Table 2: Additional Required Elements of Informed Consent, when Appropriate

Federal Regulations

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 unforeseen

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 the procedures for orderly termination of participation from the study (i.e. termination visits)

5. A statement that significant new findings developed during the course of the study which may relate to the subject's willingness to continue to participate will be provided to the subject or authorized representative

6. The approximate number of subjects involved in the study

7. A statement describing the assignment of treatments and the probability for assignment to each treatment

(Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116)

Examples of Additions that may be Required by State or Local Laws

1. A statement on the relative frequency of foreseeable adverse events (e.g. common, uncommon, rare)

2. A description of any adverse events that may be severe or life-threatening

3. A disclosure of any conflict of interest

4. A disclosure that the investigator is receiving compensation for conducting the study

5. A statement that insurance may not pay for research related procedures and who will be responsible for their cost if insurance does not pay.

6. A genetic rider describing DNA, genes, the manner in which confidentiality of genetic information will be maintained and the risk of breach of confidentiality of such information (for research containing genetic testing)

7. The anticipated prorated payment(s), if any, to the subject for participating in the study