Appendix D: Full Protocol

**Title of Project/Study:**

**Planned Inclusive Dates of Study:**

1. List of primary investigator name/command/contact information.

2. List any other individuals (internal, external, and contractor) who will interact with human subjects or have access to data collected. (Ensure all have signed Investigator’s Assurances.) For all individuals include their role in the research (i.e. Associate Investigator, Research Support Personnel, Administrative Support, stenographic services, etc.). Also include their current position or billet title, military/civilian rank or grade and any potential relationship they may have with research subjects that might conflict with their role in the research. If the Associate Investigators are contractors, indicate the company they work for. Separate agreements may be required for the participation of contactors or individuals who are not covered under the Marine Corps Institutional Assurance. Include, as an attachment to the protocol, a copy of the curriculum vitae, military biography or similar summary of qualifications for each member of the research team.

3. Provide background information on the origins of the project.

4. Identify sponsor and known, as well as potential, future users of the data/results.

5. Briefly describe the objectives of the project, the research plan, and methodology with particular emphasis on direct or indirect interaction with human subject or their identifiable data. Describe why human subjects (or their data) must be used in the research and if there are any alternatives.

Objectives:

a) Primary

b) Secondary

Research Plans:

a) Subjects

b) Inclusion and Exclusion Criteria

c) Study Design

Methodology:

6. To what other reviews if any is this study subject?

7. To what other regulations is this data collection effort subject (e.g., Privacy Act) and how will it/they be implemented?

8. How will participants be recruited? (Enclose copies of any recruitment letters, messages, etc.)

9. Describe the nature and extent of risks the collection of these data pose to the participants. Assess direct impact to the subject at the time of participation (physical, emotional), and possible future impact that the disclosure of the subject’s responses could have on his/her financial standing, career, employability, insurability, reputation, etc. Describe procedures that will be implemented to minimize this risk.

10. Describe any anticipated benefits to the participants, the Navy, and/or society.

11. How will subjects be informed of their rights? Will informed consent be obtained? (Attach a copy of the Informed Consent form or consent language to be used.)

12. Describe any question/items that will be asked or data elements that will be collected or accessed from existing databases. (Attach a copy of questions, data elements, or survey/assessment instruments. If these are currently not available, provide a sample of representative items.)

13. Do any of the questions/items/data elements used in the research involve information that is private or sensitive? If yes, describe and assess the degree of potential risk or harm to the subject if disclosed.

14. What would be the impact to the research if private or sensitive information could not be collected?

15. Describe precautions that are being used to minimize risk to the subject and safeguard the data (e.g., limiting access, storage and destruction of data, password-protected network security, etc.).

16. List all attachments to this Protocol: (e.g., Informed Consent, Survey instrument, Investigator Assurance, Privacy Act Statement, Research Plan, etc.)