

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

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

**Date: 2019.06.07 at 12.50 pm**

Updated #6a [Case money](#)

**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: 2019.03.26 at 11.56 am**

Updated version of [Forsøgspersoners rettigheder \(danish\)](#) #7a

(print document and place in your Site Master File)

**Date: 2019.03.22 at 9.56 am**

**Revised #9 a (i) [Eligibility](#)**

**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: 2019.01.24 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: 2018.11.15 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 am**

**[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, **Videnskabetisk 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 videnskabetiske 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@cruc.nu](mailto:contact@cruc.nu) to get password) (print document(s) and place in your Site Master File)**