Department of Veterans Affairs (VA) responses to comments received from OMB on February 15, 2012 regarding the Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans (201005-2900-006)

1. **Response rates.** Please update the response rate table in part B (item 1). Based on our conversation with the program staff, we are concerned that there is an inadequate basis for VA to expect response rates of 60% or 70%, especially given the experience with the last round of this survey.

We have consulted with a survey design expert, Dr. John Boyle with Abt-SRBI, which is VA's contractor for this study, and he agreed that response rates are likely to be in the range of 50 to 60% and that the addition of CATI telephone interviews to the study methodology would likely increase the overall response rates by an additional 10 percentage points, i.e., an overall response rate of about 60 to 70%. Our initial plan was to wait until preliminary response rates were available for this data collection before going to VA Office of Public Health Leadership to ask for additional funds to include CATI telephone interviews; however, based upon OMB's recommendation, we are now revising the study protocol to include CATI telephone interviews and working with the Contract Officer to modify the contract for this purpose.

2. **Nonresponse Follow-up.** We note that in the previous two rounds VA has used telephone follow-ups as a way to increase response rates and examine potential bias. The telephone collection has been necessary in previous waves to complete a substantial number of cases. It is not clear why this is not part of the protocol for the current collection. Please update the supporting statement part A (item 12) and part B (item 3) and provide the script for the telephone follow-up call.

The updated supporting statements are attached. The contractor will be asked to provide a script for the telephone follow-up call once the contract modification is in place.

3. **Non-response bias.** Please add some additional discussion to part B (item 3) on non-response bias. In particular, we encourage VA to take advantage of the information they collect about respondents (i.e., beyond one or two self-reporting health items) to help inform issues of potential non-response bias. We also encourage VA to explore ways to control for differential non-response (e.g., between deployed and non-deployed veterans).

With the addition of CATI telephone interviews, we will now be able to collect information from Veterans who never submitted responses via the web-based survey or paper questionnaire, about reasons for nonparticipation. This will help inform issues of potential non-response bias. We also plan to compare demographic and military characteristics of survey respondents and non-respondents using characteristics of the overall panel.

4. **Consent form.** We refer VA to the attached consent form from HHS, which meets HIPAA requirements and provides important information to respondents not currently included in the proposed form. <a href="http://privacyruleandresearch.nih.gov/authorization.asp">http://privacyruleandresearch.nih.gov/authorization.asp</a>

For this data collection, we applied for and received a HIPAA waiver from the Washington, DC VAMC Human Subjects office (which is the designated federal official for obtaining a HIPAA waiver for the Post-Deployment Health Epidemiology Program).

5. **Consent form.** Please also reference the Privacy Act in the confidentiality statement for the consent form, stating that the information is "confidential under the Privacy Act," not simply stating that it is "strictly confidential."

We have made this change to the consent form and will now resubmit the updated form for review and approval by the VAMC Institutional Review Board. (The earlier version of the consent form was previously reviewed and approved by the IRB.)