Appendix F: Continuing Review Report

**IRB Control No: Date:**

**Project Title:**

**PI Name: Command & Code:**

**Planned Inclusive Dates of Research:**

Complete the following items:

1. List names of current investigative staff working on this project. (Ensure all have signed the Investigator’s Assurance.)

2. Summarize progress of the research to date.

3. Describe significant events and problems particularly those that may relate to human subjects issues.

4. Describe any significant changes in, or deviations from, the protocol since it was last approved.

*5.* Summarize any new information (identified in the research or in a search of other literature), which may alter previous assessment of the risk-benefit to human subjects of the research.

6. Describe any remaining work on the project involving human subjects or identifiable personal data. Include scheduled completion date.

7. Explain any unplanned delays affecting the selection or use of human subjects.

8. Summarize the demographics of selected subjects to include the total number of subjects who gave consent to participate, number of male and female participants (if known), and the number of participants by racial/ethnic group (if known).

9. Were any subjects included who did not meet the selection criteria or should otherwise have been excluded? If so, please explain the circumstances.

10. Describe the number of incidents and reasons (if known) for subjects’ inability or unwillingness to continue participation.

11. Summarize any complaints about the research received from subjects or those investigators who have interacted with subjects.

12. Attach a copy of the current Informed Consent/Privacy Act document/language being used in this study and any Adverse Event Reports, if applicable.