**The ENCORE Study Approval Documentation Coversheet**

Please return this form to: ESAIC Secretariat/Research Clinical Trial Network before study starts in your centre to: email : encore@esaic.org

**Country:**       **Site number #: EN**

**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:**

SubmissionDATE: Click or tap to enter a date.

ApprovalDATE: Click or tap to enter a date.

*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     )**

[ ]  ***Insurance***

*Information on Consent;*

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

*If No =>* **Exemption DATE:** Click or tap to enter a date.

**Comments:**

**1B) EC Notification details:**

**EC NAME:**       **Notification DATE:** Click or tap to enter a date.

[ ]  ***Protocol and any amendments* (version     dated     )**

**Acknowledgement of receipt DATE:** Click or tap to enter a date.

*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:** Click or tap to enter a date.

[ ]  **Entire Package Approval DATE:** Click or tap to enter a date.

*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:** Click or tap to enter a date.