A. A brief (1-3 page) lay-person summary of the proposed project, including page references (when necessary) for the location of where more information can be found in the protocol. (Note: This summary will also be required for future related submissions such as progress reports and modification requests.)

B. Application/proposal for funding/support (if an application/proposal of any kind was/will be submitted to an external sponsor in order to obtain funding/support of the project, attach a copy of the full application/proposal, including all budget pages.)

C. Describe the specific aims of this project and the methodology including a description of the project, purpose, procedures, participant population (criteria for inclusion/exclusion including the attempts made to include women and members of minority groups), recruitment procedures, and how confidentiality of data will be maintained.

D. Describe the possible risks to participants (including how the project is designed to minimize those risks) and describe anticipated benefits (if any) to participants or to the body of science.

E. Describe the methods to be used in securing the informed consent (or, when involving minors, assent) of the participants. If an informed consent (or assent) form is to be used, attach it. If consent (assent) is conducted verbally, attach a written copy of the script. (See the next page for the basic elements of informed consent.)

F. Complete and attach the ‘Protocol Checklist and Submission Procedures’ page.

G. Attach the following, if applicable, to your research project: all interview/survey questions, focus group topics, survey instruments, anticipated letters/emails to participants, recruitment materials, letters of support from groups/organizations, copies of other IRB approvals, a completed ‘Checklist Form for Research Involving the Use of Prisoners as Study Participants’, and a completed ‘Checklist Form for Research Involving Children as Study Participants’.