European Society of Anaesthesiology and Intensive Care

ARCTIC-I

Approval Documentation Coversheet

Please return this form to: ESAIC Secretariat/Research Clinical Trial Network before study starts in your centre to: email ARCTIC-I@esaic.org scanned or by fax to:

Country:	**Site number #: A_ _ _-_ _ _**
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|__|

I have attached the following documents to this coversheet:

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

Does the approval explicitly mention Patient Consent is not needed? ☐ Yes ☐ No

☐ **IRB/IEC** composition/ member list

☐ Other EC document:

- Submission letter to EC
- Application form
- Evidence of receipt by EC of valid application
- Request from IEC for supplementary information
- Opinion from EC
- Request from EC to head of institute for assessment of local feasibility
- Statement from head of institute on local feasibility
- Evidence of submission of statement on local feasibility to EC

List Documents submitted;

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

☐ ***Patient information Sheet*** **(version dated)**

☐ ***Informed consent form(s)*** **(version dated)**

☐ ***Any other written information to be provided to the subject(s)***

☐ ***CRF (if applicable)*** **(version dated)**

☐ ***Advertisement for subject recruitment (if used)***

☐ ***Subject compensation (if any)***

☐ ***Any other documents given approval/favourable opinion.*** **(version dated)**

☐ ***IB***

☐ ***Insurance***

Information on Consent;

Is Patient Consent needed in your centre according to Ethics decision? Yes ☐ No ☐

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

Comments:

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

II. Regulatory authority (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 (IES**:

I have attached the following documents to this coversheet:

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

☐ ***Sponsor letter authorising CRA/monitor to conduct CA process***

☐ ***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:**