APPENDIX IV

Elements of Informed Consent

Checkboxes to be completed by reviewers

Elements of Informed Consent	YES	NO	N/A
1. Description of Research:			
A statement that the study involves research	☐	☐	☐
An explanation of the purposes of the research	☐	☐	☐
Expected duration of the subject's participation	☐	☐	☐
A description of the procedures to be followed	☐	☐	☐
Probability of random assignment to each intervention	☐	☐	☐
Identification of any procedures that are experimental	☐	☐	☐
2. Risks and Discomforts:			
A description of any reasonably foreseeable risks or discomforts to the subject	☐	☐	☐
3. Benefits:			
A description of any benefits to the subject or to others, which may reasonably be expected from the research	☐	☐	☐
4. Alternatives:			
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	☐	☐	☐
5. Confidentiality:			
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and, if relevant, that other agencies might inspect the records	☐	☐	☐

	YES	NO	N/A
6. Compensation for Injury: For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained	☐	☐	☐
7. Research Questions: An explanation of whom to contact for answers to pertinent questions about the research, whom to contact for questions regarding research subjects' rights, and whom to contact in the event of a research-related injury to the subject	☐	☐	☐
8. Voluntary Participation: A statement that participation is voluntary, that refusal to participate will involve 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	☐	☐	☐

Additional Elements of Informed Consent (When Appropriate):

☐ 1. 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.

☐ 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

☐ 3. Any additional costs to the subject that may result from participation in the research.

☐ 4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

☐ 5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

☐ 6. The approximate number of subjects involved in the study.