

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

[Print version](#) - please notice the "download" feature is situated *underneath* the pdf.

**Date: 2019.05.10 at 14.40 pm**

Receipt of received safety report from [Danish Medicines Agency and Health Research Ethics](#) #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](#), [Pocket Cards Sygeplejersker ver. 4](#) (danish) #9bv and updated [Folder Læger ver. 2.0](#) (danish), [Folder sygeplejerske ver. 2.0](#) (danish) #9bv

Updated version of educational material on [Trial medication dispensation](#) #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](#) #1b and [Newsletter 2](#) #13e and [Newsletter 3](#) #13e

(print document and place in your Site Master File)

**Date: 2019.03.05 at 3.12 pm**

Revised #13a [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](#) (print document and place in your Site Master File)

**Date: 2019.03.05 at 1.47 pm**

Edit #13b [contact details of national investigators](#) (print document(s) and place in your Site Master File)

Date: 2019.01.24 at 12.54 am

[AID-ICU Case Money \(DKK\)](#) #6a

Date: 2019.01.08 at 14.05 pm

[Annual Safety Report 2018 #4f](#) (print document(s) and place in your Site Master File)

Date: 2018.12.12 at 10.31 am

[Revideret Godkendelse fra Datatilsynet #4c](#) and [Lommekort Læger v4 #9b](#) (print document(s) and place in your Site Master File)

Date: 2018.12.11 at 12.55 pm

[AID-ICU Protocol 4.1 #1b](#) and Approval of Protocol 4.1 from [Danish Medicine Agency #4a](#) and [Danish Committee 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 #9a](#) and [1 Newsletter #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 #3a](#) and [Opgavefordelingsliste v.1.2 #3a](#) and [Forsøgspersoners Rettigheder 2018 #7a](#)

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

Date: 2018.11.30 at 14.20 pm

[AID-ICU Trial Medication #9a](#) and [1 Newsletter #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 #3a](#) and [Opgavefordelingsliste v.1.2 #3a](#) and [Forsøgspersoners Rettigheder 2018 #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](#) #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](#) #1.b (print document(s) and place in your Site Master File)**

**Date: 2018.10.31 at 4.00 pm**

**[Protocol version 4.0](#) #1.a, [SOPs](#) #9.vi and [Table of Content](#) (print document(s) and place in your Site Master File)**

**Date: 2018.09.28 at 1.30 pm**

**[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](#), [pårørende](#), [forsøgsværge](#) #7.a, [Co-enrolment list](#) #8.a, Lommekort for [læger](#) og [sygeplejersker](#) (for Danes only) #9.b.iv, and [Sign for bed](#) #9.b.vi (print document(s) and place in your Site Master File)**

**Date: 2018.09.20 at 8.45 am**

**[eCRF Baseline](#) #2 (print document(s) and place in your Site Master File)**

**Date: 2018.09.14 at 5.20 pm**

**[eCRF Discharge form](#) #2, [SAR/SUSAR](#) #9.a.v, and [SAR/SUSAR 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](#) (in Danish click [here](#)) #2, [CV template](#) (Danish only), #3.c (print document(s) and place in your Site Master File)**

**Date: 2018.09.11 at 1.45 pm**

**[Protocol amendment](#) (for Danes only) #1.b., [Collaboration agreement between Sponsor and site](#) #5.a, Lommekort for [læger](#) og [sygeplejersker](#) (for**

Danes only) #9.b.iv, [Contact information for GCP](#) (for Danes only) #15.d, [Table of content](#) (print document(s) and place in your Site Master File)

Date: 2018.09.06 at 11.15 am

[The Danish Medicine Agency](#) (in Danish, the top three documents are new) #4.a, [Videnskabsetisk komité](#) (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](#) and [Den videnskabsetiske komité](#) (in Danish) are moved to their right environment # 4.c. - apologize for the inconvenience.

Deltagerinformation [forsøgsværge](#), [pårørende](#) og [patienten](#) (in Danish) #7.a., [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](#), [Samtykke 1. forsøgsværge](#), [Samtykke 2. forsøgsværge](#), og [Samtykke pårørende](#) (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](#) (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](#), [Monitoring plan](#) (in English) and [Plan for data-verification](#) (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](#), CRF ([Screening](#), [Baseline](#), [Day form](#), [90 days follow-up](#), [1 year follow-up](#), [Discharge and readmission](#), [Withdrawal](#)) #2, [EudraCT](#) #4b, [Etisk komite](#) (Danish), #4.c, [Approval head of department](#) (in Danish [Tilladelse afdelinsledelsen](#)) #5.b, [Primay data source](#) (in Danish [Kildedata](#)) #12, [Contact details](#) #13.b, [Monitoreringsplan](#) (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, #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](#). Access to "Documents for National investigator" will still require a password to get access (you may e-mail to [contact@cric.nu](mailto:contact@cric.nu) to get password) (print document(s) and place in your Site Master File)**