

**Participant Information Sheet**

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| **Title**  | **Assessing quality of life and attitudes toward health self-management in people who have had a recent diagnosis of the bowel.** |
| **Short Title** | How does the diagnosis of a bowel condition affect quality of life and how do people manage their health? |
| **Protocol Number** | 443.16 |
| **Project Sponsor** | N/A |
| **Coordinating Principal Investigator/ Principal Investigator** | **Dr Erin Symonds** |
| **Associate Investigator(s)** | Prof Graeme Young, Prof Robert Fraser, Dr Gang Chen, Prof Julie Ratcliffe, Dr Carlene Wilson, Dr Ingrid Flight  |
| **Location**  | **Repatriation General Hospital, Flinders Medical Centre & Noarlunga Health Services.** |

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

**1. Introduction**

You are invited to take part in the research project, **Assessing quality of life and attitudes toward health self-management in people who have had a recent diagnosis of the bowel.** You have been invited because you have just had a colonoscopy and we are interested to understand how your colonoscopy result may impact on your health-related quality of life. Your contact details were obtained from the hospital appointment lists.

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 a completed questionnaire and consent form 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 Medical Centre, Repatriation General Hospital and Noarlunga Health Services, whether or not you take part.

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

The purpose of this study is to understand how having any type of bowel condition impacts upon health-related quality of life. Health-related quality of life measures the impact of health or disease on physical and psychological well-being, and it can be evaluated using various questionnaires. We hope this study will help us to understand how any conditions of the bowel impacts on health-related quality of life in Australians.

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

This research has been funded by a National Health and Medical Research Council Grant.

**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 enclosed questionnaire. The questionnaire contains four sections. Section A mainly includes questions about your health conditions, and any treatment you have received in the past 12 months. Section B contains questions about your health-related quality of life and wellbeing. Section C contains questions about your thoughts and attitudes toward managing your health. Section D includes questions about your background. We expect that the questionnaire will take about 15 minutes to complete. After finishing the questionnaire, please send it back to us using the reply paid envelope.

After 12 months we will ask you to complete another survey, containing the same questions, so we can find out if your feelings about your health have changed over the year.

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 are hoping that 200 participants with a range of bowel conditions will help us with this study.

We will be inviting individuals with and without conditions of the bowel (including bowel cancer, benign growth in the bowel (polyps), haemorrhoids and diverticular disease) to tell us about the impact they feel this has on their quality of life.

If you have an existing bowel condition, or have started taking medicine for your bowel condition, you may not be eligible to participate in this study. Please call the study helpline on (08) 8275 1075 for further information.

**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, Repatriation General Hospital or Noarlunga Health Services.

**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 the understanding of how health-related quality of life is impacted by having a condition of the bowel.

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

As this is a simple survey we do not anticipate that you will be exposed to any risk by taking part in the study. However, if you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in this research project, the research team can arrange for counselling by staff who are not members of the research team.

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

If you do complete and return the questionnaire, you may withdraw at any time, by completing and sending us the attached withdrawal form. If you decide to withdraw, we will destroy the questionnaire you completed, and will not send you the follow-up survey (if this has not already been sent to you).

**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 consent form and the questionnaires, we will assume that you have agreed to allow us to use the information 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 that only the research team will have access to. Your completed questionnaire will be stored in a locked filing cabinet within the Bowel Health Service at Flinders Centre for Innovation in 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 Medical Centre, Repatriation General Hospital and Noarlunga Health Services, 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 Flinders Centre for Innovation in Cancer and the research study is funded by a National Health and Medical Research Grant. 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.

The ethical aspects of this research project have been approved by the Southern Adelaide Clinical Human Research Ethics Committee. 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 doctor on (08) 8275 1075 or email on BOOST@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 | Villis Marshall |
| Position | 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 |
| HREC Executive Officer | Damian Creaser |
| 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)**

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



**Consent Form**

|  |  |
| --- | --- |
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| **Location**  | **Repatriation General Hospital, Flinders Medical Centre & Noarlunga Health Service** |

**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 consent to being contacted by a follow-up invitation letter 12 months after the date of my first questionnaire completion.

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 Flinders Centre for Innovation in Cancer

c/o Mail Room, Flinders Medical Centre

Bedford Park SA 5042

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**Form for Withdrawal of Participation**

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| --- | --- |
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| **Location**  | **Repatriation General Hospital, Flinders Medical Centre and Noarlunga Health Services.** |

**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 Medical Centre, Repatriation General Hospital and Noarlunga Health Services.

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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:

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