Appendix 01A Patient Information sheet and consent form

EuPreCHO: European study on perioperative management and outcome following Preoperative Transthoracic Echocardiography in noncardiac surgery patients.

Dear Patient,

We invite you to participate in an observational study by providing some of your medical data. Before deciding, we ask you to read the following information carefully. Your doctor will talk about the study with you and answer your questions.

We will enrol at least 8000 patients all over Europe. We are collecting data about a test (heart ultrasound) that is sometimes done before surgery, and how it influences the decisions doctors make.

Participation in our study is voluntary. If you prefer not to take part or withdraw your consent later on, no disadvantages will result for you. The study will **not change your treatment in any way.**

Why is this study carried out?

It is important to continuously improve how patients with known or suspected heart disease are taken care for before, during, and after surgical procedures. At present, some patients undergo a heart ultrasound (echocardiography) before surgery, while others do not. Also, we do not know if heart ultrasound influences the decisions that physicians make before, during, and after surgery. This study aims to answer the following questions:

- Are patients that were examined using heart ultrasound before surgery managed differently compared to similar patients not evaluated by heart ultrasound before surgery?
- Do patients evaluated using heart ultrasound have better outcomes at 30 days after surgery compared to similar patients not evaluated using heart ultrasound?
- Can we identify any factors that increase the chance of finding important information in heart ultrasound requested before surgery? (This will help improving the decision to evaluate or not evaluate patients using heart ultrasound before surgery in future patients).

What does participation imply?

If you decide to take part in the study, we will collect your data from before the surgery until 30 days after the surgery.

Your study participation will involve:

- Reading this information sheet and if applicable, signing the consent form
- The research team will collect information on heart ultrasound before surgery if you have had one, your medical history and how you were taken care before, during, and after surgery. ***Your care will be remained unchanged by study participation.***
- Completing a short questionnaire about your well-being (WHODAS questionnaire). This will require approximately 5 to 10 minutes.
- Providing ONE sample of blood (1 teaspoon) to measure heart parameters (high-sensitivity troponin and where applicable B-type natriuretic peptide). The research team at your centre will put every effort to collect the sample at the same time of the other blood tests required for the surgery.
- Being contacted by phone or mail by the research team 30 days after your surgery for a short interview to assess how you have been, to ask if you were readmitted to hospital, and to complete the same questionnaire on well-being. The phone interview (or completing the form sent by mail) will take approximately 10 minutes. If you are contacted by mail, the study team of your centre will provide you with a stamped return envelope.
- Your data will be encoded using a number (no identifiable data) and data storage will comply with the legal requirements issued by the General Data Protection Regulation (GDPR) by the European Union.
- Your encoded data collected within this study, may be used in the future for non-commercial research purposes such as sub-studies

What are the possible benefits of taking part?

Participation in the study will not benefit you for the current surgical procedure.

The information we get from this study will help us understand how patients are taken care after heart ultrasound. We hope to understand which patients benefit from heart ultrasound and which do not. This may help physicians to select patients in whom heart ultrasound is important and to avoid unnecessary heart ultrasound that may delay surgery or does not change outcomes after surgery. This might lead to improvements in care in the future.

What are the possible disadvantages and risks of taking part?

Possible disadvantages or risks may be discomfort from the sampling of ONE teaspoon of blood. We will make efforts to obtain the blood sample at the same time as the routine blood sample required before surgery, so that you will not be exposed to another needle stick.

Answering the questionnaires before surgery and at 30 days after surgery is also not routine, and requires your time and effort (at each timepoint approximately 10 minutes).

We will also be collecting and storing your data in a research database. Data will be encoded and data protection measures will comply with all current requirements issued by the General Data Protection Regulation (GDPR) by the European Union.

Do any additional costs arise?

There is **no** additional cost for you or your medical insurance.

What is expected from me?

Information about your well-being at 30 days after the procedure is very important for us to draw correct conclusions from the study. Therefore, it is of utmost importance that we can reach you. Your centre may contact you by telephone and/or by mail. If your centre decides to contact you by mail, the research team at your centre will provide you the forms to complete by mail with a stamped return envelope.

Is it possible to withdraw from the study even after I have agreed to it?

You are under no obligation to take part and declining to be involved will not affect the care you receive. If you agree to participate but then change your mind, you are still free to withdraw at any point, and this will not affect the care you receive. You can decide to withdraw from the study without having to provide any reason. No further data will be collected. However, encoded data that has been collected will be used in subsequent analyses. Please talk to your local investigator if you decide to opt out.

Information about data protection

According to the General Data Protection Regulation (GDPR), you have the right to be informed about how your data are protected and what are your rights regarding the processing of your personal data. For this study, the data controller (person, company, or other body that determines the purpose and means of personal data processing) is the European Society of Anaesthesiology and Intensive Care (ESAIC), Rue des Comédiens 24, 1000 Brussels, Belgium. Therefore, ESAIC is responsible for looking after your encoded data and using it properly by respecting your rights.

As required by the GDPR, ESAIC has appointed a Data Protection Officer who can be contacted at privacy@esaic.org

ESAIC has a legitimate interest to process your personal data in order to conduct the clinical study. The benefit of this study will be to develop scientifically founded recommendations for anaesthesiologists caring for patients with known or suspected heart disease having surgery with regard to heart ultrasound. Such processing is also necessary for scientific research purposes. To ensure your safety and the integrity of the results of the study, ESAIC also has a legal obligation to process your personal data. Such processing is necessary in the public interest in the field of public health.

All the personal data that could identify you directly (e.g. your name or date of birth) will be stored at locked cabinet in an office in your institution/hospital, accessible to authorised personnel only. The study team and the medical team have a duty of confidentiality with respect to the data collected.

All data collected in the research database (medical history, well-being questionnaire, treatment, and the results of heart ultrasound and blood sample results) will be encoded, this means that your identifiable data are replaced by a code. As such all the collected personal data that leaves the clinic can**not** identify you directly. The research team at your centre will be the only persons who can establish a link between the encoded data transmitted to the research database and yourself.

The data kept in your hospital will be deleted after the archiving period. Its duration of is determined by local law. All the encoded data relating to the study will be stored electronically for 25 years, a legal requirement. At the end of this period, the data will be destroyed or anonymized. The anonymization process means that data can no longer be used to identify a person by using all the means likely reasonably to be used and this process is irreversible.

The above-mentioned encoded data will be collected by the local research team and shared to ESAIC in Belgium, Ethic Committees, Regulatory Authorities, and to third parties acting on their behalf.

We only transfer the encoded data to third parties if this is permitted by law. Your (encoded) data might be transferred to a country that may not have the same level of personal data protection as your country. If your data is transferred outside of EU, ESAIC is responsible for protecting your personal data. It will ensure that either the country that will receive your data is recognized as having an adequate level of data protection, or appropriate safeguards will be put in place by ESAIC to ensure the protection of your personal data (e.g. “Standard Data Protection Clauses). You have the right to ask for a copy of these safeguards by contacting the Data Protection Officer of ESAIC.

According to the GDPR, you have the right to access and to correct the personal data collected about you, to restrict or object to its use or storage, you can also request a copy of all the information about you free of charge.

You have the right of data portability and the right to withdraw your consent to data use or storage at any time. Please, note that these rights are not absolute and will be subject to a case-by-case analysis by the Data Protection Officer of ESAIC.

If you have any questions or if you want to exercise your personal data protection rights as a participant in this study, please liaise with the study doctor or research team at your centre. They will then be able to direct your questions to the ESAIC data protection officer (via privacy@esaic.org). You should be aware that contacting any external body carries the risk of you losing your anonymity.

If you withdraw from the study or object to the processing of your information, your information will no longer be collected. However, the information collected up to the time of withdrawal or objection must remain in the study database so that the study is still scientifically valid. If information is omitted, the scientific, and therefore the ethical integrity of the research will be compromised. Moreover, your personal data must be stored for safety reasons and archiving obligations

If you believe that the processing of your data infringes GDPR, you have the right to lodge a complaint with your Country specific Data Privacy Authority.

Add here country specific DPA's contact details (including phone number and email address) all details can be found at https://edpb.europa.eu/about-edpb/board/members_en

At the end of the study, a description and the results of this clinical study will be published in specialized medical journals.

A description of the study will also be available on clinicaltrial.gov – Study Number: **NCT06409234**

These websites or publications will not include any information that can identify you.

Local contacts

Centre/Institution name: _____

Local Principle Investigator: _____

Responsible ethical board: _____

Responsible data safety officer : _____

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Patient's name in block capitals (or patient label) and patient study ID

Consent to participation in the study

I was informed by _____ (name of staff taking consent) about the study. I have received and read the written information and declaration of consent for the above study. I was given detailed written and oral information about the purpose and course of the study, the opportunities and risks of participating and my rights and obligations. I had the opportunity to ask questions. These were answered satisfactorily and completely. I had enough time to consider my decision.

The following phone number(s) may be used to get in touch with me (the patient):

_____

_____

I have been advised that my participation is voluntary and that I have the right to withdraw my consent at any time without giving a reason, without incurring any disadvantages.

I will be handed a copy of this form after signature. A copy will remain at the study centre.

I hereby consent to participate in the above study.	**☐ Yes**	**☐ No**
I hereby consent for my data obtained from this research to be re-used for future non-commercial research purposes	**☐ Yes**	**☐ No**

_____

Place, Date — Signature of patient

_____

Place, Date — Signature of staff taking consent

Data protection

I understand that I have data privacy rights and I know who to address my questions to, if necessary. ☐ **Yes** ☐ **No**

Place, Date	Signature of patient
Place, Date	Signature of staff taking consent

I was explained in detail, and I understand how my personal information will be collected and used, including sensitive information (data concerning health). ☐ **Yes** ☐ **No**

Place, Date	Signature of patient
Place, Date	Signature of staff taking consent