SEXUAL FUNCTION IN-CLINIC SAQ

1. <u>General</u>

A sexual function questionnaire will be administered during the second clinic visit. This questionnaire should be physically separate from the main SAQ and the rest of the in-clinic questionnaire. In addition to this separate questionnaire, there will be one question regarding erectile function that will be included in the main SAQ.

2. <u>SAQ Administration</u>

Each clinic can decide at which point in the visit they would like to administer the questionnaire. The participant should be at a desk or table in a private room that is free of distractions. Neither clinic staff members or the participant's spouse or partner should be in the room. All header information (study ID number and acrostic) should be filled in by staff ahead of time so they don't have to look at the questionnaires while with the participants. Clinics can develop their own procedure for having the participant return the sealed envelope containing the sexual function questionnaire to clinic staff members. A confidential SAQ drop box can be used in addition to having the questionnaire returned to a clinic receptionist or other staff member.

If a participant is not able to complete the sexual function questionnaire on their own and requires assistance from staff members, the questionnaire should not be administered.

The following script, or a similar standardize script for your clinic, should be used when describing the questionnaire to participants.

"In the MrOS study, we have asked you to complete many measures that help us understand many age related conditions. At this visit, we have one more questionnaire that we would like you to complete. These questions deal with sexual function. Little is know about these matters and how they affect the quality of older men's lives. This topic is more difficult to measure than some of the other clinic measures, so we are asking that you complete this short questionnaire. Your answers will be a valuable resource and will help us better understand how these matters affect older men's lives.

We realize this is a sensitive subject for many people so all answers will be kept confidential. I will leave you alone in this exam room and you can complete the questionnaire at your own pace. You do not have to complete this questionnaire if you choose not to do so. If you do not feel comfortable answering any or all of these questions you may leave them blank. When you are finished, you can place the forms in this sealed envelope. Again, I want to emphasize that all information collected will be held in confidence and the study form will not contain your name."

Before leaving the room, clinic staff should provide:

- 1) Sexual function questionnaire
- 2) Pen to complete the SAQ
- 3) Opaque envelope

3. <u>Questionnaire Review</u>

Clinic staff should not review the sexual function SAQ while any participants are in the clinic. After all the participants have left the clinic, the SAQ will be subject to minimal review. Clinic staff does not need to and should not contact participants to clarify any inconsistencies or missing information. The data system will be set up in a way to eliminate edits for missing questions that might exist for these questions.

The sexual function questionnaire can be submitted to the data system with the other Visit 2 TELE forms or separately. All sexual function questionnaires should be received by the data system within a month of the participant's visit 2 clinic visit. A sexual function questionnaire should be sent in for each participant that is seen in the clinic as part of visit 2. If the participant refuses to complete the questionnaire, a blank questionnaire with only the ID and acrostic completed should be submitted to the data system. No edits will appear for these missing data.

Clinics should develop their own procedure for filing the sexual function questionnaire. The questionnaire can be filed separately from other MrOS forms.