



1. Purpose

The purpose of this SOP is to clearly outline the policy related to the administration of Health Related Quality of Life (HRQOL) assessments.

2. Responsibilities

Project Leader: The CERU Project Leader, or delegate, is responsible for executing the tasks as outlined in this SOP. Study specific Work Instructions will address project specific responsibilities.

3. Procedures

- 3.1 HRQOL: is defined as the measurement of one's life quality from a health or medical perspective. HRQOL encompasses "Those attributes valued by patient, including their resulting comfort or sense of well being; the extent to which they were able to maintain reasonable physical, emotional, intellectual function; and the degree to which they retain their abilities to participate in valued activities in the family, in the workplace, and in the community".
- 3.2 HRQOL Assessments: repeated outcome measurements done over a specified period following discharge from ICU.
- 3.3 HRQOL assessment tools may be administered by interview or self-administered questionnaires. Every effort should be made to ensure a consistent mode of administration is used for the duration of the study.
- 3.4 Informed consent should be obtained from the subject(s). The subject is defined as the patient, substitute decision maker and if applicable the caregiver. Refer to SOP 204: Development & Administration of Informed Consent.
- 3.5 Once consent has been obtained the Contact Information Form (see Appendix 4.1) will be completed and forwarded to the interviewer.
- 3.6 Prior to conducting the first follow-up visit, the subject(s) will receive notification indicating the anticipated date & time. This can be done in one of the following ways:
 - 3.6.1 A study initiation letter (see Appendix 4.2).
 - 3.6.2 Face to face contact near the time of patient's hospital discharge.
- 3.7 If applicable, ensure the subject has all necessary assessment tools in preparation for their follow up visit. It may be necessary to forward a package containing this information.
- 3.8 At a pre-determined time prior to the first follow-up visit a Follow-Up Visit Letter (see Appendix 4.3) will be forwarded to the subject indicating the date & time of the visit.
- 3.9 The eligible period of assessment for a particular study visit (i.e. visit window) should be conducted in accordance with the protocol. E.g. (+/- 2 weeks for 3 month follow-up visit from ICU admit date).



Administration of HRQOL Assessments

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3.10 Refer to (Appendix 4.4) for a sample telephone script for the interviewer.

3.11 The following will be documented at the time of interview:

- 3.11.1 Location of subject (hospital, home, etc)
- 3.11.2 Date of assessment
- 3.11.3 Who responded (subject or proxy)
- 3.11.4 Mode of administration (interview or self administered)
- 3.11.5 Others as applicable. E.g. (duration of assessments)

3.12 If the subject is unable to be contacted at the scheduled interview time, the interviewer will make an additional 3 attempts to contact the subject. These attempts should occur at different times over the course of the assessment window.(i.e. am, pm)

3.13 The following reasons and corresponding dates should be documented for incomplete assessments:

- 3.13.1 Death – Subject has expired since last contact
- 3.13.2 Withdrew from study – Subject has declined further involvement with the study (consent has been withdrawn). No further contact will be made.
- 3.13.3 Lost to follow-up at assessment window – Unable to contact subject as per section 3.8
- 3.13.4 Not done – any reason other than those referred to in sections 3.12.1-3.12.3 E.g. Coordinator missed assessment window

3.14 When study participation is completed a study termination letter will be distributed (see Appendix 4.5).

4. Appendix

- 4.1 Contact Information form
- 4.2 Study Initiation Letter
- 4.3 Follow-up Visit letter
- 4.4 Sample Telephone Script
- 4.5 Study termination Letter

5. References

- 5.1 SOP #204 – Development & Administration of Informed Consent
- 5.2. Fundamentals of Clinical Trials

Coordinator Name
Address
Contact information

Study Name

Initiation Letter

Dear Mr/Mrs. Subject's Name:

I am writing you to thank you for agreeing to participate in the study name xxxxxxxxx.

The purpose of this research study is to evaluate health outcomes of subjects (*explain briefly in lay language the purpose & value of the study. Can obtain this information from the sample consent*). This study will last up to xx months (x years) (*from when you first became ill*).

It is important that we have your most current contact information (complete address, phone number and email). Please, confirm your information for yourself, your caregiver and alternate next of kin mail back the self-addressed envelope if their contact information changes.

XX weeks before the scheduled intervals (*list here*) a researcher will be contacting you to confirm a scheduled time to answer these questions about your health and quality of life. You will receive a package in the mail that will include a copy of the questionnaire that the researchers will be asking you.

If you are too sick or not able to answer the questions, the researchers will ask your caregiver to answer these questions on your behalf.

We appreciate your invaluable support in this project and we look forward to working with you. If you have any questions do not hesitate to contact me.

Regards,

Name of Interviewer

cc Caregiver
Family member

Study Coordinator Name

Address

Contact Info

Name of Study

Notification of **xx**-month follow-up survey letter

Dear Patient Name:

Recently, you gave your consent to participate in the name of study. We thank you very much for your participation, as it is really important for us to understand how people like you are doing after so many months following your critical illness.

I am writing you today to remind you that I will be conducting your **xx**-month follow-up telephone interview **on day, month, year and time.**

If this time is not agreeable to you, please notify me, Study Coordinator, immediately and we will re-schedule at your convenience.

I have enclosed documentation that you will need to complete over the phone. Please do not fill it out. It is for your reference only and will help you follow along with me at the time of your interview.

Again, many thanks for your co-operation. If you should have any questions or concerns, please do not hesitate to contact me.

Regards,

Study Coordinator Name

Sample telephone script

Hello my name is XXXX XXXX and I am the XXX XXXX for study XXXXXX

Recently, I sent you a letter indicating that I would be contacting you today.

Is this a good time to do your assessments?

If they reply no, ask about a mutually convenient time to re-schedule. Thank them for their time and mention you will talk again soon.

If they reply yes, start the assessment.

Coordinator Name

Address

Contact Information

Study Name

Termination Letter

Dear Sir/Madam;

We are writing to acknowledge that your participation in the study name is now complete.

We want to express our gratitude for your time and dedication that you have provided us over the years. Your invaluable support has provided data that will allow us to further our understanding ofxxxxxxxxxxxxxxxxxxxxxx

Again, many thanks for your co-operation.

Regards,

PI

Coordinator