Guidelines for Administering the KDQOL-SF™ Questionnaire

As part of the STOP-ACEi trial, participants will complete the KDQOL-SF™ questionnaire. The KDQOL-SF™ is a quality of life questionnaire with some questions specifically designed for patients with kidney disease. Please follow this guidance when administering the questionnaire. Please contact the STOP-ACEi trial office if you have any questions.

Why is KDQOL-SF™ data being collected for STOP-ACEi?

The KDQOL-SF™ will provide important data on the impact of the patients' CKD and the trial treatments on patient quality of life. It will tell us how the two trial treatments affect the patient's symptoms and well-being. These factors are very difficult to measure without patient input. By using the KDQOL-SF™, the patient has the opportunity to tell us how their CKD and its treatment affect them.

When to administer the KDQOL-SF™

- Administering the KDQOL-SF™ is a trial procedure and should not be performed before the participant has provided informed consent.
- The KDQOL-SF™ should be completed at the baseline, 12 month, 24 month and 36 month visits (i.e. annually).
- The questionnaire should be completed as part of the clinic visit, but before the clinical consultation or a potentially invasive/uncomfortable assessment if at all possible, as these events may unduly influence the quality of life data. While the participant is waiting to be seen in clinic is a convenient time for the questionnaire to be completed.
- The KDQOL-SF™ for the baseline visit should be completed before the participant is told which trial arm they have been randomised to.

How to administer the KDQOL-SF™

- Complete the participant and assessment details on the front of the KDQOL-SF™.
- Explain the following to the participant:
    - The information they provide is important to the trial;
    - It is important to complete all the questions as this will make sure the data can be analysed correctly, but it is fine to refuse to answer any questions;
    - It is fine to ask questions, but the research nurse must not influence the answers;
    - The questionnaire should take approximately 20-30 minutes to complete;
    - Information provided in the questionnaire will be used confidentially for trial purposes only. If the patient has any concerns, these need to be raised with their clinical care team.
- Provide the participant with a pen and a quiet area to complete the questionnaire.
- Ideally the participant should self-administer the questionnaire (i.e. complete the questionnaire by themselves). Asking the questions in an interview style or the participant completing the questionnaire with a friend or family-member may influence the responses.

- Participants may ask you for assistance, often to clarify the meaning of a question. It is fine for you to assist; however you must not influence their answers. If there is confusion, the participant should respond to what he or she believes the question asks.
- If you do need to complete a KDQOL-SF™ with a participant, or on their behalf:
    - This should be conducted in private;
    - Speak loudly and clearly and verify that the participant can hear and understand you;
    - Do not interpret items. Ask the participant to respond to what he or she believes it asks;
    - Repeat the response options as often as needed.
- You should check over the questionnaire for any missing items before the participant leaves. Please ask them to complete any questions they missed accidentally. It is fine for a participant to decline to answer any questions, but you should make a note of this.

Considerations

- If any answers raise clinical concerns, you should follow your normal local practices and procedures for handling such concerns.
- Some items on the KDQOL-SF™ are designed for patients receiving dialysis therapy (items 14L, 14M, 23 and 24). Participants entering the STOP-ACEi trial have not yet started renal replacement therapy, but may start during trial participation. If the questions do not apply, they should be skipped.