# SOP for obtaining the long-term outcomes for the CLASSIC trial

**These are the three secondary outcomes that should be obtained at 1-year follow-up: Mortality, cognitive function and Health-Related Quality of Life (HRQoL).**

**Retention strategies**

* When obtaining patient consent, please assure that the patients are informed about the 1-year contact
* Similarly, inform the relatives about the 1-year follow-up when obtaining their consent
* If the patients cannot be reached at 1-year follow-up, aim to contact the patient daily during the following 4 weeks until 1-year follow-up is obtained
* If the patient is assumed to be at work, then try to make contact during the late afternoon
* If the patient chooses to answer by e-mail (or post) the time for obtaining answers is extended by another 4 weeks, with a reminder 2 weeks after the e-mail/letter has been posted. Remark that cognitive function can only be assessed by telephone.

*We cannot contact any participants who rejected to be contacted or were withdrawn with the demand of no further data registration.*

**Procedure at 1-year follow-up:**

By personnel ***blinded*** to the trial allocation.

**Paper** questionnaires are used for the telephone interview. The interviewer enters ID number; date for interview and a signature on the paper after the interview. Then enter data into the e-CRF in Open Clinica. The paper questionnaires are to be filed in folders. Please read the instructions for both questionnaires beforehand, in order to obtain as objective answers as possible.

**Cognitive function** is assessed with a 4-items questionnaire. The Mini MoCA is a shorter version than the full MoCA. Mini MoCA covers test #*5, #8, #10 and #11* described in the main Instructions. We have made an un-official short guide for the relevant parts for the Mini MoCA. The Mini MoCA takes 5 minutes and you will need the instructions (short guide) together with the questionnaire. MoCA requires certification to conduct the cognitive function assessment, which covers the full MoCA. Mini MoCA can only be assessed by telephone or face to face and not by mail.

**HRQoL** is assessed with EQ-5D-5L. It is a 5-item questionnaire together with a VAS scale score and takes 5 minutes. We recommend conducting the interview by phone, but it is also possible to answer the questionnaire by mail. If the patient is too frail or cognitively impaired to consistently complete EQ-5D-5L, try to obtain the patients HRQoL from relatives (there is a specific questionnaire for relatives). The relative assesses the HRQoL from the relative’s point of view.

**Mini MoCA certification:** This is done here: <https://www.mocatest.org/training-certification/> and takes 1 hour. The full MoCA instructions are very helpful. The certificate is valid for two years. The certification for conducting a cognitive score with the Mini MoCA is charged USD 125 per site and will be refunded by the foundation for the CLASSIC trial. E-mail an invoice to contact@cric.nu.

**Charges:** case money contains coverage of long-term follow-up. If there is a central person conducting all following-up in a country, we kindly ask you to solve this internally. The payment for conducting 1-year follow-up for another site is Euro 100 per patient and will be paid by the including sites case-money.

**Co-enrolment:** patients might be co-enrolled in another CRIC trial (HOT-ICU and/or AID-ICU) who also obtain EQ-5D-5L. If so, you still obtain EQ-5D-5L unless the form in the eCRF are already done or you are being notified by the coordinating investigator from the other trials.

**Coordinator:** Maj-Brit Nørregaard Kjær, RN, MSc (Health Science), PhD student will coordinate and report 1-year follow-up of the CLASSIC trial.

**Contact details:** maj-brit.noerregaard.kjaer@regionh.dk or phone +45 3545 7236.