

The **PROBESE** Randomized  
Controlled Trial

**CRF Guide**

—

**Instructions for Paper/Electronic Case Report Form**

Protective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in Obese Patients

# GENERAL INSTRUCTIONS

## 1. Paper CRF vs. Electronic CRF?

With the exception of minor differences in the arrangement of data fields, the paper and electronic versions of the CRF are comparable. Depending on the technical equipment at your site, you may choose to primarily use the eCRF or to record data on paper CRF and secondarily transfer it to eCRF. All data has to be recorded in the eCRF as soon as possible.

## 2. REDCap database (eCRF) login

Your center will receive login data from our database manager (KKS Dresden) if it has provided:

- I. completed call-for-centers form
- II. confirmation of acceptance of our expectations to local investigators (see letter of invitation to local investigators/coordinators)
- III. confirmation of correct translation of the Patient Informed Consent Forms
- IV. copy of the final approval by your institutional review board
- V. names, e-mail addresses and investigator status (intraoperative vs. postoperative) of at least two local investigators to allow for blinding

*Instructions on how to login into REDCap database:*

- I. Please go to <https://redcap.med.tu-dresden.de/redcap/> directly or via the PROBESE website: <http://www.peg-dresden.de/probese/> >>> PROBESE for Physicians >>> Database and CRF.

You will find the following user interface, in which you should enter your username and password.

KKS Support (0351 458-18623)'. At the bottom of the page is a form with fields for 'Username' (containing 'blutht') and 'Password' (containing a series of dots). There are also 'Log In' and 'Forgot your password?' buttons."/>

Please log in with your user name and password. If you are having trouble logging in, please contact [KKS Support \(0351 458-18623\)](#).

Username:	<input type="text" value="blutht"/>
Password:	<input type="password" value="*****"/>
<input type="button" value="Log In"/> <a href="#">Forgot your password?</a>	

- II. Change your password initially and after every 180 days upon request from the system.
- III. After login, go to <My Projects> and then click <PROBESE>



Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. Newly created projects begin in **Development status** 🚧 as you begin to build and design them. When you are ready to begin entering real data in the project, you may move it to **Production status** ✅ to designate the project as officially collecting data. When you are finished collecting data or if you wish to stop collection, the project may be set to **Inactive status** 🔞, although it may be brought back to Production status at any time when you are ready to begin collecting data again. Also listed is the project type, which designates if the project is in **classic** 📊 or **longitudinal** 📈 data collection format.

My Projects						Filter projects by title
Project Title	Records	Fields	Instruments	Type	Status	
<a href="#">PROBESE</a>	1	1,172	24 forms			

- IV. At the PROBESE database, go to <Add/Edit Records> for data entry. You may enter data into an already existing case by typing the actual Patient Serial Number or you can create a new Patient ID. Data entry will be discussed in a separate section.



Please use following Format for Patient-ID: 001001. First 3 digits: site code, last 3 digits patient-ID

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 1 / In group: 1	
Choose an existing Patient Serial Number	-- select record --
Enter a new or existing Patient Serial Number	

  

Data Search	
Choose a field to search (excludes multiple choice fields)	-- select search field --
Search query	Begin typing to search the project data, then click an item in the list to navigate to that record.

### **3. Patient Serial Number**

In order to keep data handling simple, one patient receives just one ID. It contains both information about the randomizing study site and the patient sequence. The Patient Serial Number consists of 6 digits, the first 3 for the center and the last 3 for the patient.

You will receive or have already received the 3 digit center number by email from the trial coordinator, Thomas Bluth. If you have already received your login data for the REDCap database, but you do not know your center number, please contact [probese@peg-dresden.de](mailto:probese@peg-dresden.de).

The 3 digit patient number corresponds to the sequence of included patients, e.g. 001 for first, 002 for the second study patient included.

*How to create a new Patient Serial Number in REDCap database*

- I. After login into the PROBESE database, you may enter either an already existing or a new data record. You can select existing records either by dropdown menu or by typing the Patient Serial Number:

**PROBESE**

## Add / Edit Records

Please use following Format for Patient-ID: 001001. First 3 digits: site code, last 3 digits patient-ID

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 1 / In group: 1	
Choose an existing Patient Serial Number	-- select record -- <input type="button" value="▼"/>
Enter a new or existing Patient Serial Number	<input type="text" value="001002"/>

- II. Depending on the investigator status, you will be able to record pre- and intraoperative data (see upper screenshot) or pre- and postoperative data (see screenshot below). Initially, having a blank record, you will find all data points grey.

**PROBESE**

## Event Grid

Please use following Format for Patient-ID: 001001. First 3 digits: site code, last 3 digits patient-ID

"001002" is a new Patient Serial Number. You will need to click any of the red buttons below to create a record for this Patient Serial Number and begin entering data for it.

The grid below displays the form-by-form progress of data entered into the project for one particular Patient Serial Number for all defined events. You may click on the colored buttons to access that form for that event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

**Legend for status icons:**

- Incomplete
- Incomplete (no data saved)
- Unverified
- Complete

**NEW Patient Serial Number 001002**

Data Collection Instrument	Preoperative Visit (1)	Intraoperative Visit (2)	Postoperative Visit Day 1 (3)	Postoperative Visit Day 2 (4)	Postoperative Visit Day 3 (5)	Postoperative Visit Day 4 (6)	Postoperative Visit Day 5 (7)	Discharge (8)	Follow Up Day 90 (9)
Investigator	<span style="color: lightgray;">●</span>								
ARISCAT Score	<span style="color: lightgray;">●</span>								
Inclusion Criteria	<span style="color: lightgray;">●</span>								
Exclusion Criteria	<span style="color: lightgray;">●</span>								
Patient Details	<span style="color: lightgray;">●</span>								
History of previous disease	<span style="color: lightgray;">●</span>								
Actual Organ Function	<span style="color: lightgray;">●</span>								
Randomization		<span style="color: lightgray;">●</span>							
Anesthetic Overview		<span style="color: lightgray;">●</span>							
Drugs, Fluids, Transfusion		<span style="color: lightgray;">●</span>							
End Of Anesthesia		<span style="color: lightgray;">●</span>							
Surgical Overview		<span style="color: lightgray;">●</span>							
Protocol adherence		<span style="color: lightgray;">●</span>							
Intraoperative variables		<span style="color: lightgray;">●</span>							
Intraoperative Variables Continuation		<span style="color: lightgray;">●</span>							
Intraoperative Variables Continuation2		<span style="color: lightgray;">●</span>							
Adverse events		<span style="color: lightgray;">●</span>							

**NEW Patient Serial Number 001002**

Data Collection Instrument	Preoperative Visit (1)	Intraoperative Visit (2)	Postoperative Visit Day 1 (3)	Postoperative Visit Day 2 (4)	Postoperative Visit Day 3 (5)	Postoperative Visit Day 4 (6)	Postoperative Visit Day 5 (7)	Discharge (8)	Follow Up Day 90 (9)
Investigator	<span style="color: lightgray;">●</span>								
ARISCAT Score	<span style="color: lightgray;">●</span>								
Inclusion Criteria	<span style="color: lightgray;">●</span>								
Exclusion Criteria	<span style="color: lightgray;">●</span>								
Patient Details	<span style="color: lightgray;">●</span>								
History of previous disease	<span style="color: lightgray;">●</span>								
Actual Organ Function	<span style="color: lightgray;">●</span>								
Recovery		<span style="color: lightgray;">●</span>							
Fluids/ Drugs		<span style="color: lightgray;">●</span>							
Actual Organ Function Postop		<span style="color: lightgray;">●</span>							
Pulmonary complications		<span style="color: lightgray;">●</span>							
Extrapulmonary complications		<span style="color: lightgray;">●</span>							
Adverse Events Postop		<span style="color: lightgray;">●</span>							
Follow-Up									<span style="color: lightgray;">●</span>

#### **4. Blinding**

Before inclusion of study patients, each center has to ensure that at least two investigators are available, one for intraoperative treatment and one for postoperative follow up. Their roles have to be defined *before* inclusion of the patient. For PROBESE, both patient and investigator for postoperative follow up are blinded to allocation. However, to facilitate practicability of this trial, both investigators are able to obtain informed consent and collect data preoperatively.

To maintain blinding during data entry in the eCRF, two different accounts are created per center. Using the first user account, entry of both pre- and intraoperative data is possible, as well as randomization. Using the second account, entry of pre- and postoperative data is allowed.

# PREOPERATIVE VISIT

## 5. Inclusion and exclusion criteria

Each study patient has to meet all four of the inclusion criteria to be eligible. Eligibility must be confirmed by the local investigator.

The ARISCAT score and BMI must be determined directly before surgery in case of an unstable clinical situation. If the clinical status of the patient does not change, preoperative data can be obtained at maximum 28 days before surgery.

For measurement of body weight and height to calculate body mass index (BMI), the patient must be in underwear. The results of the measurement have to be documented traceably, e.g. in the patient's medical chart.

For ARISCAT score, actual age refers to age at the date of surgery. Preoperative SpO<sub>2</sub> must be measured in beach chair position breathing at least 10 min of room air. A patient with previous respiratory infection must have received antibiotics for a suspected respiratory infection and met at least one of the following criteria within the last month (=28 days): new or changed sputum, new or changed lung opacities, fever and leucocyte count > 12.000/ $\mu$ l. Upper abdominal surgery is defined as surgery requiring a supra-umbilical incision, e.g. pancreatic, gastric, liver, colonic, small bowel, transperitoneal kidney and bladder as well as large gynecologic and vascular surgery. Planned duration of surgery must be confirmed by the treating surgeon. If the actual duration of surgery was less than 2 hours (although expected duration was longer) the patient will be followed up until discharge without any protocol change.

If the patient does not meet any of the exclusion criteria, he/she is eligible for randomization.

## 6. Informed consent

Written informed consent must be obtained with adequate time for the patient to consider participation, e.g. at least the night before surgery. The patient should receive the *Information-For-Patients Form* and a copy of the written informed consent. Consent forms must be stored closed.

## 7. Patient Details/Previous Disease

Waist/Hip-Ratio must be measured according to WHO definition also provided in the appendix of the paper CRF (Part 9, Definitions). Briefly, waist circumference should be measured at the midpoint between the lower margin of the lowest palpable rib and the top of the iliac crest, using a stretch-resistant tape. Hip circumference should be measured around the widest portion of the buttocks, with the tape parallel to the floor. For both measurements, the subject should stand with feet close together, arms at the side and body weight evenly distributed, and should wear little clothing. The subject should be relaxed, and the measurements should be taken at the end of a normal expiration.

Obstructive Sleep Apnea: Since polysomnography is not always available in different countries, there may be patients with a diagnosis of OSA but without report of apnea/hypopnea index (AHI). In this case the STOP-BANG score should be reported.

## **8. Mandatory and non-mandatory measurements of actual organ function**

SpO<sub>2</sub>, respiratory rate (RR), heart rate (HR), mean arterial blood pressure (ABPmean), temperature, airway secretion and dyspnea as well as different pain characteristics are mandatory measurements.

Laboratory test results can be recorded on a facultative basis from the routine lab. The same applies to spirometry and chest X-rays. No diagnostics need to be done solely for the study. However, in case of pulmonary adverse events, chest X-rays may be done at the lowest clinical threshold

Pathologic findings on chest X-rays must follow the definitions of the respective postoperative pulmonary complications. For detail, please see the appendix (Part 9, Definitions) of the paper CRF.

# INTRAOPERATIVE VISIT

## 9. Randomization

To guarantee adequate sequence generation and allocation concealment, randomization is centralized, computer-based and integral part of the online database REDCap (<https://redcap.med.tu-dresden.de/redcap/>). Randomization lists are created by KKS Dresden on the basis of a variable block size randomization tool to ensure stratification per center. Access to randomization is reserved solely to the intraoperative investigator.

NEW Patient Serial Number 001002

Data Collection Instrument	Preoperative Visit (1)	Intraoperative Visit (2)	Postoperative Visit Day 1 (3)	Postoperative Visit Day 2 (4)	Postoperative Visit Day 3 (5)	Postoperative Visit Day 4 (6)	Postoperative Visit Day 5 (7)	Discharge (8)	Follow Up Day 90 (9)
Investigator	<input type="radio"/>								
ARISCAT Score	<input type="radio"/>								
Inclusion Criteria	<input type="radio"/>								
Exclusion Criteria	<input type="radio"/>								
Patient Details	<input type="radio"/>								
History of previous disease	<input type="radio"/>								
Actual Organ Function	<input type="radio"/>								
Randomization	<input checked="" type="radio"/>								
Anesthetic Overview	<input type="radio"/>								
Drugs, Fluids, Transfusion	<input type="radio"/>								
End Of Anesthesia	<input type="radio"/>								
Surgical Overview	<input type="radio"/>								
Protocol adherence	<input type="radio"/>								
Intraoperative variables	<input type="radio"/>								
Intraoperative Variables Continuation	<input type="radio"/>								
Intraoperative Variables Continuation2	<input type="radio"/>								
Adverse events	<input type="radio"/>								

*Practical advice: Please ensure to have the correct login before randomization and starting anesthesia.*

Randomization must be done directly before induction of anesthesia. A minimum of preoperative data has to be entered into the eCRF to get access to the randomization tool:

- I. Enter the names of >Intra- and Postoperative investigator< + set form >Investigator< to status >complete<
- II. Calculated ARISCAT-Score must be entered and greater than 26
- III. All inclusion criteria must be answered with >yes<
- IV. All exclusion criteria, including >Patient excluded from the study< must be answered with >no<
- V. >Written informed consent< at form >Patient details< must be answered with >yes<
- VI. Calculated BMI at form >Patient details< must be entered and even or greater than 35

 **Randomization**

Please use following Format for Patient-ID: 001001. First 3 digits: site code, last 3 digits patient-ID

 Adding new Patient Serial Number 001002

Event Name: <b>Intraoperative Visit</b>	
Patient Serial Number	001002
Visit date	<input type="text"/>    D-M-Y <small>* must provide value [DD-MM-YYYY]</small>
The randomisation field will not be displayed because the following conditions are not fulfilled:	
<ul style="list-style-type: none"><li>- form 'Investigator' is not set to status 'complete'</li><li>- not all inclusion criterias have been answered with 'yes'</li><li>- not all exclusion criterias have been answered with 'no'</li><li>- 'Patient excluded from study' was not answered with 'no'</li><li>- 'Written informed consent' is not answered with 'yes'</li><li>- ARISCAT Score is smaller than 26</li><li>- calculated BMI is smaller 35</li></ul>	
Form Status	