Protocol title	AID-ICU Agents Intervening against Delirium in the intensive care unit EudraCT number: 2017-003829-15 ClinicalTrials.gov identifier NCT03392376
SOP Name:	Procedure for obtaining EQ-5D-5L at one-year follow-up
Version	1.0
Replaces version	NA
Applies from	June 2019

Target Population: Site investigators and research staff
Responsible party: Sponsor, Lone Musaeus Poulsen
Created by: Coordinating Investigator for one-year follow-up AID ICU Camilla Bekker Mortensen

Objectives:

- To describe the procedure for obtaining EQ-5D-5L health-related quality of life from one-year survivors in the AID-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 the interviewer is blinded to the allocated intervention
- To ensure that the interviews are conducted in accordance with the EQ-5D-5L User-guide from Euroqol and that the documents are stored according to GCP requirements and AID-ICU protocol version 4.2 dated 7. June 2019

Description:

- This SOP applies for one-year follow-up at all sites.
- Research staff contact surviving patients EQ-5D-5L by telephone at one year after randomization. The time span can be expanded to one year + 30 days if feasible.
- According to the EQ-5D-5L User guide, the interviewer shall adhere strictly to the order of the EQ-5D-5L questionnaire. The interviewer must always have a paper copy of the questionnaire (telephone version) ready for registration during the interview. The paper copy represents source data and must be archived together with the AID-ICU site master file for 5 years.
- The front page of the questionnaire (See appendix Front page for EQ-5D) contains patient information (randomisation ID number), own initials and date of the conducted interview.

- Answers obtained during the interview must be entered into the eCRF after completion of the interview.
- The EQ-5D-5L at one-year follow-up can be obtained from proxy (next of kin or relevant caregiver) if the patient isn´t able to participate. Tick off "Obtained by proxy" on the paper questionnaire front page and in the eCRF.
- In case of unsuccessful contact to either patient, caregiver or next of kin, repeated contacts should be attempted up until 30 days after the date of one-year follow-up. If efforts of contact is futile at day 30 after one-year follow-up, the patient should be marked "Lost to EuroQol follow-up" at the paper questionnaire front page "notes" and in the eCRF.
- Telephone interview is the preferred method to obtain the EQ-5D-5L, but if attempt to contact the patient by telephone is unsuccessful a written questionnaire should be send by mail.
- The EQ-5D-5L questionnaire is distributed by the AID-ICU coordination centre to local investigators in relevant languages.

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

- The national investigator in collaboration with the primary site investigator

Appendix:

- EQ-5D-5L User guide
- Front page for EQ-5D source data

Compensation:

Time spent on obtaining EQ-5D-5L is compensated by the case money as agreed upon in the contract. If the follow-up is performed by an external person outside the individual site, the compensation should be covered by local site. The follow-up part of the case money is Euro 50 per patient.

Co-enrolment:

Patients might be co-enrolled in another CRIC trial (HOT-ICU and/or CLASSIC) also obtaining EQ-5D-5L at one-year follow-up. **If so, the EQ-5D-5L must be obtained unless** already performed and introduced in the eCRF. In this case, a notification from the coordinator will been sent to the site in question.

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Approved by:

20/12/19