

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

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

**Date: 2019.03.05 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, **[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)