EuroPOWER (Postoperative Outcomes Within/without an Enhanced Recovery After Surgery Protocol in Colorectal Surgery. A prospective, European, multi-centre cohort study)

(VERSION 1, July 2018)

Ethics Committee Approval Number

STUDY INFORMATION SHEET FOR PATIENTS

Dear patient,

You have been invited to participate in a research study. We would like to explain to you why this study is being conducted and what it will entail for you. Please take the time to carefully read the following information and discuss it with other people, if you wish. Please ask us if something is unclear or if you need more information. Take your time to decide if you want to participate. Your participation is important to obtain the knowledge we need, but before making a decision you must:

- Read this entire document
- Understand the information contained in the document
- Ask all the questions you consider necessary
- Consult with your doctor-trusted person
- Make a thoughtful decision
- Sign the informed consent, if you finally want to participate.

If you decide to participate, you will be given a copy of this document and a signed consent. Please keep them in case you need them in the future.

Why are you asked to participate?

You have been invited to participate in this study, because you must undergo a scheduled colorectal surgery. EuroPOWER is a study at European level, with the participation of centers throughout Europe.

What is the purpose of this study?

Our objective is to carry out a 60-day European audit of adult patients undergoing colorectal surgery, whether or not within an intensified recovery protocol or ERAS (Enhanced Recovery After Surgery) to provide detailed data describing postoperative complications and associated mortality. In addition, to determine if the application of the ERAS program affects to postoperative complications in patients who, like you, are undergoing elective colorectal surgery; and determine which are the individual factors that are associated with good surgical results. With the data obtained on postoperative complications, we can better treat patients in the future, and generate more appropriate protocols for action.

What do I have to do if I decide to participate?

Remember that your participation is voluntary and if you decide not to participate this will not affect your assistance or your relationship with the researcher. The researchers will collect preoperative data derived from the pre-anaesthesia consultation, as well as data on the surgical intervention and postoperative data. These data will always remain anonymous. In the case of an observational study, no additional intervention will be made to those ones performed regularly in your center. Neither will any extraordinary test be done. This study will not require you to make more visits to the hospital, either before or after the surgery. No biological samples will be collected specifically for this study.

Do I have an obligation to participate?

No, your participation is completely voluntary. If you decide to participate, please sign the consent form to show that you agree to participate and keep the copy that is delivered with this information sheet. If you decide not to participate in the study, your decision will not affect your treatment or the care you are receiving at this time or that you will receive in the future.

Will I get any benefit for participating?

Being a research study aimed at generating knowledge It is not expected that you will obtain direct

benefit by participating or will receive any financial compensation for it, although you will contribute to the advancement of knowledge and social benefit.

What risks or inconveniences does it have to participate?

EuroPOWER is an observational study, therefore your treatment will not change because you participate in this study. Perioperative treatment (before, during and after your surgery) will be prescribed according to the healthcare practice and your needs as a patient and will not be altered by the inclusion in the study.

Risk for confidentiality

The clinical information obtained in this project will be stored in a database protected by current legislation, under the responsibility of the institutions' investigators. These data will be kept for future studies, unless you indicate otherwise. Therefore, the results of this research can be disseminated in journals, medical databases and scientific forums. Personal data that could identify you will never be revealed. The investigators will always have the duty to protect their privacy and maintain all their information confidentially.

Privacy and use of clinical information

To carry out the study it will be necessary to consult your medical record and collect some of the information that appears in it. As of May 25, 2018, the new EU legislation on personal data is fully applicable, in particular the Regulation (EU) 2016/679 of the European Parliament and the Council of April 27, 2016 on Data Protection (GDPR). Therefore, it is important that you know the following information:

- In addition to the rights you already know (access, modification, opposition and data cancellation) you can now also limit the processing of data that is incorrect, request a copy or make the data that you have facilitated for the study be transferred to a third party (portability).
- To exercise your rights, contact the principal investigator of the study. We remind you that the data cannot be deleted even if you stop participating in the trial to guarantee the validity of the investigation and comply with the legal duties and the medication authorization requirements. You also have the right to contact the Data Protection Agency if you are not satisfied.
- Both the Center and the Promoter are responsible respectively for the processing of their data and undertake to comply with the current data protection regulations. The data collected for the study will be identified by means of a code, so that information that can identify you is not

included, and only your study doctor / collaborators will be able to relate these data to you and your clinical history. Therefore, your identity will not be disclosed to any other person except the health authorities, when they require it or in cases of medical emergency. The Clinical Research Ethics Committee, the representatives of the Health Authority in matter of inspection and the personnel authorized by the Promoter, will only be able to gain access to verify the personal data, the procedures of the clinical study and the fulfillment of the norms of good clinical practice (always maintaining the confidentiality of the information)

- The Researcher and the Promoter are required to keep the data collected for the study at least 25 years after its completion. Subsequently, your personal information will only be kept by the center for your health care and by the promoter for other scientific research purposes if you have given your consent for it, and if the law and applicable ethical requirements permit so.
- If we transfer your coded data outside the EU to the entities of our group, to service providers or to scientific researchers who collaborate with us, the participant's data will be protected with safeguards such as contracts or other mechanisms by the authorities for data protection. If the participant wants to know more about it, he/she can contact the Promoter's Data Protection Delegate.

Any new publication of research work that requires the use of data will be subject to the approval of the EuroPOWER Steering Committee and an independent ethics committee.

Withdrawal from the study

Even though you have agreed to participate, you may leave the study whenever you wish without any effect on your medical care and without having to offer any explanation. If you decide to withdraw from the study no further data will be collected, while the already collected, encoded data (identified by a number) will be anonymized. Analysis may be performed up to the point of data collection.

How can I know the results of the study?

You have the right to know the results of this study, both the general results and those derived from your specific data. The overall results of this study will be sent to medical and scientific publications and presented at meetings in the same field for dissemination. The EuroPOWER website (www.grupogerm.es) will also provide study data and updated recruitment information, both for patients and for the general public.

Who is organizing and funding this research?

This study is being carried out by a network of doctors from all over Europe. It is a European study coordinated by Dr. Javier Ripollés Melchor from the Complutense University of Madrid and professors José Manuel Ramírez, from the Lozano Blesa University Clinical Hospital in Zaragoza. The study is funded by the Spanish Group of Multimodal Rehabilitation (GERM) and REDGERM. The promoter of the study is the Spanish Multimodal Rehabilitation Group (GERM) entity to which belongs Dr. Javier Ripollés Melchor, principal investigator of the study and study Chief.

Are there economic interests in this study?

Researchers will not receive specific retribution for the dedication to the study (in addition to their usual salary as researchers or doctors). You will not be rewarded for participating. There is no possibility of this study generating benefits in the form of patents.

Who has reviewed this study?

This research study has been reviewed by an independent group of people from a Research Ethics Committee, to protect the safety, the rights, the well-being and the dignity of patients. The Autonomic Committee of Research Ethics of Aragon (Spain) has reviewed the study and has given the approval to carry it out.

What am I supposed to do now?

You must decide if you want to participate in this study. Please, think about what this involves talking to your friends and family. The research doctor and the nurse will be happy to answer any questions you may have.

When you decide, please inform your research doctor or nurse. You will be asked to sign a consent form and you will be given a copy that you must keep attached to this information sheet. Please keep these documents. If at any time you have any questions about the study, you can contact the researchers or EuroPOWER, whose contact information is indicated at the end.

Who can give me more information?

Any inquiries concerning the study should be addressed to:

Hospital Investigator:_____Telephone:_____

Research Nurse:_____Telephone:_____

If you have any questions related to your rights as a study participant you can contact the local Ethics Committee or R&D office at:

_____Telephone:_____

Thank you for taking time to read this information sheet.

Date_

CONSENT FORM

(IF NECESSARY DUE TO LOCAL REGULATORY NEEDS)

Centre Number: M_ _ _ - _ _ _

Study Number:

Patient Identification Number for this trial-- _ _ _

Name of Researcher/Site Local Coordinating Investigator: _____

Please initial all boxes

1. I confirm that I have read and understand the information sheet (Version 2, June 2018) for the above study. I have had enough time to consider the information, the opportunity to ask questions, and I have received satisfactory answers. ☐
2. I understand that my participation is voluntary and that I am free to withdraw any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that my personal data will be stored locally encoded and centrally in anonymized form. ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the EuroPOWER Team, from the relevant ethics committee, regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of staff taking consent	Date	Signature