

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

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

**Date: 2018.10.22 at 1.30 pm**

[Letter of acknowledgement of notification](#) (in Danish) #4, (print and place in your Site Master File)

**Date: 2018.10.05 at 1.50 pm**

[Patient information](#) (template) (English version) #7.a, Samtykke [patienten, pårørende og anden forsøgsværge, første forsøgsværge](#) #7.b (in Danish), and [News letters](#) #13.f, (print and place in your Site Master File)

**Date: 2018.09.26 at 12.15 am**

[Annual Safety Report](#) #4, (print and place in your Site Master File)

**Date: 2018.09.12 at 1.15 pm**

[Protocol](#) #1.a, [Approval Ethic committee](#) (in Danish) #4.c, Patient information til [patient, pårørende](#) og [forsøgsværge](#) #7.a (in Danish), (print and place in your Site Master File)

**Date: 2018.09.04 at 9.15 am**

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

**Date: 2018.08.29 at 3.15 pm**

**[HOT-ICU Monitoring and data verification plan](#) #15.d, (print and place in your Site Master File)**

**Date: 2018.08.21 at 10.45 am**

**[HOT-ICU Monitorerings og dataverifikationsplan](#) (Danish only) #15.d, (print and place in your Site Master File)**

**Date: 2018.07.03 at 8.45 am**

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

**Date: 2018.06.13 at 4.10 pm**

**[Co-enrolment list](#) #8.a (go to 8.a Co-enrolment Form and find a link to the list in the text), [News letters](#) #13.f (print and place in your Site Master File)**

**Date: 2018.04.17 at 12.15 pm**

**[News letters #13.f](#), [Standard operating procedure \(SOP\) for EuroQol follow-up \( in Danish\) #17.a](#), [Table of content](#) (print and place in your Site Master File)**

**Date: 2018.02.09 at 6.45 pm**

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

**Date: 2018.02.02 at 2.00 pm**

**[Monitoring plan](#) in English #15.d., [Daily form](#) and [Baseline](#), and for Swiss only [Screening form #2](#), (print and replace in your Site Master File)**

**IF you want to print at whole new set of all CRF documents then your find them here:**

- 1. For all but Swiss: [CRF - all in one document](#)**
- 2. For Swiss: [Swiss CRF - all in one document](#)**

**Date: 2018.01.05 at 5.15 pm**

**[Tillæg til Monitoreringsplan](#) (in Danish) #15.d., [News letters #13.f](#), (print and place in your Site Master File)**

**Date: 2017.12.06 at 4.40 pm**

**[Table of content](#) (print and place in your Site Master File)**

**Date: 2017.11.17 at 4.15 pm**

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

**Date: 2017.11.16 at 12.00 am**

**The [Co-enrolment list](#) is no longer part of the Site Master File - to get access to the list a link is to be found in the [Co-enrolment Form](#) document #8.a (remove Co-enrolment list from the Site Master File), [Table of content](#) (print and place in your Site Master File)**

**Date: 2017.11.08 at 3.30 pm**

**[The Danish Medicine Agency](#) #4.a, [EudraCT](#) #4.b, [Table of content](#) (print and place in your Site Master File)**

**Date: 2017.11.08 at 8.30 am**

**[Protocol](#) #1.a, [EudraCT](#) #4.b, [Videnskabetisk komité](#) #4.c (in Danish), [Datatilsynet](#) #4.d (in Danish), [Table of content](#) (print and place in your Site Master File)**

**Date: 2017.11.02 at 11.30 am**

**[Co-enrolment list](#) #8a, [Information to patient](#) (in Danish) #7a, (print and place in your Site Master File)**

**Date: 2017.10.24 at 1.00 pm**

**Co-enrolment list #8a (print and place in your Site Master File)**

**Date: 2017.10.17 at 8.00 pm**

**Case money #6 (print and place in your Site Master File)**

**Date: 2017.10.03 at 3.45 pm**

**Implemented in eCRF September 18, 2017: CRF - all in one document #2(1), Screening form #2 (2), Baseline form #2(2), Daily form #2(2), Withdrawal #2(2), Discharge and readmission #2(2), 90 days follow-up #2(2), 1 year follow-up #2(2), and News letter #13.f, (print and place in your Site Master File)**

**Date: 2017.09.20 at 0.15 am**

**News letters #13.f, (print and place in your Site Master File)**

**Date: 2017.09.08 at 3.45 pm**

**Co-enrolment Form #8.a, Co-enrolment list #8.a, Table of content (print and place in your Site Master File)**

**Date: 2017.08.31 at 12.30**

**[Trial initiation](#) #9.a.i, [Præsentation plejepersonale](#) #9.c.ii, [Contact details](#) #13.a, [Monitoring visits](#) #15.b, [Table of content](#) (print and place in your Site Master File)**

**Date: 2017.08.28 at 3.00 pm**

**[Samtykke patienten](#) (dansk)#13.f, [Videnskabsetisk komité](#) (dansk) #4.c, [Monitoring plan](#) (English) #15.d, [Table of content](#) (print and place in your Site Master File)**

**Date: 2017.08.21 at 4.15 pm**

**Patient information ([template](#)), #7.a, [Table of content](#) (print and place in your Site Master File)**

**Date: 2017.08.16 at 11.15 am**

**[Samtykke patienten](#), [Samtykke pårørende](#), [Samtykke forsøgsværgeren](#) #7.b, [News letters](#) #13.f, [Table of content](#) (print and place in your Site Master File)**

**Date: 2017.08.14 at 2.00 pm**

**CRF** - all in one document (**Swiss** version) #2(1), Screening form (**Swiss** Screening form) #2 (2), **Baseline form** #2(2), **Daily form** #2(2), **Table of content** (print and place in your Site Master File)

**Date: 2017.08.11 at 12.00 am**

**Remove: Collaboration agreement between Sponsor and site,#5.a (remove from Site Master File)**

**Date: 2017.07.18 at 9.00 pm**

**Receipt of notification** #4.a (print and place in your Site Master File)

**Date: 2017.07.03 at 18.00 pm**

**Primary data source** and **Kildedataliste** #12 (print and place in your Site Master File)

**Date: 2017.06.19 at 8.00 am**

**HOT-ICU Site Master File released** (print and place in your Site Master File)