INFORMED CONSENT GUIDELINES

The informed consent should include the following elements:

1. Statement that the study involves research.
2. Explanation of the purposes of the research.
3. Expected duration of the subject's participation in the research.
4. Description of the procedures to be followed.
5. Identification of any procedures that are experimental.
6. Description of any reasonably foreseeable risks or discomfort to the subject.
7. Description of any benefits to the subject or to others that may reasonably be expected from the research.
8. Disclosure of appropriate alternate procedures or courses of treatment, if any, that might be advantageous to the subject.
9. Statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained, and if applicable, a statement of the possibility that the food and drug administration may inspect the records.
10. For research involving more that minimal risk, an explanation as to whether any compensation is available if injury occurs, and if so, what they consist of, or where further information can be obtained.
11. Explanation of whom to contact for answers to pertinent questions about the research, subject's rights, and who to contact in the event of a research- related injury to the subject.
12. Statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
13. Statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue, will be provided to the subject.
14. The last sentence should explicitly read "I voluntary agree".
15. The consent form should be translated into the local language.