Rectal cancer outcomes measurement in Illawarra Shoalhaven LHD
Patient information sheet

At the Illawarra Shoalhaven Local Health District (ISLHD), we are currently working on a project aimed at better understanding the outcomes of patients diagnosed with rectal cancer. The ISLHD Colorectal Cancer Multidisciplinary Team (of which your doctor is a member) has a funding grant from the Cancer Institute NSW for this project.

The project is seeking to answer questions like:
- How does rectal cancer and its treatments affect patients’ quality of life and daily functioning?
- How many patients experience side-effects of treatment?
- How do local services and our patient group compare to others around the state and the world?

Measuring the effectiveness of cancer treatment is good clinical practice, and will contribute to the improvement of care for patients in ISLHD and the international evidence on cancer care. This project is aiming to make outcomes measurement part of normal care for rectal cancer.

You are invited to take part in this research project. This Participant Information Sheet/Consent Form tells you about the research project. It explains what the research involves. Please ask questions about anything that you don’t understand or want to know more about.

1. What does participation in this research involve?
Participation in this project will involve completing 3 questionnaires at the start of your treatment and then 2 questionnaires 6 months after treatment and then every year as part of your normal follow-up care for your cancer. The surveys will be organised by your treating doctor and will coincide with your follow-up appointments.

Entire duration of study participation: Approximately 5 years
Duration of questionnaires: It will take approximately 5-10 minutes to complete each questionnaire.
There are no costs associated with participating in this research project, nor will you be paid. You will not be required to travel or attend any special appointments for the research.

2. 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 care or relationship with your doctor or the researchers at ISLHD.

3. What are the possible benefits of taking part?
This study will investigate how the treatment and interventions for rectal cancer affect your daily functioning, what symptoms trouble you and how your symptoms affect your wellbeing. You may not derive any personal benefit from this study, but it is hoped that the study as a whole will contribute to a better understanding of the impact of rectal cancer on patients and better patient outcomes.

4. What are the possible risks and disadvantages of taking part?
There are no anticipated risks for participating in this project. You can refuse to answer any questions that make you feel uncomfortable. If you have any questions or concerns, please discuss these with your doctor.
5. What information will be gathered and what will happen to that information?
The study will gather information about patients’ rectal cancer, the treatments they have and their follow-up care. The study will also gather information about how rectal cancer and its treatment affects patients’ quality of life.

Your personal identifying information is confidential and will not be disclosed to a third parties without your consent, except as part of normal clinical care, or to meet government, legal or regulatory authority requirements. Information collected that might identify you will be stored in a password protected file at ISLHD Cancer Services.

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. Reports will summarise information across large numbers of patients rather than individuals.

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

6. Who is organising and funding the research?
This research is being conducted by a research group of health professionals who treat and manage rectal cancer in the Illawarra Shoalhaven Local Health District (ISLHD). This research is funded by the Cancer Institute of NSW.

7. 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 has been reviewed and approved by the HREC of the UOW and ISLHD, reference 2017/557.

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.

8. Further information and who to contact
If you have any questions about participating in the project, please contact the project officer Ms Brooke Selby on (02) 4253 4466 or brooke.selby@health.nsw.gov.au. If you have any concerns about this project, please contact the Ethics & Integrity Manager on 4421 4457 or email rso-ethics@uow.edu.au

If you are happy to be included in the Rectal Cancer Outcomes Study, you do not need to do anything.

For patients who WOULD NOT like to participate, please complete the form below:

I would like to be excluded from the Rectal Cancer Outcomes study [ ]
Name: ___________________________________________ Date: __________________