SQUEEZE Appendix 1AB - Patient Information Sheet and Informed Consent Form

SQUEEZE: Postoperative Vasopressor Usage: prospective, international multicentre cohort study

STUDY INFORMATION SHEET FOR PATIENTS:

You are invited to participate in an observational research study. Before deciding whether or not to take part in this study, we would ask you to carefully read the following information.

Background
After an operation, some patients develop a low blood pressure. If the blood pressure is too low, then the healthcare team may start some treatments. The commonest treatment is intravenous fluids but occasionally an infusion of medication is required – typically the medication is from a class of drugs called vasopressors, that increase blood pressure. The receipt of postoperative vasopressor infusions has never been described and that is the focus of this study.

Why have I been asked to take part in the study?
You are having surgery and may receive a postoperative vasopressor infusion.

Do I have to take part?
No. You are under no obligation. Declining to be involved will not affect the care you receive. If you agree to participate but then change your mind then you are free to withdraw at any point, without giving a reason, and this will not affect the care you receive. If you decide to withdraw from the study no further data will be collected, but data that has already been collected, and encoded (identified by a number) will remain anonymised and used in subsequent analyses.

What will happen to me if I agree to be enrolled in the study?
The healthcare research team will:

1) Collect general information on your health prior to surgery from your medical records, in particular about your medication use and previous medical and surgical history; and information on what occurred during and after your operation
2) Anonymise your information so none of it is linked to you
3) Enter this information into a secure on-line database for subsequent analysis

Participation in the study will not affect the medical care you are going to receive in any way. In particular there will not be any additional interventions or tests.

How will the results be used?
The analysis will be disseminated through publication in scientific journals and at medical conferences

What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks

What are the possible benefits of taking part?

Participation in the study will not necessarily benefit you during your hospital stay. The information we get from this study will improve our understanding of postoperative hypotension and this might lead to improvements in care in the future.

Privacy and use of clinical information

To carry out the study it will be necessary to consult your medical record and collect some of the information that appears in it. Your agreement to participate in the study will authorise study personnel to consult and process the information in the following manner:

- Study participants will be identified by a number (encoding). The key linking the study number to your personal identification will be kept confidential and will be stored at your hospital in a locked cabinet accessible to authorised personnel only.
- Anonymised information i.e. only identified by a number and without link to personal identification will be stored in a central computerised database protected through personalised and confidential username and password. No data concerning personal identification will be stored in the central computer database.
- For purposes of monitoring, audits or inspections, the European Society of Anaesthesiology, national coordinating investigators, members of the relevant ethical board or regulatory authorities will be allowed to access all study documents, including identifiable information. All handling of personal data will comply with the Good Clinical Practice Guidelines and strictly follow the legal and national requirements for data protection.

Finally, we would like to draw your attention to the fact that this informative consent document refers only to your participation in the SQUEEZE study.

Funding and organisation of the study

This study is funded by the European Society of Anaesthesiology. Your local investigator is:

Hospital Investigator: _____ Telephone: _____

Research Nurse: _____ Telephone: _____

If you have any questions related to your rights as a study participant, you can contact the local Ethics Committee or R&D office at: _____ Telephone: _____

Thank you for taking time to read this information sheet.

CONSENT FOR PARTICIPATION FORM

Centre Number: S_ _ _ - _ _ _

Study Number:

Patient Identification Number for this trial: _ _ _ - _ _ _ - _ _ _

Name of Researcher/Site Local Coordinating Investigator: _____

Please initial all boxes

1. I confirm that I have read and understand the information sheet (Version 1.0, dated 11 September 2019) for the above study. I have had enough time to consider the information, the opportunity to ask questions, and I have received satisfactory answers. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to my general practitioner (GP) being informed of my participation in the study ☐
4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of staff taking consent	Date	Signature