

# Table of Content (1 through 16) ([download](#))

*Site specific = each site need to add their own local or national documents to some of the Site Master File sections.*

**Please see [LOG](#) for latest up-loads of new documents and/or new versions of documents in Site Master File**

**Short cut to:**

- - [Instructions](#)
  - [Pocket cards and notice boards](#)
  - [Educational materials](#)

## **1) Protocol and trial synopsis**

- a) [Approved protocol](#)
- b) Approved amendments
- c) [Trial synopsis](#)

## **2) [CRF](#) (for instruction, please see 9.a.iii)**

## **3) Trial participants**

- a) [Delegation- and signature-log](#) (in Danish click [here](#))
- b) [Training log](#)
- c) [Curriculum Vitae](#) for all personnel (template) (in Danish click [here](#))

## **4) Approvals and correspondence**

- a) [The Danish Medicines Agency](#)
- b) [EudraCT](#)
- c) [The Committees on Health Research Ethics](#) (in Danish click [here](#))
- d) The Danish Data Protection Agency ([Datatilsynet](#))
- e) National and local approvals (*site specific*)
- f) Annual Safety Report

## **5) Collaboration agreement**

- a) (To be announced)
- b) [Approval from head of department](#) (template) (in Danish click [here](#))
- c) Other relevant contracts (*site specific*)

## **6) Financial affairs**

- a) [Case money](#) (template)
- b) Patient insurances (*site specific*)

## **7) Information to participants**

- a) Patient information (template) (in Danish click [here](#))
- b) Consent forms (*site specific*) (in Danish [Samtykke skabelon](#), Samtykke log, [Samtykke drejebog](#))

## **8) Co-enrolment and substudies**

- a) [Co-enrolment Form](#) (with access to Co-enrolment List) [\[add link\]](#)
- b) Quality criteria for substudies
- c) [Substudy proposal form](#) (template)

## **9) Trial documents**

- a) Trial instructions
  - i) [Eligibility](#)
  - ii) [Screening and randomisation](#)
  - iii) [eCRF](#)
  - iv) [SUSAR](#)
- b) Pocket cards, documents for a notice board in the department
  - i) Oxygenation target for notice board (in Danish click [here](#))
  - ii) Inclusion and exclusion criteria for notice board (in Danish click [here](#))
  - iii) [Pocket cards](#) (in Danish click [here](#))

- iv) [Leaflet for all clinicians](#) (in Danish [Folder fagpersonale](#))
- v) Sign for bed
- vi) [FiO<sub>2</sub> conversion tables for open systems](#)
- vii) Identification log (drawn from the eCRF-system OpenClinica)
- c) Educational material (power point presentations)
- i) [Trial Initiation](#)

Background

Design and organisation

Screening and randomization

Adherence to oxygenation target

Trial withdrawal and SUSAR

Data entry

Discharge/transfer/death

Follow-up

- ii) Information for nurses (in Danish click [here](#))

## **10) Trial Medication**

- a) [Summary of product characteristics](#) (in Danish click here for [Summary](#))

## **11) [Laboratory tests](#) (template)**

- 12) [Primary data source](#) (in Danish click [here](#))

## **13) Communication**

- a) HOT-ICU [Contact details](#) - [Steering Committee](#)
- b) Contact details - eight countries
- c) [Note to file send to Sponsor](#) (template)
- d) [Note to file received from Sponsor](#) (template)

e) Other correspondences between Sponsor and site(s) (*site specific*)

f) News letters

g) Investigator meeting

#### **14) Suspected unexpected serious adverse reactions**

a) [SUSAR form](#)

b) Standard operating procedure for SUSAR reporting

c) Documentation for reporting of SUSAR (*site specific*)

#### **15) GCP unit**

a) Contacts (monitors/GCP units) (*site specific*) (in Danish click here)

b) Monitoring visits (template) (in Danish click here)

c) Monitoring reports (*site specific*)

d) Monitoring plan (in Danish click [here](#))

e) Approval of trial initiation (*site specific*)

f) Correspondence with the monitor (e.g. GCP-unit) (*site specific*)

#### **16) Trial completion**