**Participant Information Sheet**

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| --- | --- |
| **Title**  | The value of interval faecal occult blood testing in colonoscopic surveillance programs for those at above-average risk for colorectal cancer, Phase 3. PART 2. |
| **Short Title** | Assessing the diagnostic performance of FIT against colonoscopy |
| **Protocol Number** | 422.13 |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Erin Symonds |
| **Associate Investigator(s)** | Prof Robert Fraser, Prof Peter Bampton, Dr Charles Cock, Dr Sandy Craig, Ms Jayne Sandford, Mr Cherian Thomas |
| **Location**  | Flinders Centre for Innovation in Cancer, Flinders Medical Centre, Noarlunga Hospital |

**Part 1 What does my participation involve?**

**1. Introduction**

### You are invited to take part in the research project, *Assessing the diagnostic performance of FIT against colonoscopy*. This is a continuation of our previous research through which you may have already received offers of screening for bowel cancer using faecal immunochemical tests (FIT, also known as a home stool test). You have been invited because you are currently scheduled to have a colonoscopy through the Southern Co-Operative Program for the Prevention of Colorectal Cancer (SCOOP) program.

This Information Sheet 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. If you return the completed FIT to us, it will be assumed that you have provided us with permission to use the information you provide in the manner described below.

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 at Flinders Centre for Innovation in Cancer, Flinders Medical Centre and Noarlunga Hospital whether or not you take part.

**2 What is the purpose of this research?**

The purpose of this study is to understand the accuracy of FIT relative to colonoscopy with regard to detecting both colorectal cancer and polyps that are pre-cancerous. While much is known about the effectiveness of FIT as a general screening tool, we would like to gather data on its effectiveness when compared to colonoscopy, in a population of people who are under surveillance with colonoscopy.

The enclosed FIT is to be performed the week before your colonoscopy appointment.

By comparing the results of the FIT and your colonoscopy, we will confirm the accuracy of the FIT. This information in the future could be used by clinicians to help determine how often colonoscopy needs to be performed.

This research has been initiated by the study lead scientist, Dr Erin Symonds.

**3 What does participation in this research involve?**

If you are willing to help us with this research project, we would be grateful for your assistance by completing the FIT the week prior to your colonoscopy appointment. We have enclosed the FIT kit, information on how to complete the test and a reply paid envelope to mail the test back to us. We will not report the results of this additional FIT to you or your doctors, as the colonoscopy that you are scheduled to undergo is the most thorough way of assessing the health of your colon.

We also request access to the colonoscopy and any associated histopathology reports that will come from the colonoscopy that you will soon have. This will allow us to compare the results from the FIT to the findings from your colonoscopy.

A research nurse might call you in the next week to find out if you have any questions about completing the test.

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

**4 Other relevant information about the research project**

We will be inviting individuals to complete the FIT who are scheduled to undergo colonoscopies through the SCOOP program.

We are hoping that 2000 participants undergoing colonoscopy surveillance within the SCOOP program will complete this additional FIT. This study will run for three years.

**5 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.

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 Flinders Medical Centre or Noarlunga Hospital.

**6 What are the possible benefits of taking part?**

There is unlikely to be any direct benefit to you personally from taking part in this study. However, your participation in this research will improve our understanding of the effectiveness of a common bowel cancer screening tool.

**7 What are the possible risks and disadvantages of taking part?**

As this is a simple faecal test, the same type that may have already been provided to you through the SCOOP program, we do not anticipate that you will be exposed to any risk by taking part in this study.

**8 What if I withdraw from this research project?**

If you complete and return the FIT, you may still withdraw at any time, by completing and sending us the attached withdrawal form. If you decide to withdraw, we will removed your data from the study and destroy any samples you may have provided for this study.

**9 What happens when the research project ends?**

The results of this study will be submitted for publication in a research journal. Only de-identified data will be published. Your identity will remain anonymous at all times. You are able to request a copy of the publication once it is available.

**Part 2 How is the research project being conducted?**

**10 What will happen to information about me?**

By completing and returning the FIT kit and consent form, we will assume that you have agreed to allow us to use your information on file and the test results for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Only the research team will have access to your information. All personal information will be treated in the strictest confidence. Electronic documents will be stored on a password-protected computer within a locked office of Flinders Centre for Innovation in Cancer that only the research team will have access to. 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.

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.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

**11 Complaints and compensation**

If you feel some distress from participating in this study you may withdraw from this study if you wish and your care at Flinders Centre for Innovation in Cancer, Flinders Medical Centre and Noarlunga Hospital will not be affected in any way. By participating in this study you do not give up any of your legal rights.

**12 Who is organising and funding the research?**

This research project is being conducted by Dr Erin Symonds from the Bowel Health Service at Flinders Centre for Innovation in Cancer.

The FIT kits will be provided by Eiken Chemical Company (Japan), but this company has not had any involvement in the study design, nor will they be involved in the analysis or reporting of study results. No member of the research team will receive a personal financial benefit from your or their involvement in this research project (other than their ordinary wages).

**13 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.

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.

**14 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 you can contact the study helpline or the principal study scientist on (08) 8275 1075, email on SCOOP@flinders.edu.au, or contact any of the following people:

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | Susie Byrne |
| Position | Clinical Nurse Coordinator  |
| Telephone | (08) 8204 7402 |
| Email | susie.byrne@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:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Paula Davies |
| Position | Asst. Director, SAHLN Office for Research |
| Telephone | (08) 8204 6453 |
| Email | Health.SALHNofficeforresearch@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:

|  |  |
| --- | --- |
| Reviewing HREC name | Southern Adelaide Clinical Human Research Ethics Committee |
| Position | Executive Officer |
| Telephone | (08) 8204 6453 |
| Email | Health.SALHNofficeforresearch@sa.gov.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

 **Local HREC Office contact (Single Site -Research Governance Officer)**

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| --- | --- |
| Position | Research Governance Officer |
| Telephone | (08) 8204 6453 |
| Email | Health.SALHNofficeforresearch@sa.gov.au |

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**Consent Form**

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| --- | --- |
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| **Location**  | Flinders Centre for Innovation in Cancer, Flinders Medical Centre, Noarlunga Hospital |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me.

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

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

Please return this form using the enclosed reply paid envelope or to the address below:

Reply Paid 84971

Bowel Health Service

Level 3 North, Flinders Centre for Innovation in Cancer

c/o Flinders Medical Centre

Bedford Park SA 5042.

21749

**Form for Withdrawal of Participation**

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| --- | --- |
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| **Location**  | Flinders Centre for Innovation in Cancer, Flinders Medical Centre, Noarlunga Hospital |

**Declaration by Participant**

I wish to 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 Flinders Centre for Innovation in Cancer, Flinders Medical Centre and Noarlunga Hospital.

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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