HOT-ICU
Handling Oxygenation Targets in the Intensive Care Unit

Research Unit for
Anaestesia og Intensive
Care Medicin
Mølleparkvej 8A
9000 Aalborg
Direkte 97 66 17 15
Mail: forsk.anaestesien@rn.dk

Protokol title:	HOT-ICU Handling Oxygenation Targets in the Intensive Care Unit EudraCT number 2017-000632-34, ClinicalTrials.gov Identifier: NC03174002
SOP name:	Procedure for obtaining EuroQol EQ-5D-5L at one-year follow-up
Version:	1.0
Replaces version	NA
Applies from:	1 June 2018

Target population: Site Investigators and research staff

Responsible party: Sponsor, Professor Bodil Steen Rasmussen

Created by: Coordinating Investigator Olav Lilleholt Schjørring

Objectives

- To describe the procedure for obtaining EQ-5D-5L health-related quality of life data from one-year survivors in the HOT-ICU trial
- To ensure the highest possible EQ-5D-5L response rate within 30 days from date of one-year follow-up
- To ensure that interviews are conducted as according to the EQ-5D-5L User Guide and that documents are stored as according to GCP requirements and HOT-ICU protocol version 1.2, 24 October 2017 (EudraCT number: 2017:000632-34)
- To ensure that the EQ-5D-5L interviewer is blinded to the allocated oxygenation target

Description:

- From the date of the first one-year follow-up up until the date of the last one-year follow-up at the respective site (estimated June 2020), research staff contact surviving patients for EQ-5D-5L telephone interview
- The interviewer must be blinded to the trial intervention, therefore only research staff who has not handled screening, randomisation, eCRF data entry, or daily clinical treatment of included patients at the respective site can conduct the interview
- According to the EQ-5D-5L User Guide, the interviewer should stick literally to the phases in the EQ-5D-5L questionnaire for telephone interview, hence the interviewer should always have a paper copy of the questionnaire to fulfil during the interview. This paper copy represents source data and should be archived with the HOT-ICU site master file for at least 5 years
- Fill in the front page of the questionnaire with patient information and the date of the conducted interview

CRIC
Centre for Research in Intensive Care

HOT-ICU
Handling Oxygenation Targets in the Intensive Care Unit

Research Unit for
Anaestesia og Intensive
Care Medicin
Mølleparkvej 8A
9000 Aalborg
Direkte 97 66 17 15
Mail: forsk.anaestesien@rn.dk

- After completion of the interview the answers should be entered into the eCRF by a non-blinded member of the research staff
- If a patient is incapacitated at one-year folllow-up, the EQ-5D-5L should be sought obtained by proxy from relevant caregiver or next of kin. Check "obtained by proxy" on the paper questionnaire front page and in the eCRF
- If initial contact to the patient/caregiver/next of kin is unsuccessful, repeated contacts should be attempted up until 30 days after the date of one-year follow-up. If efforts to obtain EQ-5D-5L data is futile at day 30 after one-year follow-up the patient should be marked "Lost to EuroQol follow-up" at paper questionnaire front page "notes" and in the eCRF
- Telephone interview is the preferred option for EQ-5D-5L obtainment; however, if a site specifically wishes to use EQ-5D-5L self-complete versions upon patient attendance or through mail distribution, this may be an acceptable alternative *if specifically authorised by the coordinating centre*. When self-complete versions by mail are used primarily, if no answer to distributed questionnaires has been received in due time (after two weeks at the latest), telephone follow-up should be conducted
- All EQ-5D-5L versions are distributed from the HOT-ICU coordinating centre to local investigators in relevant languages. Make sure to use the specific EQ-5D-5L telephone interview versions for telephone obtainment and the specific paper self-complete versions for self-completion

Responsible party for obtaining local EQ-5D-5L:

- National investigator in collaboration with the primary site investigator

Vedhæftet:

- EQ-5D-5L User Guide
- EQ-5D-5L_front_page_v.1.0_01Mar2018

Approved 16 April 2018	**Af:** Professor, overlæge, ph.d. **Bodil Steen Rasmussen** Klinik Akut Anæstesi og Intensiv Afdeling Aalborg Universitetshospital

CRIC
Centre for Research in Intensive Care