**Checklist before initiating the HOT-ICU trial**

**All documents to be used in the HOT-ICU trial can be found in this Site Master File (SMF), but are also available**

**at** [www.cric.nu/hot-icu/](http://www.cric.nu/hot-icu/) **(trial documents) for download and - when relevant – prepared to be filled in electronically.**

|  |  |
| --- | --- |
| **National Approvals:** Place in SMF #4.e |  |
| **Patient information:** Place in SMF #7.a |  |
| **Consent forms:** Place in SMF #7.b |  |
| **Delegation log:** To be filled in and placed in SMF #3 |  |
| **Training log:** Documentation for training of personnel at the delegation log. Place in SMF #3. |  |
| **CV:** Short CV for all involved personnel (not req. for nurses handling trial medication only). Place in SMF #3. |  |
| **Approval from department:** Sign the document ‘Approval from head of department’. Place in SMF #5. |  |
| **Data source verification:** Place in SMF #12. |  |
| **Laboratory tests document:** Return copy of document to coordinating centre and Place in SMF #11. |  |
| **First registration day:** Inform the coordinating centre of when the ’registration day’ starts in your department. The electronic case report form will be adjusted according to this to make you registration easier. |  |
| **Access to eCRF:** Return to coordinating centre the provided excel file (a template to be completed) with name and email of all who needs access to the eCRF (personnel randomising patients and entering data). Access to the medication dispensing system will be a common password for the whole department. |  |
| **Trial medicine:** IMP sheet to confirm medicine has arrived, accountability between IMP sheet, IMP storage and SUP-ICU Medicine Dispensing System. |  |
| **Medicine handling:** Procedure for handling and dispensing SUP-ICU medicine available at IMP location |  |
| **Medicine facilities:** Appropriate medicine storage facilities, temperature within allowed range,….. |  |
| **Approval of trial initiation:** Place in SMF #15.e |  |

Coordinating investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (print) Date Signature

SIV (monitor): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (print) Date Signature

***If you need login for the demo version of the eCRF please let us know!***