Place in Site Master File #7d,iii

Procedure for obtaining consent in Denmark

All patients with COVID-19 and severe hypoxia will be temporarily incompetent. The patient is legally included in COVID STEROID 2 trial if surrogate consent is obtained before inclusion according to Komitéloven §4.

Obtain surrogate consent from:

- **the first trial guardian** (doctor) before randomisation
- **next of kin** after randomisation by telephone. Next of kin is defined as relatives, friends, or other acquaintances in regular contact with the trial participant. We accept a search for the next of kin for **one week**. If **NO** next of kin is identified, the participant will be withdrawn from the trial intervention – data registration continues based on the trial guardian consent. If a next of kin is identified, consent will be attempted until the participant either dies or has regained competence.
- **the second trial guardian** (doctor) as soon as possible after randomisation

Consent from participant:

- As soon as possible after the participant have regained competence (preferably during the index admission)
- Attempt to obtain consent from the participant until **28 days after randomisation** or discharge from hospital. If consent has not been obtained, try again **before follow-up at day 90** and again **before follow-up at day 180**.
- We will inform the participant **before inclusion** in the trial if the treating clinician assesses that the clinical condition of the participant allows so. In these cases, we will not include the patient, if he/she does not wish to participate. If the patient agrees to enter the trial, we will not consider this a legally binding consent due to the clinical condition (critical illness and hypoxia). Once the participant has regained competence, we will inform him/her both verbally and in writing. Hereafter, we will obtain the formal written consent.

If consent is withdrawn by participant or next of kin:

- Remember to ask if the participant or next of kin accept further data registration and 180-day follow-up by telephone.

More information is provided in 'Appendix 6: Informed Consent' in the protocol