APPENDIX 2.7.1.1 ESSENTIAL ELEMENTS OF THE CONSENT FORM

The following information shall be provided to each subject in seeking informed consent:

1. An explanation of the purposes of the research including the expected duration of the subject's participation, a description of all procedures and the identification of any procedures that are experimental.
2. A description of any foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others which may reasonable be expected from the research.
4. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
5. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the subject.
6. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Sample Consent Form

You are invited to participate in a study of (*state what is being studied*). We hope to learn (*state what the study is designed to discover or establish*). You were selected as a possible participant in this Study because (*state why and how the subject was selected*).

If you decide to participate, we (*or: ____ and associates*) will (*Describe the procedures to be followed, including their purposes, how long they will take, and their frequency. Describe the discomforts and inconveniences reasonably to be expected, and estimate the total time required. Describe the risks reasonably to be expected, and any benefits reasonably to be expected.*)

(*If applicable, describe appropriate alternative procedures that might be advantageous to the subject, if any. Any standard treatment that is being withheld must be disclosed.*)

Any information obtained in connection with this study that can be identified with you will remain confidential and will be disclosed only with your permission. In any written reports or publications, no one will be identified or identifiable and only aggregate data will be presented. (*If you will be releasing information to anyone for any reason, you must state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure*).

(*If the subject will receive compensation, describe the amount or nature. If there is a possibility of additional costs to the subject because of participation, describe it. If there is a possibility of a research-related physical injury, information as to the medical treatment and compensation available should be included.*)

Your decision whether or not to participate will not affect your future relations with the (*institution or agency*) in any way. If you decide to participate, you are free to discontinue participation at any time without affecting such relationships.

If you have any questions, please ask us. If you have any additional questions later, (*name and phone number*) will be happy to answer them.

You will be offered a copy of this form to keep.

You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above, have had your questions answered, and you have decided to participate. You may withdraw at any time without prejudice after signing this form should you choose to discontinue participation in this study.

_____ _____

Signature Date

_____ _____

Signature of Parent or Legal Guardian Date
(*Include this line if applicable*)

_____ _____

Signature of Investigator Date