

## APPENDIX XII

### SCHEDULE Y: INFORMED CONSENT

#### 1. Checklist for study Subject's informed consent documents

##### 1.1 *Essential Elements:*

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all invasive procedures and
4. Description of any reasonably foreseeable risks or discomforts to the Subject
5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records
8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
9. Compensation and/or treatment(s) available to the Subject in the event of a trial-related injury
10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury
11. The anticipated prorated payment, if any, to the Subject for participating in the trial
12. Subject's responsibilities on participation in the trial
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
14. Any other pertinent information

##### 1.2 *Additional elements, which may be required*

- (a) Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.
- (b) Additional costs to the Subject that may result from participation in the study.
- (c) The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
- (d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.
- (e). A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable
- (f) Approximate number of Subjects enrolled in the study

#### 2. Format of informed consent form for Subjects participating in a clinical trial

*Informed Consent form to participate in a clinical trial*

Study Title:

Study Number: