



# Instructions - ExSituLiver.org

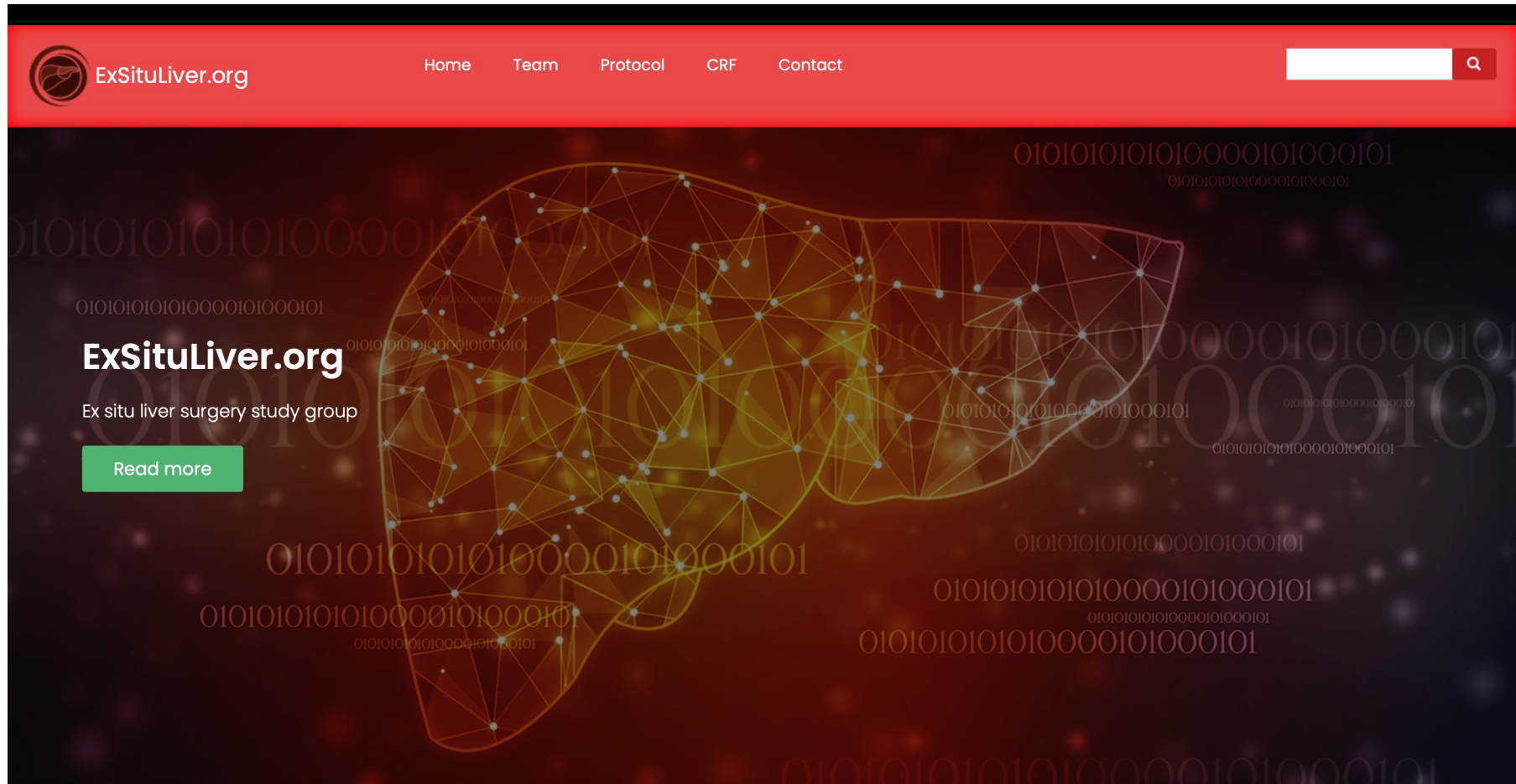
## Instructions Contents

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## About ExSituLiver.org

- ExSituLiver.org is a collaborative of international surgeons to study the outcomes of ex situ liver surgery.
- The goal of ExSituLiver.org is to improve the practice of ex situ liver surgery by sharing of research and innovation.
- This study aims at identifying the true morbidity, mortality and long-term outcomes after ex situ liver surgery as well as modifiable predicting factors of outcome.
- All members will be PubMed cited as group authors in all publications derived from ExSituLiver.org
- This project can be approved as an audit, quality improvement program, may require formal ethics / IRB approval by the local institutions. It is the responsibility of the local PI to receive approval.

# ExSituLiver.org



**Please type [exsituliver.org](https://exsituliver.org) at your browser address bar to access our platform.**



## Protocol



Click on the flags above to download the short protocol in different languages.

### International study on ex situ Liver Surgery Outcomes – ExSituLiver.org

**Introduction:** Ex situ liver surgery allows liver resection with vascular reconstruction in patients who have liver tumors at surgically critical locations. Only few studies with a low number of cases about ex situ liver surgery are currently available in the literature, most limited to short-term outcomes. The aim of this study is to identify the true world-wide morbidity, mortality, and long-term outcomes after ex situ liver surgery. The second aim is to identify modifiable predicting factors to improve the outcomes after ex situ liver surgery.

**Eligibility:** Any surgeon worldwide performing ex situ liver surgery is eligible to participate in this study. There are no minimum number of cases to be submitted or selection criteria for centers.

**Time period and team members:** Each participant may form a team of 3 members in total. Both prospective and retrospective patient enrolment is accepted. The end of the patient enrolment is set on 30 October 2023.

**Inclusion criteria:** Only ex situ liver surgery cases will be included allowing all indications (benign and malignant).

**Exclusion criteria:** Ante situm, or in situ liver surgery under hypothermic perfusion are excluded.

**Outcomes:** The primary endpoint of the analysis will be 90-day mortality. Secondary endpoints will be the 90-day postoperative complication rates, liver failure rates requiring cadaveric liver transplantation, as well as up to 5 year

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**Please read the short version of the registry protocol available in 10 different languages.**

ExSituLiver.org Home Team Protocol **Registration** CRF Contact

## Create new account

Log in **Create new account** Reset your password

**Email address**

*The email address is not made public. It will only be used if you need to be contacted about your account or for opted-in notifications.*

**Username**

*Several special characters are allowed, including space, period (.), hyphen (-), apostrophe ('), underscore (\_), and the @ sign.*

**Picture**

no file selected

*Your virtual face or picture.  
One file only.  
2 MB limit.  
Allowed types: png gif jpg jpeg.*

▼ Contact settings

**Personal contact form**

*Allow other users to contact you via a personal contact form which keeps your email address hidden. Note that some privileged users such as site administrators are still able to contact you even if you choose to disable this feature.*

## User login

**Username**

**Password**

- [Create new account](#)
- [Reset your password](#)

**Please register your participation by clicking on the Registration Link.  
This way you will be able to access the electronic Case Report Form (sCRF) and submit cases.**

ExSituLiver.org

Home Team Protocol Registration CRF Contact

## Create new account

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**Email address**

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One file only.  
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## User login

**Username**

**Password**

Log in

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**This is the registration form. Please complete it accurately.  
This information will be used for future publications and authorship.**

Department

City

State (US only) - None -

Country  
- Select a value -

Role Member

Please allow "Member" unless you were invited to be a Committee Member.

Show row weights

| ADDITIONAL COLLABORATORS |                      |
|--------------------------|----------------------|
| .1                       | <input type="text"/> |
| .1                       | <input type="text"/> |

OPTIONAL: Please add above the additional two collaborators from your institution (Names, titles, and emails separated by a comma ";"). You may complete this at a later stage. Each collaborator (max 3 per team including yourself) will receive co-authorship in future publications. Eg. John Smith, MD, mail@me.com.

I agree to agree to comply with the Study Protocol and the Terms and Conditions available at ExSituLiver.org

Your message / comments to the Chief Investigators (optional)

Create new account

Please add here the full name of the 2<sup>nd</sup> local collaborator of your institution.

Add here the full name of the 3<sup>rd</sup> local collaborator.

These details will be used for authorship in future publications.

Each local team will be comprised of 3 investigators

Contact us if you require additional collaborators.



# Case Report Form

[View](#) [Edit](#) [Delete](#) [Revisions](#)

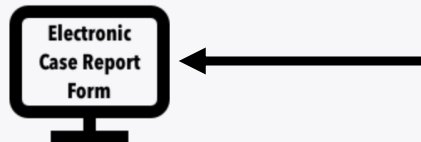
The **electronic Case Report Form (eCRF)** will be available here soon.

Paper version of the Case Report Forms (CRF) available for download:



This is the paper version of the CRF that can be used for preparation, sharing, as well as submission to the ethics committee.

Electronic Case Report Form (CRFs) for online case submissions:



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**Click on the electronic Case Report Form (eCRF) icon to access the case submission page.**



# Electronic Case Report Form (eCRF)

Submitted by Dimitri Raptis on Sun, 01/29/2023 - 23:52  
Electronic Case Report Form (eCRF)

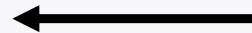
## Patient Characteristics

Please enter below a unique case identification (Case ID) number as an identifier. Do not use the hospital number or other patient identifiers.

Please keep a separate list of anonymized case numbers linking to the patient hospital number somewhere safe at your institution. This will help you identify patients in the CRF for further editing if needed.

[Click here to access a random number generator if you wish \(Min: 100000, Max: 1000000\)](#)

Case ID\*



Age\*  years

This is the age of the patient at the time of the primary operation.

Gender\*

Male  Female

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**The Case ID should be a random number, no hospital numbers, initials or date of births allowed. You may click on the link above to access the random number generator.**

Complications types & grades according to the Clavien-Dindo Classification until 90 days postop\* 

|                                  | NO                    | 1                     | 2                     | 3A                    | 3B                    | 4A                    | 4B                    | 5                     |
|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Abdominal wall dehiscence        | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Ascites                          | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Bile leak                        | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Biliary stricture                | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Biloma                           | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Bowel obstruction                | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Cardiac                          | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Deep vein thrombosis             | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Gastrointestinal (other)         | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Intra-abdominal fluid collection | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Liver failure                    | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Neurologic                       | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Pleural effusion                 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Portal vein thrombosis           | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Portal vein stenosis             | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Postoperative bleeding           | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Pulmonary embolism               | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

**The CRF captures morbidity until 90 days postoperatively using the Clavien-Dindo Classification of postoperative complications.**

**This table will capture both the type and the grade of complications. The first column represents the type of complication, the remaining columns indicate the grade of the complication severity.**

**Please ensure you are familiar with the Clavien-Dindo Classification of postoperative complications before you submit any cases.**

**This classification is available under the “Member Menu” right sidebar of our platform.**

Data completion ?

|   | YES                   | NO                    |
|---|-----------------------|-----------------------|
| Data until 90 day postop complete                         | <input type="radio"/> | <input type="radio"/> |
| Long-term data (follow up, recurrence, survival) complete | <input type="radio"/> | <input type="radio"/> |

*You may submit this case and complete it at a later stage. Please specify data completion below. Cases with incomplete data submission will be excluded from the analysis.*

Comments (optional)

By clicking on the **"Save Draft"** button, you may return to this form later and it will restore the current values. You will not be able to submit another case until the current form is submitted.

By clicking on the **"Submit"** button, your case will be permanently saved and you will be able to fill out and submit the next case. If you would like to update or change existing cases, please click on the **"My submitted cases"** link available at the right menu bar.

**Please specify if the data until 90 days postoperatively as well as long-term follow up data are complete. Finally, when ready, please click on the Submit button**

# Electronic Case Report Form (eCRF)


Submitted by Dimitri Raptis on Sun, 01/29/2023 - 23:52  
Electronic Case Report Form (eCRF)

## Patient Characteristics

Please enter below a unique case identification (Case ID) number as an identifier. Do not use the hospital number or other patient identifiers.

Please keep a separate list of anonymized case numbers linking to the patient hospital number somewhere safe at your institution. This will help you identify patients in the CRF for further editing if needed.

[Click here to access a random number generator if you wish \(Min: 100000, Max: 1000000\)](#)

Case ID\* 

Age\*  years

This is the age of the patient at the time of the primary operation.

**Gender\***

Male  Female

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**To view or edit your submitted cases, please click on the link titled “My submitted cases (edit).”**

## My submitted cases

Action Lock submission

Apply to selected items

| <input type="checkbox"/> | CASE ID* | PROCEDURE PERFORMED                              | DATA COMPLETION  | NON-ADMIN EDIT LINK  |
|--------------------------|----------|--|--|----------------------|
| <input type="checkbox"/> | 1929402  | Ex situ liver resection Sg 4a, 8, and Sg 5 wedge | <ul style="list-style-type: none"><li>• Data until 90 day postop complete: Yes</li><li>• Long-term data (follow up, recurrence, survival) complete: No</li></ul> | <a href="#">Edit</a> |

Apply to selected items

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**This will list all your submissions. You may sort the list by clicking on the Case ID\* parameter. You may also search a case with a specific Case ID by using the "CNTL F" for PC or "CMND F" for Mac function. Then click on "Edit" to view and update your submitted case.**

ExSituLiver.org Home Team Protocol CRF Contact

# Conversion calculator

Please wait for a few seconds for the calculator widget below to load. Thank you.

**Conversion Calculators**

- Height
- Weight
- Bilirubin
- Creatinine
- Dates
- rBiostatistics.com

**Height**

**Feet:**

**Inches:**

**Conversion Results**

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**We have developed conversion calculators to ensure uniform data collection.**

**Please use them when converting height, weight or laboratory units.**

**The "Dates" link on the left will provide you with the number of days between two dates for your convenience.**

ExSituLiver.org Home Team Protocol CRF Contact

## Clavien-Dindo Classification of postoperative complications

| Grades         | Definition   |
|----------------|--|
| <b>Grade 1</b> | Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions<br>Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside. |
| <b>Grade 2</b> | Requiring pharmacological treatment with drugs other than such allowed for grade 1 complications. Blood transfusions and total parenteral nutrition are also included.   |
| <b>Grade 3</b> | Requiring surgical, endoscopic or radiological intervention  |
| - 3a           | Intervention not under general anesthesia  |
| - 3b           | Intervention under general anesthesia  |
| <b>Grade 4</b> | Life-threatening complication (including CNS complications)* requiring IC/ICU-management   |
| - 4a           | single organ dysfunction (including dialysis)  |

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**Here is the Clavien-Dindo Classification of postoperative surgical complications**



## Contact

### Chief Investigator Lead

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### Administration Committee Lead

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### Research & Development Lead

- Dimitri Raptis: [draptis@btinternet.com](mailto:draptis@btinternet.com) | +447584560889

*The ExSituLiver.org Team*

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**Please feel free to contact us at any time.**



**Thank you!**