUH will make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from CUH and regulatory organisations may look at your medical and research records to check the accuracy of the research study. CUH will pass these details to their Research and Development department along with the information collected from your medical records. The only people in CUH who will have access to information that identifies you will be people who need to audit the data collection process. The people who analyse the test results will not be able to identify you and will not be able to find out your name or contact details.

All information will be held on a secure database which is maintained by Cambridge Trials Unit. The database can only be accessed by authorised users who agree to abide by data protection regulations. Any paper based trial and personal data, including signed consent forms, will be stored in locked filing cabinets in a locked office with access restricted only to authorised personnel in a secure building which requires electronic tags to enter.

What happens to my samples?

Your stool and blood samples will be collected and processed at CUH. At the earlier stages of the study, the processed samples will be sent to the laboratory at Imperial College London to be tested with the microchip. At the later stages of the trial, the testing on the microchip will also be done at CUH. The results of the microchip-based test will be documented and then the stool and blood samples will be discarded.

What will happen to the results of this study?

We hope that the results of the study will help to develop an innovative, non-invasive, easy-to-use, lab-free, sample-to-result, point-of-care microchip-based colorectal cancer specific test that will enable fast detection of multiple tumour genetic markers specific to colorectal cancer in blood and stools, with the potential to promote personalised patient care and serve as a diagnostic, prognostic, and monitoring tool. We also hope to show that patients and healthcare professionals are willing to use the test as part of standard care if it were to be made available in the future.

This microchip-based test could be used in the future to provide a quick answer as to whether or not your GP should send you for a colonoscopy or equivalent procedure. As these procedures are invasive, uncomfortable and have risks, and are expensive and have long waiting lists, we hope that our tests will provide some quick reassurance for those who test negative, and for those who test positive they should be given priority for any further investigations.

Furthermore, this test may be used at the hospital outpatient clinic setting to assess if a patient requires more investigations, as part of diagnosis or surveillance, such as colonoscopy and CT scan. In addition, identification of specific genetic markers included on this microchip-based test may help in patient prognosis (by categorising patients based on their risk profile for cancer progression) and help to guide treatment (by predicting response to different types of treatment), and overall improve colorectal cancer patients outcomes.

If you would like a copy of the final study report (not individual results) this will be through our study's Twitter or website or Facebook page. You can however request a mailed newsletter of our study results at study completion by contacting the Study Manager (details below) or returning the contact card provided.

Will I be paid for taking part?

Unfortunately, we are unable to offer any money to people who agree to take part.

Who has funded and reviewed this study?

The study has been funded by Penguins Against Cancer (https://www.penguinsagainstcancer.org.uk) and Red Trouser Day (https://redtrouserday.com).

The study documentation has been reviewed by London City & East NHS Research Ethics Committee.

What if there is a problem?

If you have any concerns about your NHS care, please discuss this with your GP or hospital doctor.

If you have any questions or concerns about your participation in this study, please contact:

Dr Constantinos Simillis Chief Investigator Addrenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Hills Road, CB22 0QQ c.simillis@nhs.net 01223348219	**Study Team** Address Email Telephone

Alternatively, if you wish to speak to an independent person, you should contact your local Community Health Council.

If we cannot resolve your concerns or problem, then Cambridge University Hospitals NHS Foundation Trust has an NHS complaints procedure. Please write to:

Chief Executive, Cambridge University Hospitals NHS Foundation Trust, Addrenbrooke’s Hospital, Hills Road, CB22 0QQ. Telephone: 01223 805000; Email: