

**Participant Information Sheet**

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| **Study title:** | The 10Ten study: Quality of Life after Surgery for Recurrent Rectal Cancer. | |
| **Principal investigator:** | **Professor Frank Frizelle**  **Department of Surgery, Christchurch**  **Head of Department** | Contact phone number:  03 364 8174 |

**Introduction**

Thank you for showing an interest in this project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, before deciding whether or not to participate.

If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

**What is the aim of this research project?**

The aim of this project is to measure the quality and quantity of the lifespan in patients with locally recurrent rectal cancer. It aims to compare survival rates as well as quality of life in those who have surgery to those who do not have surgery. It also aims to compare how other factors, such as whether having clear resection margins (i.e. absence of tumorous tissue in the resected margin under a microscope) or having co-occurring chemotherapy and/or radiotherapy influence the quality and quantity of the lifespan.

Gaining information on quality and quantity of the lifespan in people with locally recurrent rectal cancer will allow more informed treatment decisions (e.g., whether or not to offer a patient surgery, chemotherapy, and/or radiotherapy) in the future. Your participation in this research will assist future patients in making treatment decisions regarding surgical and medical intervention.

**Who is funding this project?**

This study has received a small seeding fund from the Canterbury Medical Research Foundation.

**Who are we seeking to participate in the project?**

This study is recruiting those aged 18 and over with resectable (i.e. operable) locally recurrent rectal cancer; this will include participants who receive surgery and those who do not. We are not recruiting people with primary cancer (i.e. newly diagnosed) or with inoperable tumours. If you choose not to be recruited, your data will not be analysed for this research.

**If you participate, what will you be asked to do?**

If you choose to take part in this research, you will be asked to allow the investigators to access your disease related health information and will also be asked to complete questionnaires numerous times over five years. You will be asked about your demographics and quality of life at baseline; you will be asked about your quality of life at 3 months, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 48 months, and 60 months. Conversely, if you choose not to take part in the study, the care provided to you will not be changed or prejudiced due to this decision; this is a purely voluntary study. There is no reimbursement for time or expenses.

**Is there any risk of discomfort or harm from participation?**

This study does not influence any aspect or quality of the care you will receive. You will be asked to answer questions about your quality of life at various time points after your diagnosis of locally recurrent rectal cancer; there is a small chance answering questions will cause psychological distress but no other aspects will cause any potential harm. Should this occur you will be referred to your principle clinician with the recommendation for counselling as appropriate. If any other risks or adverse effects become apparent during the course of the study, you will be duly informed.

**What specimens, data or information will be collected, and how will they be used?**

The results from biopsies and surgical specimens that would normally be collected as part of your usual care will be collected, but no biopsies or surgical specimens will be collected as part of the study in itself.

It is possible that data generated in this study, but not reported, will be made available for use in future research (e.g., for inclusion in an individual data meta-analysis). If this happens, it will be ensured all data will be provided in a purely de-identified manner.

**What about anonymity and confidentiality?**

The anonymity and confidentiality of the information you provide for this study will be ensured by a process called de-identification wherein a study ID is allocated to you; only the primary investigators will be able to link your study ID to your identity and health information. All of your electronic information relating to the study will be stored on a secure password protected database and all hardcopy information will be stored under lock and key. These will only be accessible to the primary investigators. If any information is shared with a third party (e.g., a statistician or an overseas researcher), no information identifying you (e.g., NHI number or full name) will be provided to them.

**If you agree to participate, can you withdraw later?**

You may withdraw from participation in the project at any time and without any disadvantage to yourself. If you do withdraw, you may choose to have all your information removed or alternatively you may choose to have all information obtained in the study retained as part of the study.

**Any questions?**

If you have any questions now or in the future, please feel free to contact either:

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| **Michelle Falloon**  **Clinical Studies Research Nurse**  **Department of Surgery, Christchurch** | Contact phone number:  03 364 1154 |
| **Dr Andrew McCombie**  **Postdoctoral Research Fellow**  **Department of Surgery, Christchurch** | Contact phone number:  0272626111 |
| **Professor Frank Frizelle**  **Principle Investigator**  **Department of Surgery, Christchurch** | Contact phone number:  03 364 8174 |

This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.



**The 10Ten study: Quality of Life after Surgery for Recurrent Rectal Cancer.**

***Principal Investigator: Professor Frank Frizelle (***[***frank.frizelle@cdhb.health.nz***](mailto:frank.frizelle@cdhb.health.nz) ***or***

***03 3648174)***

**CONSENT FORM FOR PARTICIPANTS**

Following signature and return to the research team this form will be stored in a secure place for ten years.

Name of participant:…………………………………………..

1. I have read the Information Sheet concerning this study and understand the aims of this research project.
2. I have had sufficient time to talk with other people of my choice about participating in the study.
3. I confirm that I meet the criteria for participation which are explained in the Information Sheet.
4. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.
5. I know that my participation in the project is entirely voluntary, and that I am free to withdraw from the project at any time without disadvantage.
6. I understand that if I withdraw, I may have all my information removed at my request or alternatively if I choose I may consent to leave my information in the data collected.
7. I know that as a participant I will allow the researchers to access my medical records and will be requested to completed questionnaires about my quality of life on numerous occasions over five years.
8. I know that the questionnaire will measure my quality of life for five years and that if the line of questioning develops in such a way that I feel hesitant or uncomfortable I may decline to answer any particular question(s), and /or may withdraw from the project without disadvantage of any kind.
9. I understand the minimal risk of discomfort or harm as explained in the Information Sheet.
10. I know that when the project is completed all personal identifying information will be removed from the paper records and electronic files which represent the data from the project, and that these will be placed in secure storage and kept for at least ten years.
11. I understand that the results of the project may be published and be available in the University of Otago Library
12. I know that there is no remuneration offered for this study, and that no commercial use will be made of the data.

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| Signature of participant: |  | Date: |
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