

# Clinical Trial Informed Consent Form

Research name: Safety and efficacy of enhanced recovery after surgery in patients undergoing emergency laparotomy: A single center randomized controlled trial

Research number: 2023-YLS-010

Research institute: Tianjin Hospital, Tianjin

The physician in charge of the study: Jianing Lu

Document Date/Approval date: October 20, 2023

You will be invited to participate in a clinical study. This informed consent gives you some information to help you decide whether to participate in this clinical study or not. Please read it carefully. If you have any questions, please ask the researchers responsible for the study.

Your participation in this study is voluntary. This study has been reviewed by the ethics review committee of the research institute. If you have questions related to the subjects' rights and interests, please contact The Clinical Research Ethics Committee of Tianjin Hospital at 138 2166 0137. Email: tjyylwyh@163.com

Research purpose: The study is used for the purpose of informing the medical profession or the general public about the safety and efficacy of enhanced recovery after surgery (ERAS) programs in patients undergoing emergency laparotomy for acute abdominal disease and similar matters.

Research process: If you agree to participate in this study, we will number each subject and create a medical record file. Due to the need of clinical diagnosis or treatment, you will have to perform some surgical operations, and the tissue removed during the operation will be removed for routine clinical pathological examination. Your case report will be published on websites and journals around the world. The printed and online versions will be available to doctors, media and the public.

Risk and discomfort: For you, all information will be confidential. Your operation will be performed by professionals such as surgeons.

Benefits: By studying your case, it will help diagnose the disease, provide the necessary advice for your treatment, or provide useful information for the study of the disease.

As a study subject, you have the following responsibilities: provide true information about your medical history and current physical condition; Inform the study physician of any discomfort during the study period; Not to take restricted drugs, food, etc.; Tell your research doctor if you have been involved in other studies recently or are currently involved in other studies.

Privacy issue: if you decide to participate in this study, your personal data in and during the study are confidential. Your tissue specimen will be identified by a study number rather than your name. Information that identifies you will not be disclosed to anyone other than members of the research group unless your permission is obtained. All research members and research bidders are required to keep your identity confidential. Your file will be kept in a locked filing cabinet for researchers only. To ensure that the study is conducted in accordance with the regulations, if necessary, members of the government management department or the ethics review committee may refer to your personal data in the research unit as required. When the results of this study are published, no information about you will be disclosed.

If you are injured by participating in this study: you can receive free treatment and/or compensation if there is any harm associated with the clinical study.

You may choose not to participate in this study, or at any time inform the researcher to request withdrawal from the study. Your data will not be included in the study results, and any medical treatment and benefits will not be affected.

If you need additional treatment, or if you don't follow the study plan, or if you have any injuries related to the study or for any other reason, the investigator may terminate your continued participation in the study.

You can keep track of the information and information related to this study and the progress of the study. If you have any questions related to this study, or if you have any discomfort or injury during the study, or if you have any questions about the rights and interests of participants in this study, you can contact us by Tel:022-60578951 or e-mail: [lujianing2006@163.com](mailto:lujianing2006@163.com).

## **Consent Form**

I have read an informed consent form.

I have the opportunity to ask questions and all questions have been answered.

I understand that participation in this study is voluntary.

I can choose not to participate in this study, or quit at any time after informing the researcher without any discrimination or reprisals, and my medical treatment and rights will not be affected.

If I need other treatment, or if I don't follow the study plan, or if there is any injury related to the study or if there is any other reason, the research physician may terminate my involvement in this study.

I will receive a signed copy of the informed consent.

Patient's name: \_\_\_\_\_

Signature of patient: \_\_\_\_\_

Date: \_\_\_\_\_

I have accurately informed the subject of this document that he/she has read this informed consent and has demonstrated that the subject has the opportunity to ask questions. I certify that he/she consented voluntarily.

Researcher's name: \_\_\_\_\_

Signature of researcher: \_\_\_\_\_

Date: \_\_\_\_\_

(note: if the subject is illiterate, the fashion requires the signature of the witness; if the subject is incompetent, the signature of the agent is required.)