Appendix H: UPIRTSO/Unanticipated Problem or Serious Adverse Event Report

**IRB Control No: Date:**

**Project Title:**

**PI Name: Command & Code:**

Type of Report: *(refer to Chapter 18 of Policy and Procedures for Marine Corps Human Research Protection Program)*

\_\_ Unanticipated Problem involving Risk to Subjects or Others (UPIRTSO)

­­­\_\_ Unanticipated Problem

\_\_ Serious Adverse Event

Date event occurred (if known):

Date event discovered:

1. Clearly summarize the adverse event (s). Describe any actions taken following the event(s).

2. How does this event (do these events) relate to the research (e.g., directly caused by the research, tangential to the research, an unrelated event)?

3. Discuss any patterns or trends among all adverse events occurring on this project.

4. Describe recommendations for changes in protocol to correct for and prevent future adverse events.