SUSTAIN-EUROPE

European Society of Anaesthesiology and Intensive Care

SUSTAIN-EUROPE Appendix 5 – Study Approval Documentation Coversheet

Please return this form to: ESAIC Secretariat/Research Clinical Trial Network before the study starts in your centre.
Email: sustain-europe@esaic.org

Country:	**Site number #: SE_ _ _-_ _ _**
Principal Investigator Last name:	**first name:**
Institution Name:	**City**:

I. Ethics Committee (IRB/IEC) Approval

Is Ethics Approval MANDATORY for this centre?

Yes ☐ *(fill in section 1A)*

No ☐ *(fill in 1B)*

1A) EC Submission and Approval details

Approval by Country / Pivotal **IRB/IEC** ☐ Regional **IRB/IEC** ☐ Local **IRB/IEC** ☐

IRB/IEC NAME:

Submission DATE: |__|__| - |__|__| -202|__|

Approval DATE: |__|__| - |__|__| -202|__|

List any additional documents submitted to EC(e.g. Protocol, Patient information sheet, CRF, …)

……

I have attached the following documents to this coversheet:

☐ Approval/favourable opinion **of IRB/IEC** (dated and listing the documents approved)

List any additional EC documents attached to this coversheet (e.g. IRB/IEC Composition, submission letter, …) ……

Information on Consent;

Patient Consent is mandatory ? ☐ Yes ☐ No

Is it explicitly mentioned in the ethics approval letter ? Yes ☐ No ☐

If No => **Exemption DATE: |__|__| - |__|__| -202|__|**

1B) EC Notification details:

EC NAME: **Notification DATE: |__|__| - |__|__| -202|__|**

☒ ***Protocol and any amendments*** **(version dated)**

Acknowledgement of receipt DATE: |__|__| - |__|__|-202|__|

I have attached the following documents to this coversheet:

☐ **IRB/IEC** acknowledgement of receipt of notification (dated and listing the documents received)

☐ EC exemption of Patient Informed Consent

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II. Regulatory authority (RA/CA/IES) authorisation/approval/ notification of protocol (where required)

Is **Regulatory authority** approval also mandatory for this centre? Yes ☐ *(fill in section 2)* No ☐

2) Regulatory/health Authority/other Approval details:

Approval by: ☐ **NAME of Regulatory authority**:

List any additional documents submitted to Regulatory Authority (e.g. Protocol, Patient information sheet, CRF, …)

……

I have attached the following documents to this coversheet:

☐ Approval/favourable opinion **of Regulatory Authority** (dated and listing the documents approved)

☐ ***Competent authority (CA) approval***

☐ ***Submission letter to CA***

☐ ***Application form***

☐ ***Evidence of receipt by CA of a valid application***

☐ ***Notification by CA of grounds for non-acceptance***

☐ ***CA approval (no grounds for non-acceptance), if applicable***

Entire Package Submission DATE: |__|__| - |__|__|__| -202|__|

Entire Package Approval DATE: |__|__| - |__|__|__| -202|__|

I have attached the following documents to this coversheet:

☐ Approval letter (dated and listing the documents approved)

☐ Other document:

Total # of pages incl. attachment:

Name: **Signature:** **Date:**

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