

**GUIDELINES FOR INFORMED CONSENT
FOR QUESTIONNAIRE STUDIES**

The following guidelines should be used for the preparation of protocols and consent forms for FCCC studies that include the use of questionnaires.

In the protocol, the investigator should:

1. Describe clearly the relationship between the objectives of the study and the questionnaires to be completed.
2. Provide a sound rationale for the need for the study.
3. Justify the appropriateness of the questionnaires to the cognitive or physical condition of the participants (such as, low reading level for person with low education; economy of items for very sick individuals).
4. Ensure that instructions and item orders are comprehensible and unambiguous.
5. Ensure that redundant items are minimized or eliminated.
6. Ensure that potentially threatening or sensitive items are presented in a sensitive manner (for example, items about sexual practices may be preceded by a statement recognizing that these are highly personal issues, including a rationale for their inclusion, and assurance that completion is voluntary).
7. Include the procedures for how participants will be contacted and how and where the instruments are to be completed (such as, interview by phone, in clinic, by mail, etc.).
8. Explain precautions that will be taken to reduce burden to participants.

In the informed consent, the investigator should:

1. Give a realistic estimate of the time it takes to complete the instruments and the number of data points in the study.
2. Avoid use of abbreviations, acronyms, and medical language that may not be understood by the participants.
3. Make a clear statement of the withdrawal procedures for the study and the disposition of any data provided (for example, can a participant refuse to answer certain questions but still continue in the study? If a patient withdraws from the study, what happens to their data and Bio Samples?).
4. If specimens are included in the study, include the amount in common measures (such as, tablespoons or ounces).
5. If data and/or samples are likely to be used in future research, adapt the statement from the sample consent form on "future studies".
6. Include a statement that the confidentiality of hard copy data and computerized data will be maintained. Indicate who will have access to data.
7. Include a statement that the individual may refuse to answer specific questions.