APPENDIX D: FORMAT FOR DETAILED RESEARCH PROTOCOL

Investigators develop research protocols to inform grant agencies, academic programs, professional bodies, etc., how they plan to conduct research studies. For the purpose of IRB review, a research protocol should be submitted if it includes relevant details not reported on the Expedited/Full Review Form (see Appendix C).

RECOMMENDED FORMAT FOR DETAILED RESEARCH PROTOCOL:

A. PURPOSE: State briefly the purpose of the study; usually this will include the hypothesis which is to be tested.

B. BACKGROUND: Describe past studies and, if relevant, experimental or clinical findings which led to the plan for this project. This must be succinct and comprehensible without extensive reference to other material. A few pertinent references may be cited. In some cases -- e.g., as in cases where earlier studies have produced conflicting evidence -- it will be necessary to cite these studies and explain how it was decided to rely on one side or the other. For studies designed to compare or evaluate therapies, there should be a statement of the relative advantages or disadvantages of alternative modes of therapy. This section should ordinarily be less than one page long; however, when necessary it may be longer.

C. SPECIFIC LOCATION OF STUDY: Where will the research take place? (When other institutions are involved it may be necessary to secure the approval of their Institutional Review Boards.)

D. PROBABLE DURATION OF PROJECT: This should be the estimate for the entire study. (IRB reapproval is required at least every year as long as the study is continued. In specific cases, more frequent reapproval may be required.)

E. RESEARCH PLAN: This is an orderly description of the intended procedures as they directly affect the subjects. There need not be a detailed account of techniques that do not affect the human subject. Include length of time for various procedures and frequency of repetition, any manipulation that may cause discomfort or inconvenience, and plans for follow-up. If questionnaires or non-standard rating scales are to be used, include copies. (If the rating scale is a standard and familiar one, it is only necessary to name it and no copy need be submitted.)

Statistical considerations: Studies which cannot be expected to answer the questions posed by the research, because of small numbers, low statistical power or other major flaws in research design, can provide no benefit to the subject and cannot justify even the smallest degree of subject inconvenience, let alone risk. Therefore, except for pilot studies, which are clearly designed to further the development of a more extensive research protocol, this section should include a) the number of subjects expected to enter
the study, b) a statement about the statistical power of the study to test the major hypothesis, and c) a summary of the plans for statistical analysis.

F. ECONOMIC CONSIDERATIONS: Describe any material inducements that will be offered to subjects in return for their participation: e.g., direct payment, free services, etc. Describe any schedule of payment to subjects based on their complete or partial participation. Will early withdrawal from the study result in a reduced payment? Does it make a difference whether it is the subject or the investigator who decides to terminate the subject's participation? Explain any bonus a subject may receive for completion of the study. These partial or bonus payments must also be explained in the consent form.

G. SUBJECT POPULATION: Describe the requirements for the subject population including the total number of subjects and controls and their ages. If special groups -- e.g., prisoners, children, fetuses, the mentally disabled -- are part of the subject population, please indicate this.

List the specific inclusion and exclusion criteria. If only healthy subjects are to be included, state how you will assure that they are healthy, e.g., take a history, do a physical exam, laboratory tests.

NOTE: If an advertisement will be used to solicit subjects, attach a copy to the protocol.

H. RISKS: Describe and assess any risks -- physical, psychological, social, economic, legal, or other. If other methods of research present lesser risks, describe those, if any, that were considered and why they will not be used. In general, risks to subjects must be minimized by (a) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. Describe the procedures you have taken to minimize these risks. For all research involving any risk of physical injury, these risks must be specified. If there are none, state: "There are no risks of physical injury." If there are risks of physical injury, there should be for each injury a careful estimate of its probability and severity as well as of its potential duration and the likelihood of its reversibility.

I. CONSENT PROCEDURES: Describe consent procedures to be followed, including how, where, and by whom informed consent will be obtained. The consent form should be appended to the protocol exactly as you plan to submit it to the funding agency and to the subject.

Oral consent: Although written consent forms are generally required, if the investigator believes that oral consent is appropriate, he or she should put on the consent form the information to be presented to the subject and, in this section of the protocol, justify the request for waiver of the requirement for documentation of consent.

J. PROTECTION OF SUBJECT: Describe procedures (including confidentiality safeguards) for protecting against or minimizing injuries (physical, psychological and social) and provide an assessment of their likely effectiveness. There should be a clear statement about procedures for early detection of adverse effects and what steps, if any,
will be taken to avoid serious injury to subjects. For example, the subject might be withdrawn from the study or a corrective action might be taken.
When appropriate, the subject should be assured that steps will be taken to assure confidentiality. This is particularly important in studies in which information will be recorded which, in the view of the subject, is sufficiently sensitive so that he or she would not wish persons other than the investigators to have access to it. Whatever measures are taken to assure confidentiality should also be discussed in general terms in the consent form.

If videotapes are to be made for research purposes, a separate section of the consent form should be used to cover this. It should state when the tape will be erased, that the subject has the right to demand erasure at any time, and the circumstances, if any, under which the tape might be used for purposes other than the research described in the protocol -- e.g., educational purposes.

K. POTENTIAL BENEFITS: Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work.

L. THE RISK-BENEFIT RATIO: This section should consist of the investigator's explanation of how he or she concluded that 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.

(Revised August, 2005)