SQUEEZE – GDPR clarification (for the patient)
(document applicable where ESA is Controller)

The following document is divided in two parts.
Part A) is addressed to the patient and should be explained orally or in writing by the Investigator to the patient.
Part B) is for the Investigator only.

A) Addressed to the investigator and should be explained orally or in writing to the patient.

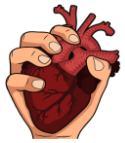
Your personal data will be processed for scientific purposes, i.e. the execution of a clinical trial regarding the following:

SQUEEZE study investigates the postoperative vasopressor usage: a prospective international observational study. The study goal is to describe the incidence of postoperative vasopressor therapy. There are two main objectives : determining what proportion of patients receive postoperative vasopressor infusions, and the incidence of associated organ dysfunction as well as their clinical outcomes, but also identifying factors in variation of care (patient, condition, surgery, and intraoperative management), that are associated with receipt of postoperative vasopressor infusions.

Your information will be transferred to the ESA, a non-profit organisation based in Brussels, Belgium. Here is more information about the ESA:

<u>General information</u>

Who are we?	European Society of Anaesthesiology (ESA in short) based at: Rue des Comédiens, 24, 1000, Brussels, Belgium.
Contact us	Please check with the local investigator for more information.
Who will receive my data?	☑ Employees and Subcontractors of ESA, involved in the research project ☑ Health organizations ☑ Education organizations ☑ Research organizations
Transfer outside Europe	Maybe, yes. We protect your data to the maximum; it is possible that data is less well protected in certain countries outside Europe but even in this situation we put everything into place to continue protecting your data.



Data

How long do you keep my data 💾?	According to Belgium law: 25 years minimum. Please check with your local investigator for more information about your national legislation concerning data storage in your country.
As a patient, can I change my data? 🧐	Yes, check your data and if needed change it. Just ask your investigator. You can always decide stop being a part of the trial in which case no new data will be added. Your data will never be used for direct marketing.
I'm not happy, can I complain somewhere? 😤	Sure, on this website: https://www.dataprotectionauthority.be/

Legal

What gives you the right to process my data ?	**Art. 6, 1, e** of the GDPR for ordinary data: Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller; **Art. 9, 2, j** of the GDPR for 'sensitive' data: processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

B) This second part is a clarification of GDPR for the Investigator

The General Data Protection Regulation was created to protect E.U. citizen's data. The Regulation also takes into account the requirements of Scientific Research's need for data. This is why no consent is required for the processing of the personal data in the framework of this clinical trial.
The European Data Protection Board (EDPB) rendered an advice on the application of the GDPR on clinical trials.
The processing thereof can be justified based on:

- **Explicit consent of the data subject; <u>or</u>**
- **The general public interest and scientific purposes**. It is, thus, possible to process the personal data in the framework of a clinical trial without obtaining the data subject's consent. The EDPB even prefers this second justification over the processing based on consent: *"The EDPB considers that as an alternative to data subject's consent, the lawful grounds of processing provided under Article 6(1)(e) are more appropriate".*

Furthermore, the EDPB considers […] that the appropriate Article 9 condition for all processing operations of sensitive data for purely research purposes could be […] "*scientific ... purposes in accordance with Article 89(1) based on Union or Member State law*"(Article 9(2)(j)).

Thank you for your attention.

Best regards,

SQUEEZE and ESA Quality Management Teams