NPS Institutional Review Board
Research Protocol Continuing Review Form

Last updated 8/13/12

Form Purpose: Continuing review is required to extend the expiration date of an active protocol. All research activities must stop at expiration (interaction with subjects, analysis of data containing PII, etc.)

Instructions: Please submit this completed form (w/ required attachments) for all research involving human subjects to the Institutional Review Board at least 21 days prior to the expiration date of your existing protocol. If the continuing review report is not approved by the IRB and the NPS President by the expiration date, your protocol will expire and all research activities must stop.

About Continuing Review: Federal Regulation 32 CFR 219.109 states that: "An IRB shall conduct continuing review of research…at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research."

Background Information			
Protocol Number		Principal Investigator	
Protocol Title			
Date current review expires:		Estimated date of research completion:	

Research Design and Procedures

1.Provide a brief project summary to include the objectives of the research, a summary of the research plan/methods, and a summary of findings to date including preliminary results.

2. Provide a summary of any new and relevant information, published or unpublished, that has come available since the last IRB review. Especially information that may affect the IRB's deliberations about the risk and benefits associated with the research.

3. Provide a summary of any problems or changes in the research since the last IRB review. This includes informed consent procedures, privacy/confidentially protections, subject enrollment and recruitment, etc.

3b. If changes were implemented, were the first approved by the IRB? ☐ Yes

4. Provide a summary of any multi-center trial reports and attach a copy of the reports if applicable.

Subject Recruitment

1. Total number of subjects enrolled:

2. Number of subjects enrolled since last IRB review:

3. Number of additional subjects to be enrolled:

4. Have any subjects withdrawn or been excluded for the study? ☐ No ☐ Yes, explain why below.

5. Provide a summary of subject experiences or any complaints about the research since the last IRB review.

6. If vulnerable populations have been enrolled, describe the protections and if they are adequate.

7. Summarize any difficulties associated with the informed consent process since last IRB review.

Research Risks

1. Provide a current risk to potential benefit assessment based on study results.

2. Please describe what risks, side effects, or discomforts have been observed to this date. Please include physical, psychological, social, and economic risks.

3. Describe any Unanticipated Problems or Serious Adverse Events that include risks to the subjects.

4. Have any instances of non-compliance with the approved protocol occurred? ☐ No ☐ Yes, explain below.

5. Have or do any of the above risks require modification to the research protocol (recruitment, consent, design, etc)?

☐ No ☐ Yes, explain what modifications are needed and submit an IRB amendment form.

Additional Information

1. Has the research protocol expired?

☐ No ☐ Yes, explain the why a lapse in approval occurred and indicate if research continued after expiration.

2. Please provide any additional information the IRB should consider, especially related to subject risks and benefits.

Required Attachments

Attach the following documents to this Continuing Review Form.

- ☐ Approved IRB consent form with IRB approval stamp.
- ☐ IRB Amendment form if requesting changes to the protocol.

Helpful Descriptions and Definitions

Vulnerable Populations: Include active duty, NPS students and staff, minors, elderly, pregnant women, etc.

Unanticipated Problem: any incident, experience, or outcome that meets all of the following criteria; (1) unexpected, (2) related or possibly related to participation in the research, and (3) suggests that the research places subjects or others a great risk of harm (including physical, psychological, emotional, economical, legal, or social harms).

Adverse Event: An event that is serious, unexpected, and related to the research.

Principal Investigator's Statement of Assurance

- As the principal investigator I assume overall responsibility for the protection of human subjects. I assume responsibility for ensuring the integrity and ethical conduct of the student researcher(s) and I certify that any student researcher(s) is/are fully competent to accomplish the goals and techniques stated in the attached proposal.

- I will not implement changes to approved research without IRB and institutional approval except when necessary to eliminate apparent immediate hazards to the subject.

- I will inform the IRB Chair or Vice Chair, and the Medical Monitor (if research is greater than minimal risk) of any Unanticipated Problems and Serious Adverse Events within 24 hours. I will submit an Unanticipated Problem and Serious Adverse Events Report Form to the IRB within 5 days.

- I understand that human subjects research activities, including recruitment, may not commence until the IRB completes review, recommends approval, and the President approves the research.

- I understand that the research must be reviewed by the IRB and approved by the President before the expiration date or all research activities must stop and I will l submit a End of Experiment report, consent forms and research data to the Human Research Protection Office.

- I have read and understand the NPS Instruction on the Protections of Human Subjects and NPS IRB and HRPP Policy and Procedures.

PI Signature:
(May sign with CAC)

Date: