Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Bowel Health Service, Flinders Centre for Innovation in Cancer,
Department of Surgery, Flinders Medical Centre,
Flinders University, Noarlunga Health Service,
The Queen Elizabeth Hospital, Lyell McEwin Hospital
and Royal Adelaide Hospital.

Title	Novel blood biomarker tests to detect adenocarcinomas
Short Title	**Cancer detection with a blood test**
Protocol Number	162.16
Project Sponsor	N/A
Coordinating Principal Investigator/ Principal Investigator	**Assoc Prof Erin Symonds**
Associate Investigator(s)	Prof G Young, Prof C Karapetis, Dr S Pedersen, Prof D Watson, Dr D Hussey, Dr M Chong, Dr M Eaton, Dr A Rose, Dr T Wilson, Dr J Winter, L Sheehan-Hennessy, A/Prof M Michael, Dr H Kanhere, Dr L Dandie, Prof T Price, Dr A Roy, Dr S Barreto, S Byrne and M Horsnell.
Location	Flinders University, Noarlunga Health Service, Flinders Centre for Innovation in Cancer, Flinders Medical Centre, The Queen Elizabeth Hospital, Lyell McEwin Hospital and Royal Adelaide Hospital.

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, *Novel blood biomarker tests to detect adenocarcinomas*. This is to help us better understand how to detect and prevent specific cancers. We have previously developed a blood test for the detection of bowel cancer which is an adenocarcinoma type of cancer. This research project is aiming to see if this blood test is also able to detect and monitor other adenocarcinoma cancers, such as breast cancer, prostate cancer, lung cancer, pancreatic cancer, oesophageal cancer stomach (gastric) cancer, as well as other digestive tract cancers, such as those in the gallbladder, biliary tree, duodenal and other periampullary areas.

You have been invited to take part in this study because you are currently undergoing some tests to determine if you need further treatment, or you have had treatment for one of the cancers named above.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described.

2 What is the purpose of this research?

The aim of the study is to determine if the blood test, that has been developed to detect bowel cancer, will also be able to detect breast cancer, prostate cancer, gastric cancer, lung cancer, pancreatic cancer, oesophageal cancer as well as other digestive tract cancers. We are interested in cancers because they have some similarities to bowel cancer.

The study team have been involved in the development of this new test for bowel cancer, based on detecting changes in the blood. It checks for different types of "molecular markers", which signify that cancer might be present.

The goal of these tests is to identify individuals who have a higher chance than normal of having cancer and therefore might benefit from further medical investigation to confirm this. A new blood test will have beneficial health outcomes as early detection of cancer allows earlier treatment when the prognosis is better. We are also interested in looking at whether the blood test can be used to monitor the effect of treatment on the different cancer types.

This research has been initiated by the study doctor, Associate Professor Erin Symonds.

This research has been funded by a Flinders Medical Centre Foundation Seeding Grant as well as Clinical Genomics, *(a commercial laboratory, involved with tests for cancer detection*) and a *Medical Research Future Fund* (MRFF) Grant.

3 What does participation in this research involve?

You will be asked to participate in this study if you are:

- over 18 years of age
- have had a recent diagnosis or investigations for breast cancer, prostate cancer, gastric cancer, oesophageal cancer, lung cancer, pancreatic cancer, or any other digestive tract cancers (as named on page 1) and have not yet received any treatment or surgery **OR**
- have had treatment for any cancers, that are named above, within the last 3 years.

This study primarily involves a series of blood sample collections, which will be taken before, during and after your treatment. There are also options for researchers to access a small sample of your tissue or biopsy samples.
These blood collections will usually take place when you attend an appointment with your doctor, or we can arrange a home visit or meet you at your closest pathology clinic, whatever is easiest for you.

We will also ask you some questions about your medical and surgical history, and also ask your permission to access your medical and pathology reports which are associated with your cancer diagnosis and treatment.

If you wish to participate in this study, we will ask you to sign a consent form, to indicate your agreement to the following:

BLOOD SAMPLE COLLECTION:

DURING INVESTIGATIONS OR BEFORE TREATMENT:

- Collection of a 35 mL sample of blood (4 small tubes), on the first occasion.

We can collect this at a time when you may need other blood tests, or separately before you receive any treatment for cancer. This will be done using a standard needle and blood collection tubes.

DURING TREATMENT:

- Collection of 27mL samples of blood (3 small tubes), taken in the middle of your treatment, or at 1-2 monthly intervals throughout your treatment, depending on your treatment schedule

AFTER TREATMENT:

- Collection of 27mL blood sample (3 small tubes) taken at approximately 6 monthly intervals for up to three years after your treatment. We would obtain this sample of blood when you have an existing appointment, or as a separate visit, or as a home visit, in the same manner as above.

TISSUE AND BIOPSY SAMPLES: *(Optional)*

- Should you have a biopsy or surgery as part of your treatment we would like to request your permission to store and test some of the tissue collected. These samples will be stored in the tissue bank at Flinders Medical Centre and the tissues will be used in the research laboratories at Flinders Centre for Innovation in Cancer at a later date.

MEDICAL INFORMATION:

- We will also ask you some questions about your medical and surgical history, and ask your permission to access your pathology reports which are associated with your cancer diagnosis and treatment.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

4 What do I have to do?

No dietary or lifestyle restrictions are required for the blood test.
You do not need to fast from any food or liquid before this blood test.

We will collect blood from you for this study, at a time that is suitable for you.

5 Other relevant information about the research project

We are collecting blood from 700 participants in total. We will collect blood samples from 100 participants with oesophageal cancer, 100 with prostate cancer, 100 with gastric cancer, 100 with

lung cancer, 100 with pancreatic cancer, 100 with other digestive tract cancers and 100 with breast cancer, before and after treatment.

This research will be done through Flinders University, Flinders Medical Centre and Noarlunga Health Service, Lyell McEwin Hospital, The Queen Elizabeth Hospital and Royal Adelaide Hospital and run by a team of researchers who have specialised in gastrointestinal, breast, lung, digestive tract and urological cancer research.

We are currently enrolling an additional 150 participants with gastric or oesophageal cancer (within the last 3 years).

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with any of the hospitals involved in this study.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Being involved in this research study will not affect any treatment that your physician has planned for you. The support that you receive after your diagnosis will be as recommended by your treating physician and their team. Please discuss this study with the research staff before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

The aim of this project is to develop new biomarkers for cancer detection and to monitor the effectiveness of treatment. The results will be analysed at the completion of the study, which means that they will not be fed back to the treating physicians during the study. At the completion of the study, the results will be presented to the scientific and medical community in a de-identified form.

There will therefore be no clear benefit to you from your participation in this research as you and your doctor will not receive any results from the tests that we are developing during the study. However possible benefits to the wider community may include the development and commercialisation of a screening blood test that will allow the detection of breast, prostate, pancreas, stomach, oesophageal, lung and other digestive tract cancers at an earlier and more curable stage, as well as a blood test to monitor cancer treatment. Earlier detection of cancer means treatment is more likely to be successful.

9 What are the possible risks and disadvantages of taking part?

Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

If you become upset or distressed as a result of your participation in the research, the study coordinators will be able to arrange for counselling. Any counselling will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

The main part of this study is to collect some blood samples from you. It is optional for you to also provide some excess tissue from your biopsy or surgery.

The blood and any biopsy/tissue samples collected will be identified by a code number so that no individuals can be identified from the samples. All blood samples will be stored securely for the duration of the study and any remaining samples will be destroyed once all tests are complete. Any tissue sample that you provide for the purposes of this research study will be stored in the Tissue Bank located at Flinders Medical Centre (FMC). Once your tissue sample has been stored, it may be used for other research purposes, but only following approval by the local ethics committee. Additional testing cannot be conducted without the ethics committee's approval and your written consent.

By signing the consent form and ticking the optional check box, you are giving us permission to store your samples. The samples will only be used for study related purposes, and no other analyses other than study related analyses will be performed.

Your blood sample will be processed at Flinders University then your frozen, de-identified samples will be sent to Clinical Genomics, a laboratory in New Jersey, USA, to look for new biomarkers in the blood that may indicate the presence of cancer. Following the analysis of your blood sample/s by Clinical Genomics, any remaining sample will be disposed of and not stored.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. However, in this study the results will only be analysed at the end of the study, which means that no new information will arise during your involvement in this study.

12 Can I have other treatments during this research project?

You may have other treatments during this research, however, please let the study staff know if you are participating in any other clinical trials. The only study requirement is to have your blood sample collected at the specific time frames, before, during and after treatment.

No fasting or medication restrictions are required.

13 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team on the study hotline (08) 8275 1075, or complete the study withdrawal form which is included as the last page of this document.

When withdrawing, if you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. Withdrawing from this research will not affect your current or future care at Flinders Medical Centre, Noarlunga Health Service, The Queen Elizabeth Hospital, Lyell McEwin Hospital or Royal Adelaide Hospital.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, without your permission. You should be aware that data collected up to the time you withdraw consent will form part of the study results.

14 Could this research project be stopped unexpectedly?

This should not happen but we will inform you if the project stops before the end of the study.

15 What happens when the research project ends?

Once the research project ends, all of the samples will be tested and data will be analysed. Summarised findings (which will not identify any study participants) will be reported at local and international conferences and in scientific journals. You will be provided with a summary of the results when the research project is complete. It is possible that the outcomes of this project will be used to commercialise the blood test for screening for different cancers.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The project investigators and nurses associated with this study will be the only persons with access to your personal details. This information will be kept in the locked research offices in locked filing cabinets and in password protected computers within Flinders Centre for Innovation in Cancer and The Queen Elizabeth Hospital. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

We will use a participant identification code and enter you on our database that is protected by password. This database along with the code is only accessible by a few members of the Bowel Health Service team based at Flinders Centre for Innovation in Cancer and The Queen Elizabeth Hospital.

All study documents will be retained for at least 15 years following completion of the trial. During the study, paper records will be maintained securely at Flinders Centre for Innovation in Cancer and The Queen Elizabeth Hospital, in a secure office.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. A summary of the results of the study will be mailed to you on request.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to

request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.
Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

Should you wish to make a confidential complaint, you may contact the Executive Officer Southern Adelaide Clinical Human Research Ethics Committee at the Flinders Medical Centre on 8204 6453 or email *Health.SALHNOfficeforResearch@sa.gov.au*

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research project is being conducted by the departments of gastroenterology and surgery, with A/Prof Erin Symonds coordinating the research, and is funded by a seeding grant from the Flinders Medical Centre Foundation, Clinical Genomics and a *Medical Research Future Fund* (MRFF), 2021.

In the interest of transparency, we would like you to know that two of the investigators on this study have an association with the company, Clinical Genomics (*a commercial laboratory, involved with tests for cancer detection)*. Professor G. Young provides paid consulting services for Clinical Genomics and family members of Prof Young hold shares in the company. Dr S. Pederson is employed by Clinical Genomics as the chief scientist and is also a shareholder in the company. Neither Prof Young nor Dr Pederson will be personally involved in the analysis of the findings from this study. This will be performed independently by a statistician at Flinders University.

A provisional patent application related to this study has been submitted by Flinders University. The application covers the use of the blood test in detecting other types of cancers. The new data generated from this study could be used to support a full patent application. A/Prof Symonds, Prof Young, Dr Hussey and Dr Pedersen are inventors on the patent and should the study outcomes support the use of the blood test to detect other cancers then the University's commercialisation manager will negotiate with Clinical Genomics the terms of a License agreement. A/Prof Symonds, Dr Hussey and Prof Young would be entitled to returns under the Flinders University Intellectual Property Policy, but any funds being returned to the University will be distributed according to university policy and will benefit research studies. If the study outcomes lead to the development of a commercial blood test for cancer screening, the shareholders of Clinical Genomics may receive a financial benefit.

By taking part in this research project you agree that samples of your blood or tissue (or data generated from analysis of these materials) may be provided to Noarlunga Health Service, Flinders University, Flinders Medical Centre and Clinical Genomics.

These institutions may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

There will be no financial benefit to you or your family from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to

be of commercial value to Noarlunga Health Service (NHS), Flinders University (FU), Flinders Medical Centre (FMC), The Queen Elizabeth Hospital (TQEH), Lyell McEwin Hospital (LMH), Royal Adelaide Hospital (RAH) and Clinical Genomics (CG).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Southern Adelaide Local Health Network. Governance approval has been given by the Central Adelaide Local Health Network and the Northern Adelaide Local Health Network.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the study principal investigator on (08) 8275 1075 or any of the following people:

Clinical contact person (FMC and NHS)

Name	Lorraine Sheehan-Hennessy
Health Network	Southern Adelaide Local Health Network (SALHN)
Sites	Flinders Medical Centre and Noarlunga Health Service
Position	Clinical Nurse Coordinator
Telephone	(08) 8204 7403
Email	Lorraine.Sheehan-Hennessy@sa.gov.au

Clinical contact person (TQEH, LMH and RAH)

Name	Mehgan Horsnell
Health Network	Central Adelaide Local Health Network (CALHN) Northern Adelaide Local Health Network (NALHN)
Sites	Lyell McEwin Hospital The Queen Elizabeth Hospital Royal Adelaide Hospital
Position	Research Nurse Coordinator
Telephone	0421 210 221
Email	Mehgan.Horsnell@sa.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Complaints contact person

Name	Southern Adelaide Local Health Network
Position	Manager, Research Governance and Ethics
Telephone	(08) 8204 6453
Email	Health.SALHNofficeforResearch@sa.gov.au

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Southern Adelaide Clinical HREC
HREC Executive Officer	Executive Officer
Telephone	8204 6453
Email	Health.SALHNofficeforResearch@sa.gov.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Local HREC Office contact (Research Governance Officer – LMH)

Lead Reviewing HREC	Southern Adelaide Clinical HREC
Health Network	Northern Adelaide Local Health Network (NALHN)
Sites	Lyell McEwin Hospital
HREC Executive Officer	Executive Officer
Telephone	8204 6453
Email	Health.NALHNRgo@sa.gov.au

Local HREC Office contact (Research Governance Officer – TQEH and RAH)

Lead Reviewing HREC	Southern Adelaide Clinical HREC
Health Network	Central Adelaide Local Health Network (CALHN)
Sites	The Queen Elizabeth Hospital and Royal Adelaide Hospital
HREC Executive Officer	Executive Officer
Telephone	8204 6453
Email	Health.CALHNResearchGovernance@sa.gov.au

Consent Form - *Adult providing own consent*

Title	Novel blood biomarker tests to detect adenocarcinomas
Short Title	Cancer detection with a blood test
Protocol Number	162.16
Project Sponsor	*N/A*
Coordinating Principal Investigator/ Principal Investigator	Assoc Prof Erin Symonds
Associate Investigator(s)	Prof G Young, Prof C Karapetis, Dr S Pedersen, Prof D Watson, Dr D Hussey, Dr M Chong, Dr M Eaton, Dr A Rose, Dr T Wilson, Dr J Winter, L Sheehan-Hennessy, A/Prof M Michael, Dr H Kanhere, Dr L Dandie, Prof T Price, Dr A Roy, Dr S Barreto, S Byrne and M Horsnell.
Location	Flinders University, Noarlunga Health Service, Flinders Centre for Innovation in Cancer, Flinders Medical Centre, The Queen Elizabeth Hospital, Lyell McEwin Hospital and Royal Adelaide Hospital.

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

☐ **I agree to blood samples being taken, before, during and after treatment, where possible.**
[As outlined in the Participant Information Sheet, Version 12.1, 16/11/2021]

_____
Please Initial

☐ *Optional:*
I agree to the storage and analysis of my tissue sample collected at either my surgery or at biopsy

_____
Please Initial

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Researcher†
(please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Opt-out / Withdrawal of Participation *Adult providing own*

Title	Novel blood biomarker tests to detect adenocarcinomas
Short Title	Cancer detection with a blood test
Protocol Number	162.16
Project Sponsor	*N/A*
Coordinating Principal Investigator/ Principal Investigator	Assoc Prof Erin Symonds
Associate Investigator(s)	Prof G Young, Prof C Karapetis, Dr S Pedersen, Prof D Watson, Dr D Hussey, Dr M Chong, Dr M Eaton, Dr A Rose, Dr T Wilson, Dr J Winter, L Sheehan-Hennessy, A/Prof M Michael, Dr H Kanhere, Dr L Dandie, Prof T Price, Dr A Roy, Dr S Barreto, S Byrne and M Horsnell.
Location	Flinders University, Noarlunga Health Service, Flinders Centre for Innovation in Cancer, Flinders Medical Centre, The Queen Elizabeth Hospital, Lyell McEwin Hospital and Royal Adelaide Hospital.

Declaration by Participant

I wish to opt-out/withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with any of the hospitals as named above.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.