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

<u>Print version</u> - please notice the "download" feature is situated *underneath* the pdf.

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 <u>AID-ICU Steering Committee</u> (print document and place in your Site Master File)

Date: 2019.03.05 at 1.47 pm

Edit #13b <u>contact details of national investigators</u> (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

<u>Annual Safety Report 2018 #4f</u> (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

<u>AID-ICU Trial Medication</u> #9a and <u>1_Newsletter</u> #13e (print document(s) and place in your Site Master File)

Date: 2018.11.27 at 16.10 pm

<u>Delegation- and signature-log_v.1.2 #3a and Opgavefordelingsliste</u> 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

<u>Protocol version 4.0</u> #1.a, <u>SOPs</u> #9.vi and <u>Table of Content</u> (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 <u>patienten</u>, <u>pårørende</u>, <u>forsøgsværge</u> #7.a, <u>Coenrolment list</u> #8.a, Lommekort for <u>læger</u> og <u>sygeplejersker</u> (for Danes only) #9.b.iv, and <u>Sign for bed</u> #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

<u>Guideline to notes and discrepancies in OpenClinica</u> (in Danish click <u>here</u>) #2, <u>CV template</u> (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 <u>forsøgsværge</u>, <u>pårørende</u> og <u>patienten</u> (in Danish) #7.a., <u>Samtykke drejebog</u> (in Danish) #7.b. (print document(s) and place in your Site Master File)

Date: 2018.07.26 at 2.45 pm

<u>Samtykke patienten, Samtykke 1. forsøgsværge, Samtykke 2.</u> <u>forsøgsværge, og Samtykke pårørende</u> (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

<u>Table of content, Monitoring plan</u> (in English) and <u>Plan for data-verification</u> (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 to get password) (print document(s) and place in your Site Master File)