INTERNATIONAL VALIDATION OF THE LOCALLY RECURRENT RECTAL CANCER – QUALITY OF LIFE (LRRC-QOL) QUESTIONNAIRE

We are writing to you to invite you to take part in the Locally Recurrent Rectal Cancer – Quality of Life (LRRC-QoL) research study to develop an international questionnaire to measure quality of life specifically for patients with locally recurrent rectal cancer.

The LRRC-QoL study is part of an international collaborative study coordinated by a research team based at the University of Leeds in the United Kingdom. Participation in the study is voluntary and will not affect the medical care you receive. Before deciding whether to participate in the study, please read this patient information leaflet explaining the study and what participating in it would involve.

You can participate in the study either online or via post. If you would like to participate in the study via post, please let your medical team know and they will be able to provide you with a postal information pack. If you would like to participate in the study online, the study website can be accessed at: https://ctru.leeds.ac.uk/lrrc-qol.

If you have any questions at all regarding the study please get in touch with your doctor or medical team, alternatively you can contact the research team via email: LRRCQoL@leeds.ac.uk.

LRRC QoL

PelvEx Collaborative BOWEL RESEARCH UK. UNIVERSITY OF LEEDS PELICAN cancer foundation CURING BELOW THE BELT CANCERS

WHAT IS THE PURPOSE OF THE STUDY?

Locally recurrent rectal cancer, meaning cancer which returns close to the origin site, affects approximately 10% of people following treatment of rectal cancer. The extent of the burden that locally recurrent rectal cancer has on people's overall quality of life is poorly reported.

There are many questionnaires that are used to assess quality of life, however, these questionnaires have not been validated for this specific group of patients. Validation means checking that the questionnaire is relevant to specific patient groups.

The **LRRC-QoL** is a questionnaire that has been designed specifically to measure quality of life in patients with locally recurrent rectal cancer. The **LRRC-QoL** was developed in patients from the UK and Australia. This study aims to validate the **LRRC-QoL** for use in Canada and other countries internationally.

WHAT WOULD TAKING PART INVOLVE?

If you choose to participate, it will involve completing a number of documents including:

- A consent form,
- A demographics form
- The **LRRC-QoL** questionnaire,
- Three other questionnaires concerning quality of life.

Following this, you will be asked to complete the **LRRC-QoL** questionnaire during a telephone interview with a researcher from the United Kingdom.

The aim of the interview is to give us a better understanding of how you interpret the questions in the **LRRC-QoL** questionnaire. Completing the additional questionnaires will allow us to better understand the impact of locally recurrent rectal cancer on your quality of life.

Please let your medical team know if you would like to participate in the study and they will provide you with either a link to the website or with a participation pack via post depending on your preference.

If you choose to participate via post, the participation pack will contain the documents described above in addition to a self-addressed, stamped envelope to enable you to return these documents to your medical team.

You will also receive two copies of the **LRRC-QoL** questionnaire. One copy to complete and return and one copy to keep and complete during a telephone interview.

WHAT ARE THE BENEFITS OF TAKING PART?

There are no personal benefits to taking part. However, this study will deliver wider benefits in that it will provide information regarding quality of life in patients being treated for locally recurrent rectal cancer in many centers internationally. It will also allow the **LRRC-QoL** to be used in future international research.

WILL MY PARTICIPATION BE CONFIDENTIAL?

Only your medical team and the research team will be informed of your participation in the study.

Your information will remain confidential. The only time that your details may be disclosed is if the researcher is concerned that you pose a danger to yourself (for example if you are thinking of harming yourself) or others and we may need to inform appropriate authorities.

WHAT WILL HAPPEN IF I WOULE LIKE TO PARTICIPATE?

If you would like to participate in the study, please let your medical team know and you may participate either online or via post by completing the consent form and questionnaires.

Following this, we will contact you via telephone to arrange a convenient time for the interview. The interview can be conducted either via telephone or using Microsoft Teams.

The interview will be audio-recorded and transcribed (writing down what has been said during the interview). Your name will be removed from the research data and replaced with an anonymous identifier.

The responses you provide to the questionnaires and information provided by your medical team concerning your treatment and pattern of locally recurrent rectal cancer, will be stored in a database using an anonymous identifier. This database will be stored at the University of Leeds in the United Kingdom where the research team are based.

WHAT WILL HAPPEN TO MY DATA?

Your name and telephone number will be stored on an encrypted file server at the University of Leeds solely to enable us to contact you for the purposes of this study. This information will be destroyed following the interview.

Audio-recordings of the interviews will be destroyed once they have been transcribed. The transcripts and the database will be held securely on an encrypted file server at the University of Leeds with strict limits on who can access it.

The online consent form and questionnaires will be collected and stored securely on an online database called REDCap. The database of questionnaire responses will also be held securely on an encrypted file server at the University of Leeds with strict limits on who can access it. All of the computers storing patient data must meet special security arrangements.

This research is in the public interest, which means our results will be used to improve the health of patients in the future. Because of this, if you agree to take part in the study, we will be able to use information about you, including sensitive information about your health. If you would like more information regarding this, please see: https://ctru.leeds.ac.uk/privacy/

WHAT IF I NO LONGER WANT TO PARTICIPATE?

Participating in the study is voluntary, you can decide to stop participating (withdraw your consent) at any time, including during the interview.

Completing the questionnaire and discussing this in the interview will involve reflecting upon your experience of locally recurrent rectal cancer. Should you find this at all distressing please inform us and the interview will be stopped.

You do not need to explain why you would like to stop participating. Withdrawing from the study will not affect your treatment for locally recurrent rectal cancer.

WHO IS ORGANISING AND FUNDING THIS STUDY?

Funding for this study has been provided by Bowel and Cancer Research and by the Pelican Cancer Foundation.

The study is being coordinated by a research team based at the Clinical Trials Research Unit at the University of Leeds in the United Kingdom.

https://ctru.leeds.ac.uk/