

## **Log for new documents and/or new versions updated:**

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

**Date: 2017.04.11 at 11.50 am**

[News letter](#) , #Fane 13.f, 14'th News letter (print and place in your Site Master File)

**Date: 2017.03.20 at 3.40 pm**

[SUP-ICU Samtykkelog \(skabelon\)](#) , #Fane 7.b (print and place in your Site Master File)

**Date: 2017.03.10 at 4.00 pm**

**REMINDER:** [Annual Safety report](#) , #Fane 4 (print and place in your Site Master File)

**Date: 2017.03.10 at 3.00 pm**

[News letter](#) , #Fane 13.f, 13'th News letter (print and place in your Site Master File)

**Date: 2017.02.10 at 11.00 am**

**News letter** , #Fane 13.f, 12'th News letter (print and place in your Site Master File)

**Date: 2017.01.10 at 10.30 am**

**News letter** , #Fane 13.f, 11'th News letter (print and place in your Site Master File)

**Date: 2017.01.05 at 8.30 am**

*For Danish sites only:*

**Table of content** for Site Master File

Nyt **Appendix 7** (7.2), #Fane 1.b

**Korrigeret godkendelse VEK**, #Fane 4.c

Deltager information **forsøgsværgen**, **pårørende**, **patienten**,  
**Procedure for videregivelse af mundtlig deltagerinformation**,  
#Fane 7.a,

**Samtykke patienten**, **Samtykke pårørende**, **Samtykke forsøgsværge**, **Samtykke drejebog** #Fane 7.b

(print and place in your Site Master File)

**Date: 2016.12.06 at 11.10 am**

**[News letter](#)** , #Fane 13.f, tenth News letter (print and place in your Site Master File)

**Date: 2016.11.09 at 3.15 pm**

**[News letter](#)** , #Fane 13.f, ninth News letter (print and place in your Site Master File)

**Date: 2016.10.10 at 11.15 am**

**[News letter](#)** , #Fane 13.f, eight News letter (print and place in your Site Master File)

**Date: 2016.09.29 at 3.15 pm**

**[Background](#), [Screening and randomisation](#), [Trial medication](#), [Data entry](#), [Withdrawal](#), [SAR/SUSAR and unblinding](#), [Information for nurses](#) (in [Danish](#)), [Discharge/transfer/death](#) (*new paragraph*), #Fane 9.c.i-viii, and [Table of contents](#), (print and place in site master file).**

**Date: 2016.09.23 at 12.45 am**

**[Lommekort](#), #Fane 9.b.iv, and Folder for [Læger](#), [Plejepersonale](#), #Fane 9.b.v (Danish sites only), Leaflet for [Clinicians](#), [Nurses](#) #Fane 9.b.v (print and place in Site Master File)**

**Date: 2016.09.14 at 1.15 pm**

**[Appendix 7](#), #Fane 1.b (amendment)**

**[Procedure for videregivelse....](#), [Deltager-information forsøgsværgen](#), [Deltager-information pårørende](#), [Deltager-information patienten](#), #Fane 7.a, (Danish sites only, print and place in Site Master File)**

**[Samtykke patienten](#), [Samtykke pårørende](#), [Samtykke forsøgsværge](#), [Samtykkelog \(new document\)](#), [Samtykke drejebog \(new document\)](#), #Fane 7.b, (Danish sites only, print and place in Site Master File)**

**[Approval from SST](#), [Approval from VEK](#), [Minutes from meeting with SST and VEK](#), #Fane 4.a and 4.c, (Danish sites only, print and place in Site Master File)**

**Date: 2016.09.12 at 12.30 am**

**[News letter](#) , #Fane 13.f, eight News letter (print and place in your Site Master File)**

**Date: 2016.08.30 at 2.30 pm**

**[Contact list](#), #Fane 15.a, Contact list for GCP-units in DK (Danish sites only, print and place in Site Master File)**

**Date: 2016.08.17 at 12.00 am**

**[News letter](#)** , #Fane 13.f, seventh News letter (print and place in your Site Master File)

**Date: 2016.08.09 at 10.40 am**

**[Annual Safety Report](#)**, #Fane 4.f (new), **[Table of Content](#)** updated, # at top of Site Master File (print and place in your Site Master File)

**Date: 2016.07.11 at 11.15 am**

**[News letter](#)** , #Fane 13.f, sixth News letter (print and place in your Site Master File)

**Date: 2016.06.20 at 3.10 pm**

**[News letter](#)** , #Fane 13.f, fifth News letter (print and place in your Site Master File)

**Date: 2016.05.10 at 2.40 pm**

**[News letter](#)** , #Fane 13.f, fourth News letter (print and place in your Site Master File)

**Date: 2016.04.15 at 1.40 pm**

**[News letter](#) , #Fane 13.f, third News letter (print and place in your Site Master File)**

**Date: 2016.03.08 at 10.45 am**

**Trial medication to notice board (English), website address corrected, #Fane 9.b (print and place in your Site Master File) [New version](#)**

**Date: 2016.03.07 at 1.45 pm**

**Danish Data Protection Agency , update, #Fane 4.d (in Danish only, print and place in your Site Master File) [New version](#)**

**Date: 2016.03.03 at 3.40 pm**

**[News letter](#) , #Fane 13.f, second News letter (print and place in your Site Master File)**

**Date: 2016.02.09 at 8.40**

**[News letter](#) , #Fane 13.f, first News letter (print and place in your Site Master File)**

**Date: 2016.01.19 at 11.30 am to 12.30 pm**

**Please notice, in the files below you need to replace the contact information at the end of the document with the contact information at your location (local site).**

**1. Information for Participant (#Fane 7.a. in Danish) has been changed from pdf- to word-format.**

**1. Deltager-information forsøgsværgen [New version](#)**

**2. Deltager-information pårørende [New version](#)**

**3. Deltager-information patienten [New version](#)**

**Date: 2016.01.07**

**1. CRF (#Fane 2) [New version](#)**

**2. SUP-ICU medication dispensing system in Danish (#Fane 9.b.i) [New version](#)**

**3. Educational materials (#Fane 9.c.iii) [New version](#)**

**4. Educational materials (#Fane 9.c.vii) in English [New](#)**

**5. Educational materials (#Fane 9.c.vii) in Danish [New version](#)**