**Table of Content (1 through 16) (**[**download**](http://www.cric.nu/aid-icu-table-of-content-site-master-file/)**)**

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

**Please see**[**LOG**](http://www.cric.nu/aid-icu-log-for-site-master-file/)**for latest up-loads of new documents and/or new versions of documents in Site Master File**

**Short cut to:**

* [Instructions](http://www.cric.nu/aid-icu-instructions/)
* [Pocket cards, notice boards etc.](http://www.cric.nu/aid-icu-pocket-cards-and-notice-boards/)
* [Educational materials](http://www.cric.nu/aid-icu-educational-material/)

**1) Protocol and trial synopsis**

a) [Approved protocol](http://www.cric.nu/aid-icu-protocol/)

b) [Approved amendments](http://www.cric.nu/aid-icu-protocol-amendment/) (in Danish click [here](http://www.cric.nu/aid-icu-protocol-amendment-danish/))

c) [Trial synopsis](http://www.cric.nu/aid-icu-trial-synopsis/)

**2)**[**CRF**](http://www.cric.nu/aid-icu-crf-pdf-format/)**(for instruction, please see 9.a.iv.)**

**3) Trial participants**

a) [Delegation- and signature-log](http://www.cric.nu/aid-icu-delegation-and-signature-log/) (in Danish click [here](http://www.cric.nu/aid-icu-opgavefordelingsliste/))

b) [Training log](http://www.cric.nu/aid-icu-training-log/)

c) Curriculum Vitae for all personnel ([template](http://www.cric.nu/aid-icu-cv-all-personnel-template/)) (in Danish click [here](http://www.cric.nu/aid-icu-cv-for-sundhedspersonale-dansk/))

**4) Approvals and correspondence**

a) [The Danish Medicine Agency](http://www.cric.nu/aid-icu-the-danish-medicine-agency/)

b) [EudraCT](http://www.cric.nu/aid-icu-eudract/)

c) [The Committees on Health Research Ethics](http://www.cric.nu/aid-icu-the-committees-on-health-research-ethics/) (in Danish click [here](http://www.cric.nu/aic-icu-den-videnskabsetiske-komite-region-sjaelland/))

d) [The Danish Data Protection Agency](http://www.cric.nu/aid-icu-datatilsynet-godkendelse-instruks-og-databehandleraftale/) (Datatilsynet)

e) National and local approvals *(site specific)*

g) Annual Safety Report

**5) Collaboration agreement**

a) [Collaboration agreement between Sponsor and site](http://www.cric.nu/aid-icu-collaboration-agreement-between-sponsor-and-site-template/) (template)

b) [Approval from head of department](http://www.cric.nu/aid-icu-approval-from-head-of-department/) (template)(in Danish click [here](http://www.cric.nu/aid-icu-tilladelse-afdelingsledelsen/))

c) Other relevant contracts *(site specific)*

**6) Financial affairs**

a) [Case money](http://www.cric.nu/aid-icu-case-money-international/)

b) Patient insurances *(site specific)*

**7) Information to participants**

a) [Patient information](http://www.cric.nu/aid-icu-patient-information-template/) (template) (in Danish click [here](http://www.cric.nu/aid-icu-deltager-information/))

b) Consent form *(site specific)* (in Danish click [here](http://www.cric.nu/aid-icu-samtykke/))

**8) Co-enrolment and substudies**

a) [Co-enrolment Form](http://www.cric.nu/aid-icu-co-enrolment-form/) (with access to [Co-enrolment List](http://www.cric.nu/aid-icu-co-enrolment-list/))

b) [Quality criteria for substudies](http://www.cric.nu/aid-icu-quality-criteria-for-substudies/)

c) [Substudy proposal form](http://www.cric.nu/aid-icu-sub-study-proposal-form/) (template)

**9) Trial documents**

a) Trial instructions

i) [Eligibility](http://www.cric.nu/aid-icu-eligibility/)

ii) [Screening and randomisation](http://www.cric.nu/aid-icu-screening-and-randomisation/)

iii) [Trial medication](http://www.cric.nu/aid-icu-trial-medication/)

iv) [eCRF](http://www.cric.nu/aid-icu-ecrf/)

v) [SAR/SUSAR](http://www.cric.nu/aid-icu-sarsusar/)

vi) [SOP](http://www.cric.nu/aid-icu-sops/)

b) Pocket cards, documents for a notice board in the department

i) [Trial medication for notice board](http://www.cric.nu/aid-icu-trial-medication-for-notice-board/) (in Danish click [here](http://www.cric.nu/aid-icu-forsogsmedicin-til-opslagstavlen/))

ii)[Inclusion and exclusion criteria for notice board](http://www.cric.nu/aid-icu-inclusion-and-exclusion-criteria-for-notice-board/) (in Danish click [here](http://www.cric.nu/aid-icu-inklusion-og-eksklusion-kriterier/))

iii) [Trial synopsis for notice board](http://www.cric.nu/aid-icu-trial-synopsis-for-notice-board/)

iv) [Pocket cards](http://www.cric.nu/aid-icu-pocket-cards/) (in Danish [læger](http://www.cric.nu/aid-icu-lommekort-laeger/)/[sygeplejersker](http://www.cric.nu/aid-icu-lommekort-sygeplejersker/))

v) Leaflet for [clinicians](http://www.cric.nu/aid-icu-leaflet-clinicians/)/[nurses](http://www.cric.nu/aid-icu-leaflet-nurses/) (in Danish [læger](http://www.cric.nu/aid-icu-folder-laeger/)/[sygeplejersker](http://www.cric.nu/aid-icu-folder-sygeplejerske/))

vi) [Sign for bed](http://www.cric.nu/aid-icu-sign-bed/)

c) Educational material (power point presentations)

i) [Initiation](http://www.cric.nu/aid-icu-trial-initiation/)

ii) Screening and randomisation

iii) [Trial medication dispensing](http://www.cric.nu/aid-icu-trial-medicine-dispensing/) (in Danish click [here](http://www.cric.nu/aid-icu-forsogsmedicin-dispensering/))

iv) Data entry

v) Withdrawal

vi) SAR/SUSAR and un-blinding

vii) Information for nurses (in Danish click [here](http://www.cric.nu/aid-icu-information-til-plejepersonale/))

**10) Trial Medication**

a) [Labels](http://www.cric.nu/aid-icu-labels/)

b) [Summary of product characteristics](http://www.cric.nu/aid-icu-summary-of-haloperidol-characteristics/) (in Danish click [here](http://www.cric.nu/aid-icu-produktresume-haloperidol/))

c) [Drug disposal form](http://www.cric.nu/aid-icu-drug-disposal-form/)

d) Receipt of trial medication

e) Instruction for temperature logger

**11) Laboratory tests (template)**

**12)**[**Primary data source**](http://www.cric.nu/aid-icu-primay-data-source/)**(in Danish click**[**here**](http://www.cric.nu/aid-icu-kildedataliste/)**)**

**13) Communication**

a) Contact details - Steering Committee

b) [Contact details](http://www.cric.nu/aid-icu-contact-details-national-investigators/)-  Denmark - Finland - Norway - UK - Italy - Spain - Germany

c) [Note to file](http://www.cric.nu/aid-icu-note-to-file-tofrom-sponsor-template/) (template)

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

e) News letters

f) Investigator meeting

**14) Serious adverse reactions ans suspected unexpected serious adverse reactions**

a) [SAR/SUSAR report form](http://www.cric.nu/aid-icu-sarsusar-report-form/)

b) Documentation for reporting of SAR/SUSAR *(site specific)*

**15) GCP unit**

a) Contacts (monitors/GCP units) *(site specific)*(in Danish click [here](http://www.cric.nu/aid-icu-kontaktoplysninger-gcp/))

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

c) Monitoring reports *(site specific)*

d) [Monitoring plan](http://www.cric.nu/aid-icu-monitoring-plan-english/) and [Plan for data-verification](http://www.cric.nu/aid-icu-plan-for-data-verification-english/) (in Danish click[here](http://www.cric.nu/aid-icu-monitoreringsplan-dansk/))

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

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

**16) Trial completion**