

**APPENDIX D**

**ELEMENTS OF REVIEW**

The IRB must review your protocol by the following criteria:

1) The Risks to the subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2) The risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116.

5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 46.117.

6) When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.

7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8) Contact, financial and personal relationships with the sponsor must be disclosed, as the IRB is required to assess whether there may be a conflict of interest.