

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

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

**Date: 2019.11.04 at 14:06 pm**

**Uploaded newsletter no. 7 #13f (print document(s) and place in your Site Master File)**

**Date: 2019.09.03 at 14.00 pm**

**Uploaded [Approval from Danish Ethics Committee #4b](#), [SOP Acute Hepatic Failure #9avi](#), [Newsletter no. 6 #13f](#) (print document(s) and place in your Site Master File)**

**Date: 2019.08.16 at 13.00 pm**

**Uploaded [Newsletter 4 and Newsletter 5 #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 #4d](#)**

**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 afdelingsledelsen) #5.b, Primary 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)**