**AID-ICU LOG for new documents and/or new versions updated**

[Print version](http://www.cric.nu/aid-icu-log-for-site-master-file-print-version/) - please notice the "download" feature is situated *underneath* the pdf.

## Date: 2019.08.16 at 13.00 pm

## Uploaded [Newsletter 4 and Newsletter 5](http://www.cric.nu/aid-icu-newsletters/) #13e

## Date: 2019.07.17 at 07.40 am

## Updated Protocol version 4.2 dated 7 June 2019 and #1a, [Approval from Danish Medicines Agency](http://www.cric.nu/aid-icu-the-danish-medicine-agency/) #4d

## Date: 2019.05.10 at 14.40 pm

## Receipt of received safety report from [Danish Medicines Agency and Health Research Ethics](http://www.cric.nu/aid-icu-annual-safety-report/) #4d, Approval of 1. amendment Danish Dataprotection Agency (danish) #4c (print document(s) and place in your Site Master File)

## Date: 2019.04.12 at 13.18 pm

## Updated versions of [Pocket cards Læger ver. 5](http://www.cric.nu/aid-icu-lommekort-laeger/), P[ocket Cards Sygeplejersker ver. 4](http://www.cric.nu/aid-icu-lommekort-sygeplejersker/) (danish) #9bv and updated [Folder Læger ver. 2.0 (danish)](http://www.cric.nu/aid-icu-folder-laeger/), [Folder sygeplejerske ver. 2.0 (danish)](http://www.cric.nu/aid-icu-folder-sygeplejerske/) #9bv

## Updated version of educational material on [Trial medication dispensation](http://www.cric.nu/aid-icu-forsogsmedicin-dispensering/) #9ciii

## (print document and place in your Site Master File)

## Date: 2019.03.19 at 1.08 pm

## 1-year follow-up protocol cognitive function #1b and Newsletter\_2 #13e and Newsletter\_3 #13e

## (print document and place in your Site Master File)

## Date: 2019.03.19 at 1.08 pm

## [1-year follow-up protocol cognitive function](http://www.cric.nu/aid-icu-protocol-amendment-english/) #1b and [Newsletter\_2](http://www.cric.nu/aid-icu-newsletters/)  #13e and [Newsletter\_3](http://www.cric.nu/aid-icu-newsletters/) #13e

## (print document and place in your Site Master File)

## Date: 2019.03.05 at 3.12 pm

## Revised #13a [AID-ICU Steering Committee](http://cric.nu/aid-icu-steering-committee) (print document and place in your Site Master File)

## Date: 2019.03.05 at 1.47 pm

## Edit #13b [contact details of national investigators](http://cric.nu/aid-icu-contact-details-national-investigators) (print document and place in your Site Master File)

## Date: 2019.03.05 at 1.47 pm

## Edit #13b [contact details of national investigators](http://cric.nu/aid-icu-contact-details-national-investigators) (print document(s) and place in your Site Master File)

## Date: 2019.01.24 at 12.54 am

## [AID-ICU Case Money (DKK](http://cric.nu/aid-icu-case-money-denmark/)) #6a

**Date: 2019.01.08 at 14.05 pm**

[**Annual Safety Report 2018 #4f**](http://www.cric.nu/aid-icu-annual-safety-report/)**(print document(s) and place in your Site Master File)**

## Date: 2018.12.12 at 10.31 am

## [Revideret Godkendelse fra Datatilsynet](http://www.cric.nu/aid-icu-datatilsynet-godkendelse-instruks-og-databehandleraftale/)#4c and [Lommekort\_Læger\_v4](http://www.cric.nu/aid-icu-lommekort-laeger/) #9b (print document(s) and place in your Site Master File)

## Date: 2018.12.11 at 12.55 pm

## [AID-ICU Protocol 4.1](http://www.cric.nu/aid-icu-protocol/) #1b and Approval of Protocol 4.1 from [Danish Medicine Agency](http://www.cric.nu/aid-icu-the-danish-medicine-agency/) #4a and [Danish Committee on Health Research Ethics](http://www.cric.nu/aid-icu-the-committees-on-health-research-ethics/) #4b (print document(s) and place in your Site Master File)

## Date: 2018.11.30 at 14.20 pm

## [AID-ICU Trial Medication](http://www.cric.nu/aid-icu-sop-trial-medication/) #9a and [1\_Newsletter](http://www.cric.nu/aid-icu-newsletters/)#13e (print document(s) and place in your Site Master File)

## Date: 2018.11.27 at 16.10 pm

## [Delegation- and signature-log\_v.1.2](http://www.cric.nu/aid-icu-delegation-and-signature-log/) #3a and [Opgavefordelingsliste v.1.2](http://www.cric.nu/aid-icu-opgavefordelingsliste/) #3a and [Forsøgspersoners\_Rettigheder 2018](http://www.cric.nu/aid-icu-forsogspersoners-rettigheder/) #7a

## (print document(s) and place in your Site Master File)

## Date: 2018.11.30 at 14.20 pm

## [AID-ICU Trial Medication](http://www.cric.nu/aid-icu-sop-trial-medication/) #9a and [1\_Newsletter](http://www.cric.nu/aid-icu-newsletters/)#13e (print document(s) and place in your Site Master File)

## Date: 2018.11.27 at 16.10 pm

## [Delegation- and signature-log\_v.1.2](http://www.cric.nu/aid-icu-delegation-and-signature-log/) #3a and [Opgavefordelingsliste v.1.2](http://www.cric.nu/aid-icu-opgavefordelingsliste/) #3a and [Forsøgspersoners\_Rettigheder 2018](http://www.cric.nu/aid-icu-forsogspersoners-rettigheder/) #7a

## (print document(s) and place in your Site Master File)

## Date: 2018.11.15 at 12.45 pm

## Patient information template (english)\_v2 #7a and Table of Content updated (print document(s) and place in your Site Master File)

## Date: 2018.11.09 at 13.45 pm

## [Samtykke-log\_template\_v2.0\_09Nov2018.xlsx](http://www.cric.nu/aid-icu-samtykke-log/) #7b (print document(s) and place in your Site Master File)

**Date: 2018.11.09 at 11.34 pm**

[**Approved amendment 'Protocol follow-up EQ-5D-5L**](http://www.cric.nu/aid-icu-protocol-amendment/) **#1.b (print document(s) and place in your Site Master File)**

**Date: 2018.10.31 at 4.00 pm**

[**Protocol version 4.0**](http://www.cric.nu/aid-icu-protocol/) **#1.a,** [**SOPs**](http://www.cric.nu/aid-icu-sops/) **#9.vi and** [**Table of Content**](http://www.cric.nu/aid-icu-table-of-content-site-master-file/) **(print document(s) and place in your Site Master File)**

**Date: 2018.09.28 at 1.30 pm**

[**Drug disposal form**](http://www.cric.nu/aid-icu-drug-disposal-form/) **#10.c (print document(s) and place in your Site Master File)**

## ****Date: 2018.09.26 at 5.00 pm****

## Deltager information [patienten](http://www.cric.nu/aid-icu-deltager-information-patienten/), [pårørende](http://www.cric.nu/aid-icu-deltager-information-parorende/), [forsøgsværge](http://www.cric.nu/aid-icu-deltager-information-forsogsvaergen/) #7.a, [Co-enrolment list](http://www.cric.nu/aid-icu-co-enrolment-list/) #8.a, Lommekort for [læger](http://www.cric.nu/aid-icu-lommekort-laeger/) og [sygeplejersker](http://www.cric.nu/aid-icu-lommekort-sygeplejersker/) (for Danes only) #9.b.iv, and [Sign for bed](http://www.cric.nu/aid-icu-sign-bed/) #9.b.vi (print document(s) and place in your Site Master File)

## ****Date: 2018.09.20 at 8.45 am****

## [eCRF Baseline](http://www.cric.nu/aid-icu-baseline-form/) #2 (print document(s) and place in your Site Master File)

## ****Date: 2018.09.14 at 5.20 pm****

## [eCRF Discharge form](http://www.cric.nu/aid-icu-discharge-form-crf/) #2, [SAR/SUSAR](http://www.cric.nu/aid-icu-sarsusar/) #9.a.v, and [SAR/SUSAR report form](http://www.cric.nu/aid-icu-sarsusar-report-form/) #14 (print document(s) and place in your Site Master File)

## ****Date: 2018.09.12 at 5.15 pm****

## [Guideline to notes and discrepancies in OpenClinica](http://www.cric.nu/aid-icu-guideline-to-notes-and-discrepancies-in-openclinica/) (in Danish click [here](http://www.cric.nu/aid-icu-guideline-til-notes-and-discrepancies-i-openclinica/)) #2, [CV template](http://www.cric.nu/aid-icu-cv-for-sundhedspersonale-dansk/) (Danish only), #3.c (print document(s) and place in your Site Master File)

## ****Date: 2018.09.11 at 1.45 pm****

## [Protocol amendment](http://www.cric.nu/aid-icu-protocol-amendment-danish/) (for Danes only) #1.b., [Collaboration agreement between Sponsor and site](http://www.cric.nu/aid-icu-collaboration-agreement-between-sponsor-and-site-template/) #5.a, Lommekort for [læger](http://www.cric.nu/aid-icu-lommekort-laeger/) og [sygeplejersker](http://www.cric.nu/aid-icu-lommekort-sygeplejersker/) (for Danes only) #9.b.iv, [Contact information for GCP](http://www.cric.nu/aid-icu-kontaktoplysninger-gcp/) (for Danes only) #15.d, [Table of content](http://www.cric.nu/aid-icu-table-of-content-site-master-file/)  (print document(s) and place in your Site Master File)

## ****Date: 2018.09.06 at 11.15 am****

## [The Danish Medicine Agency](http://www.cric.nu/aid-icu-the-danish-medicine-agency/) (in Danish, the top three documents are new) #4.a, [Videnskabsetisk komité](http://www.cric.nu/aic-icu-den-videnskabsetiske-komite-region-sjaelland/) (in Danish, the top two documents are new) #4.c. (print document(s) and place in your Site Master File)

## ****Date: 2018.08.30 at 12.00 am****

## Approval of amendments from ethic committee has mistakenly been misplaced as amendments for the protocol - There are no amendments for the protocol #1.b., and the amendments - [The committees on health research ethics](http://www.cric.nu/aid-icu-the-committees-on-health-research-ethics/) and [Den videnskabsetiske komité](http://www.cric.nu/aic-icu-den-videnskabsetiske-komite-region-sjaelland/) (in Danish) are moved to their right environment # 4.c. - apologize for the inconvenience.

## Deltagerinformation [forsøgsværge](http://www.cric.nu/aid-icu-deltager-information-forsogsvaergen/), [pårørende](http://www.cric.nu/aid-icu-deltager-information-parorende/) og [patienten](http://www.cric.nu/aid-icu-deltager-information-patienten/) (in Danish) #7.a., [Samtykke drejebog](http://www.cric.nu/aid-icu-samtykke-drejebog/) (in Danish) #7.b. (print document(s) and place in your Site Master File)

## ****Date: 2018.07.26 at 2.45 pm****

## [Samtykke patienten](http://www.cric.nu/aid-icu-samtykke-patienten/), [Samtykke 1. forsøgsværge](http://www.cric.nu/aid-icu-samtykke-stedfortraedende-1/), [Samtykke 2. forsøgsværge](http://www.cric.nu/aid-icu-stedfortraedende-2/), og [Samtykke pårørende](http://www.cric.nu/aid-icu-samtykke-erklaering-parorende/) (all in Danish) #7.b and for national investigators only the .xml file for EudraCT is now available in "National Investigator Documents"  (print document(s) and place in your Site Master File)

## ****Date: 2018.07.02 at 9.15 am****

## [Lommekort](http://www.cric.nu/aid-icu-lommekort/) (in Danish) #9.b.iv (print document(s) and place in your Site Master File)

## ****Date: 2018.06.20 at 1.00 pm****

## [Table of content,](http://www.cric.nu/aid-icu-table-of-content-site-master-file/) [Monitoring plan](http://www.cric.nu/aid-icu-monitoring-plan-english/) (in English) and [Plan for data-verification](http://www.cric.nu/aid-icu-plan-for-data-verification-english/) (in English) #15.d (print document(s) and place in your Site Master File)

## ****Date: 2018.05.04 at 4.00 pm****

## [Table of content](http://www.cric.nu/aid-icu-table-of-content-site-master-file/), CRF ([Screening](http://www.cric.nu/aid-icu-screening-form-crf/), [Baseline](http://www.cric.nu/aid-icu-baseline-form/), [Day form](http://www.cric.nu/aid-icu-day-form-crf/), [90 days follow-up](http://www.cric.nu/aid-icu-90-days-follow-up-crf/), [1 year follow-up](http://www.cric.nu/1_year_follow_up_crf/), [Discharge and readmission](http://www.cric.nu/aid-icu-discharge-form-crf/), [Withdrawal](http://www.cric.nu/aid-icu-withdrawal-form-crf-2/)) #2, [EudraCT](http://www.cric.nu/aid-icu-eudract/) #4b, [Etisk komite](http://www.cric.nu/aic-icu-den-videnskabsetiske-komite-region-sjaelland/) (Danish), #4.c, [Approval head of department](http://www.cric.nu/aid-icu-approval-from-head-of-department/) (in Danish [Tilladelse afdelinsledelsen](http://www.cric.nu/aid-icu-tilladelse-afdelingsledelsen/)) #5.b, [Primay data source](http://www.cric.nu/aid-icu-primay-data-source/) (in Danish [Kildedata](http://www.cric.nu/aid-icu-kildedataliste/)) #12, [Contact details](http://www.cric.nu/aid-icu-contact-details-national-investigators/) #13.b, [Monitoreringsplan](http://www.cric.nu/aid-icu-monitoreringsplan-dansk/) (Danish) #15.d (print document(s) and place in your Site Master File)

## ****Date: 2018.04.24 at 3.40 pm****

## [Godkendelse af tillægsprotokol VEK](http://www.cric.nu/aic-icu-den-videnskabsetiske-komite-region-sjaelland/), #4.c (in Danish) (print document(s) and place in your Site Master File)

## ****Date: 2018.04.23 at 12.30 pm****

## AID-ICU trial documents are now accessible at the [homepage](http://www.cric.nu/aid-icu/). Access to "Documents for National investigator" will still require a password to get access (you may e-mail to contact@cric.nu to get password)  (print document(s) and place in your Site Master File)