MOPED Study Approval Documentation Coversheet

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

Country:	**Site number #: M_ _ _-_ _ _**
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:**