

## **Informed Consent form for the International Liver Surgery Outcomes Audit - [LiverGroup.org](#)**

This **Informed Consent Form** is for men and women who attend the [*please add the name of your clinic here*] and who we are invited to participate in the International Liver Surgery Outcomes Audit - [LiverGroup.org](#).

The international **Chief Investigators** of [LiverGroup.org](#) are: Professor Alessandro Serrablo from the University of Zaragoza, Spain and Massimo Malagó from the University College London, UK. The local Principal Investigator at [*please add here the Name of the Clinic, Hospital / University*] is [*please add here the Name of Principal Investigator*].

[*please add here the Logo of your Clinic / Institution in colour and high resolution*]

This **Informed Consent Form** has two parts:

- A. Information Sheet** (to share information about the audit with you)
- B. Certificate of Consent** (for signatures if you agree to take part)

You will be given a copy of the full **Informed Consent Form**.

**To proceed with the Information Sheet (PART A), please go to the next page.**

## **PART A: Information Sheet**

### **Introduction**

We are conducting a worldwide clinical audit that seeks to assess the complication and death rates of patients undergoing liver surgery. **Clinical audit** is a way to find out if healthcare is being provided in line with standards and lets care providers and patients know where there could be improvements. The aim is to allow quality improvement to take place where it will be most helpful and will improve outcomes (i.e. complication and mortality rates) for patients.

We are going to give you information and invite you to be part of this clinical audit. You do not have to decide today whether or not you will participate in it. Before you decide, you can talk to anyone you feel comfortable with about this audit. There may be some words that you do not understand. Please ask your doctor to stop as he goes through the information and he/she will take time to explain. If you have any questions later, you can ask the doctor or the staff.

### **Purpose of the clinical audit**

The safety of liver surgery has dramatically improved over the last 20 years, however complications and death rates differ among countries and hospitals. The purpose of **LiverGroup.org** is to improve the practice of liver surgery by sharing of information and innovation worldwide.

### **Type of clinical audit**

**LiverGroup.org** is a new collaborative of liver surgeons worldwide to study the complications and death rates of patients after liver surgery. This will be achieved by including, in a password protected and encrypted electronic database, anonymous data of patients undergoing liver surgery over a three-month period worldwide. This type of audit is called a "snapshot" clinical audit as it will record data during a short period of time worldwide.

### **Participant selection**

We are inviting all adult patients (18 years or older) undergoing liver surgery to participate in the **LiverGroup.org** clinical audit.

### **Voluntary Participation**

Your participation in **LiverGroup.org** clinical audit is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this clinical audit, you will be offered the treatment that is routinely offered in this clinic/hospital. You may change your mind later and stop participating even if you agreed earlier.

### **Information on the **LiverGroup.org** clinical audit**

Several risk factors, such as age, type of disease and medical history and different types of treatments will be associated with complication and death rates in a statistical analysis. This way we may provide a verified record of the true complication and death rates as well as what could be causing them. As **LiverGroup.org** is a clinical audit, this will not influence the

type of treatment that you are offered, thus there will be no health risks involved if you agree to participate.

### **Duration**

The **LiverGroup.org** clinical audit will take place in 2019 with an enrolment period of three months and anonymous patient data will be collected over a three-month period after enrolment.

### **Benefits**

If you participate in the **LiverGroup.org** clinical audit, there will be no direct health benefit for you but your participation is very likely to help us improve the practice of liver surgery and hence future generations are likely to benefit from it.

### **Reimbursements**

You will not be given any money or gifts if you agree to participate in The **LiverGroup.org** clinical audit.

### **Confidentiality**

We will not be sharing the identity of those participating in the research. The information that we collect from the **LiverGroup.org** clinical audit will be kept strictly confidential. Information about you that will be collected during the research will be put away and no-one but the local doctors will be able to see it. Any information about you will have a number on it instead of your name, date of birth, date of operation, or any other personal identifier. Only the local doctors will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the local Principal Investigator (*[please add here the Name of Principal Investigator]*) at our clinic (*[please add here the Name of the Clinic, Hospital / University]*).

### **Sharing the Results**

The knowledge that we get from doing this clinical audit will be presented in conferences and published in scientific journals in order that other interested people may learn from our research.

### **Right to Refuse or Withdraw**

You do not have to take part in the **LiverGroup.org** clinical audit if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way. It is your choice and all of your rights will still be respected.

### **Who to Contact**

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: (*[please add here the Name of Principal Investigator, the address, telephone number and email address]*).

### **Accreditation**

This Information Sheet was written by the Management Committee members of **LiverGroup.org** and it complies with the guidelines provided by the World Health Organisation Research Ethics Review Committee (WHO ERC), Avenue Appia 20, CH-1211 Geneva, Switzerland [[http://www.who.int/ethics/review-committee/informed\\_consent/en/](http://www.who.int/ethics/review-committee/informed_consent/en/)].

## **PART B: Certificate of Consent**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

### **Statement by the doctor taking consent**

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of doctor/person taking the consent \_\_\_\_\_

Signature of doctor /person taking the consent \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

