Date

To: ***Ethics Committee/Institutional Review board Name***
Hospital Name, City, Country

Dear Madam, Dear Sir,

We wish to apply for approval of the project entitled “SQUEEZE: Postoperative vasopressor usage: a prospective, International, multicentre observational study” and sponsored by the European Society of Anaesthesiology (ESA).

Please find enclosed the SQUEEZE Study Protocol (Final) v 1.11 dated May 2019 and its appendices.

The SQUEEZE study is an observational study. Only data that will be collected are the ones requested in the Case Report Form (CRF) see attached.

The site staff and investigators will follow hospital routines and NOT CHANGE PATIENT CARE to their routine clinical practice. Further, participation does not prevent routine functional capacity assessment by the attending physicians.

- All data will be encoded, and the original documents remain in the local hospital. Only pseudonymised data will be entered in the central, secured database located at the European Society of Anaesthesiology. Data entry will occur via a secure website.

To minimize nonresponder bias, it is critically important that all patients corresponding to eligibility criteria (and selected by a random process, if applicable), be approached and recruited in the study. Therefore, in consideration of the minimal data safety risk associated with participation, we apply for waiver of written informed consent.

Should you consider our application for a waiver of written informed consent as appropriate we would kindly ask you to include in your approval letter a formal statement indicating that “informed written consent is waived by the local IRB/ruling authority”.
Should you, in contrast, consider an informed written consent as warranted, we would kindly ask you to review and if applicable approve the enclosed informed consent forms (SQUEEZE Appendix 1AB - Patient Information Sheet and Consent Participation Form 11 SEP 2019).

We thank you in advance for the evaluation of the submitted protocol and appendices.,

Sincerely yours,

Name and Signature
Local Coordinator /National Coordinator
XXXX

I. REQUESTOR INFORMATION		
Name:		
Institutional Affiliation:	Email:	Phone:
Current Address:		
City	Country:	ZIP Code:

II. PROJECT IDENTIFICATION
Project Title: SQUEEZE ClinicalTrials.gov identifier: # NCT03805230
Project Aim: To answer the question: "What proportion of patients receive postoperative vasopressor infusions following major noncardiac surgery and the associated health economic impacts of postoperative vasopressor therapy?" For patient postoperative hypotension management: 1a) Is there variation in practice between clinicians, hospitals and countries? 1b) How are these variations associated with clinical outcome?

III. STEERING COMMITTEE CO-CHIEF INVESTIGATORS		
Name: **Ib Jammer**	Address Haukeland University Hospital Department of Clinical medicine Laboratoriebygget, 7	
City: Bergen	Zip Code: 5020	Country: Norway
Name: **Ben Creagh-Brown**	Address Royal Surrey County Hospital Section of Clinical medicine and Aging Leggett Building, Daphe Jackson Road	
City: Guildford	Zip Code: GU2 7XH	Country: UK

IV. LEAD RESEARCH INSTITUTION/STUDY SPONSOR
ESA Research Department European Society of Anaesthesiology Rue des Comédiens 24 1000 Brussels, Belgium The Clinical Trial Network of the European Society of Anaesthesiology can be contacted via: Pierre Harlet and Flavia Pirovano; squeeze@esahq.org