Research Advisory Committee on Gulf War Veterans' Illnesses Comments and Recommendations Regarding VA Gulf War Illness Research Strategic Plan

February 1, 2012

The VA Gulf War Illness Research Strategic Plan 2012-2016 (as modified with the changes discussed January 31, 2012) is an encouraging step toward establishing an effective Gulf War research program. It is focused on priority research topics identified by the Committee in its 2004 and 2008 reports. It addresses the two areas of inquiry recommended by the Institute of Medicine 2010 report: 1) "continued surveillance of Gulf War veterans" and 2) "a renewed research program with substantial commitment to well-organized efforts to better identify and treat multisymptom illness in Gulf War veterans." [Institute of Medicine, Gulf War and Health, Vol. 8, 2010] It commits VA to achieving these goals within the timeframe of the plan. It has the support of ORD staff and the members of the Committee, the Gulf War Steering Committee (GWSC), and the National Research Advisory Council (NRAC).

The Committee commends the Office of Research and Development for both the content of the strategic plan and the process that produced it, involving VA staff and expert outside advisors working together. Eleven members of the Committee and Committee staff served with VA staff and NRAC members on the working groups that drafted the strategic plan.

ORD staff and Committee members agree that the strategic plan is not currently actionable for two reasons. First, it describes more objectives than can be funded with the resources available, and there is no prioritization or costing of these objectives. Second, some important objectives require the participation of VA offices in addition to ORD, and while some of these offices participated in the strategic planning process, they have not formally committed to the plan.

ORD intends to address these issues as follows. First, once the strategic plan has been adopted by both the Committee and the National Research Advisory Council, ORD will develop an operational plan based on the strategic plan, identifying specific objectives, costing, and timelines. Second, it will seek to persuade the other offices involved to adopt the strategic plan and commit to carrying out its objectives.

- 1. The Committee recommends adoption of the strategic plan with the following caveats.
 - a. Recognizing that the operational plan will be the actionable plan, and that other documents expressing similar goals have not produced results in the past, the Committee recommends that outside advisors be consulted in the preparation of the operational plan (such as through an expanded GWSC, as provided for in the strategic plan) and that the content of the operational plan be presented to the Committee and the NRAC for review and advice before final decision.

- b. The Committee recommends that other VA offices adopt the strategic plan and operational plan, so that the result is a single, VA-wide research program.
- c. The Committee recommends that, in addition to soliciting pilot studies of treatments by RFA, a treatment research center or other directed process should be established to supplement the identification and initiation of promising treatment pilot studies.
- 2. The Committee recommends that the program be funded at not less than \$15 million annually, VA-wide, reflecting the need identified by the IOM for a "substantial commitment" and the pledge by VA to replace the University of Texas Southwestern program with one of similar size.
 - a. ORD should no longer categorize as "Gulf War research" projects outside the two areas of inquiry recommended by the Institute of Medicine 2010 report: 1) "continued surveillance of Gulf War veterans" and 2) "a renewed research program with substantial commitment to well-organized efforts to better identify and treat multisymptom illness in Gulf War veterans."
 - b. Funding for the Million Veteran Program should be categorized as "Gulf War research" only for studies specifically of Gulf War multisymptom illness.
- 3. The Committee recommends that the administration and conduct of the program each have unified leadership, reflecting the IOM recommendation that the program be "well-organized" in a manner capable of ensuring its success.

a. Administration

- 1. Within VA, it is essential that the Gulf War Illness Research Program be undertaken as a unified VA research effort, implemented cooperatively by all VA divisions that contribute to research and data gathering efforts relevant to the health of 1990-1991 Gulf War veterans. This includes, most prominently, the Office of Research and Development (ORD) and the Office of Public Health (OPH). VHA leadership, to which both report, should establish a mechanism to ensure this cooperation.
- 2. Within ORD, the administration of the program should be centralized under the Director of Deployment Health. Currently, major elements of ORD's Gulf War research program are organized as cooperative studies and do not report to the Director of Deployment Health.

b. Conduct

1. It is desirable that the conduct of the Gulf War Illness Research Program be centralized under a single, full-time leader – a highly qualified scientist "who goes to bed at night and wakes up in the morning thinking about how to solve this

problem," in the words of Dr. Stephen Hauser, chairman of the committee that authored the 2010 IOM report.

- 2. A Center of Excellence or virtual Center of Excellence should be considered as a model for execution of major elements of the program. This model has been effectively used by ORD to expedite progress in research related to other challenging veterans' health problems (such as the Center of Excellence for Returning War Veterans in VISN 17).
- 3. For research studies funded through general RFA's, the Gulf War merit review panel should be made up of individuals with current expertise in Gulf War research.
- 4. The Committee is pleased that the Office of Public Health attended the meeting and participated in the discussion of the strategic plan. The Committee, however, is concerned to learn that OPH submitted its revised longitudinal survey to OMB approximately a year ago. The Committee has not been shown the revised survey, but it appears likely that the changes made did not substantially address the Committee's recommendations of Nov. 2010.

The Committee recommends that the revised longitudinal survey not proceed until the Committee staff has an opportunity to review it, and that the survey be revised further if necessary to meet research program needs.

The Committee respectfully submits these recommendations, mindful of the need "to speed the development of effective treatments, cures, and, it is hoped, preventions" for Gulf War multisymptom illness, as stated in the preface to the IOM report, which further noted, "We believe that, through a concerted national effort and rigorous scientific input, answers can likely be found."