

OFFICE OF RESEARCH OVERSIGHT

SPECIAL REVIEW OF ALLEGATIONS
RELATED TO RESEARCH CONDUCTED BY
THE VETERANS HEALTH ADMINISTRATION
OFFICE OF PUBLIC HEALTH

Washington, DC



July 5, 2013

Veterans Health Administration

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EXECUTIVE SUMMARY

INTRODUCTION

The Office of Research Oversight (ORO) was charged with conducting a special review of allegations related to research conducted by the VHA Office of Public Health (OPH) presented by a former OPH employee (the Complainant) during a Hearing of the Subcommittee on Oversight and Investigations of the United States House of Representatives Committee on Veterans Affairs (*March 13, 2013, Gulf War: What Kind of Care are Veterans Receiving 20 Years Later?*).

The purpose of the review was to evaluate each allegation, make findings of fact, draw conclusions, and provide recommendations to the Under Secretary for Health (USH) regarding the need for a full scale official investigation of the allegations.

ORO's review included individual interviews on April 16-17, 2013, with the Complainant, OPH leadership and professional staff, and the Chair of the Institutional Review Board (IRB) with responsibility for oversight of the research, and an evaluation of over 3000 pages of relevant documentation, including research protocols, e-mail and other communications, and published articles. In addition, draft report findings were forwarded to the Complainant, OPH officials, and the IRB Chair for factual corrections.

CONCLUSIONS and RECOMMENDATIONS

ORO made the following conclusions and recommendations based on its review:

Allegation #1: Policy Bias

Conclusion: ORO concluded that OPH does not maintain a policy bias against neurological causes for Gulf War illness (i.e., chronic multisymptom illness – CMI), chronic fatigue syndrome-like (CFS-like) illness, etc. ORO noted that OPH surveys are not designed to identify cause and effect relationships.

Recommendation: ORO recommends that OPH analyze and publish as soon as possible the available data from the *New Generation Study* and the *Gulf War Follow-up Study*, including any data suggesting potential neurological bases for CMI.

Allegation #2: Data Availability

Conclusion: ORO concluded that VA policy does not require that OPH provide its study data to other VA researchers or to researchers outside VA.

Recommendation: Once the VA Policy on Public Access to VA Research Data is finalized, ORO recommends that OPH implement the Policy as quickly as possible.

Allegation #3: Selective Data Release

Conclusion: ORO concluded that profound scientific and programmatic disagreements between OPH leadership and the Complainant regarding the priorities for analyzing and reporting data from the *New Generation Study*, combined with the fact that OPH has not yet completed exhaustive analyses of these data, resulted in intense frustration and distrust on the part of the Complainant. Despite the Complainant's passionate commitment to the belief that analyses of data related to environmental exposures warranted the highest priority, ORO concluded that OPH leadership had both the authority and the responsibility to set program priorities, even if OPH staff disagreed.

Recommendation: ORO recommends that OPH complete the analyses of data from the *New Generation Study* as expeditiously as possible.

Allegation #4: Selective Data Exclusion

Conclusion: As in Allegation #3 above, ORO concluded that despite profound scientific and programmatic disagreements between OPH leadership and the Complainant, OPH leadership had both the authority and the responsibility to set program priorities.

However, submission of an abstract that listed the Complainant as an author without the Complainant's explicit prior approval was clearly inappropriate and violated widely-accepted standards within the scientific community.

Recommendation: OPH should implement policy and procedures to prohibit the practice of including any individual's name in any publications (i.e., abstracts, poster presentations, or manuscripts) without the explicit approval of the individual.

Allegation #5: Gulf War Family Registry Data

Conclusion: ORO concluded that Gulf War Family Registry data appeared to have been lost when the Austin Data Center upgraded its systems in 2005. Loss of the Registry data was not attributable to current OPH leaders or personnel. ORO noted that OPH staff who had responsibility for the Registry are no longer employed by VA, and current OPH staff had little knowledge of the Registry's use or history. ORO found no approved Record Control Schedule that would have permitted destruction of these data.

Recommendation: OPH should establish policy and procedures to ensure that research data are retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Record Control Schedule (RCS 10-1) as required by VHA Handbook 1200.05 §26.h.

Allegation #6: Gulf War Illness Research Advisory Committee (RAC) Recommendations

Conclusion: ORO concluded that OPH considered the recommendations of the Gulf War Illness RAC and accepted those that it considered constructive and practicable. ORO concluded that OPH leadership had both the authority and the responsibility to use its own professional judgment in evaluating the RAC's recommendations.

Recommendations: None

Allegation #7: Scientific Review of RAC Recommendations

Conclusion: ORO concluded that the scientific review of RAC recommendation requested by the VA Chief of Staff was conducted in an objective and professional manner. ORO found no evidence that OPH officials made false statements to the VA Chief of Staff related to his request.

Recommendation: None

Allegation #8: Institute of Medicine (IOM) Study

Conclusion: ORO concluded that the IOM study, *Gulf War and Health: Treatment for Chronic Multisymptom Illness*, was conducted in an objective and professional manner in accordance with IOM standards. ORO found no evidence that OPH officials chose, or inappropriately influenced the selection of, panel members or witnesses for the IOM study.

Recommendation: None

Allegation #9: Follow-up of Suicidal Ideation**Conclusions:**

1. ORO concluded that OPH provided adequate protections for subjects in the *New Generations Study*, given prevailing standards at the time the study was conducted and the evidence available to OPH when the Complainant later raised the possibility of contacting Veterans who had participated in the study.
2. ORO concluded that in delaying implementation of “Hot Comment” call-backs in the pilot phase of the *Gulf War Follow-up Study* from June 11 through July 31, 2012, OPH fell short of the requirement to minimize risks to study subjects under VA regulations at 38 CFR 16.111(a)(1) and VHA policy (VHA Handbook 1200.05 §10.d and §17.a).

ORO did not find OPH’s rationale for this delay to be persuasive.

- a. Relative to the belief that call-backs could undermine Veterans’ trust in OPH privacy and confidentiality guarantees, ORO noted that changes to the study’s informed consent document to provide for such call-backs had been approved by the IRB on June 1, 2012. Paper-and-pencil survey questionnaires were first mailed to the 500 potential pilot phase participants on June 25, 2012, and included the revised consent document. Prior to the June 25 mailing, only five “preliminary” *Gulf War Follow-up Study* pilot phase participants had completed the survey. All five participated in the on-line version of the study.
- b. Relative to the decision that the need for call-backs required an evaluation prior to implementation, ORO noted that implementation of call-backs during the pilot phase of the *Gulf War Follow-up Study* not only would have permitted evaluation of the need for call-backs, but also would have permitted evaluation of the call-back procedure itself (as described in the “Hot Comments” protocol amendment submitted to the IRB by the Complainant) prior to initiation of the main phase of the study.

- c. ORO further noted that the number of call-backs needed for the 500 *Gulf War Study* pilot phase participants could have been anticipated to be quite modest and, therefore, practicable to implement.

The overall response rate for the *New Generation Study* (Barth et al.) was 34% (20,563 of 60,000), including the 1360 Computer Assisted Telephone Interview (CATI) subjects (who were the only subjects eligible for call-backs). Of those 1360 subjects, 92 (7%) required call-backs. Thus, it would have been reasonable to estimate that if 40% (200) of the *Gulf War Follow-up Study* pilot phase participants completed surveys, roughly 20 (10% of 200) would need call-backs. [Note: In reality, 167 Veterans completed surveys by the time call-backs began on August 1, 2012, and 6 of those Veterans (4% of 167) required call-backs; a total of 211 Veterans completed surveys prior to initiation of the main phase of the *Gulf War Follow-up Study* on September 10, 2012.]

Thus, OPH should either have arranged for a mental health professional to conduct the call-backs for the expanded pilot phase of the study by June 25, 2012, or postponed the expanded pilot phase until a mental health professional could be found to conduct the call-backs.

3. ORO concluded that the Complainant, as PI of the *Gulf War Follow-up Study*, had both the authority and the responsibility to report to the IRB his concerns about minimizing risks to subjects who demonstrated suicidal ideation in their on-line and paper-and-pencil survey responses.

VHA Handbook 1200.05 §3.ss(2) defines the PI as a qualified person designated to direct a research project or program. The PI oversees scientific, technical, and day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of that team. VHA Handbook 1200.05 §9.b and §9.r further define the PI's responsibilities, respectively, to include ensuring that "there are adequate resources to carry out the research safely" and "reporting all unanticipated problems involving risks to subjects" to the IRB.

ORO found that OPH officials, both in their actions relative to the *Gulf War Follow-up Study* and in their statements to ORO, demonstrated an inadequate understanding of the PI's authorities and responsibilities under VHA policy. As a result, these authorities and responsibilities were compromised.

4. ORO concluded that the Chair of the IRB responsible for oversight of the *Gulf War Follow-up Study* was slow to address the possible need for additional protections for participants in the pilot phase of the study because he was initially unaware of the limitations being placed on the PI's authority by OPH leadership and later unclear about who in OPH was actually responsible for the conduct of the study.

ORO found that the IRB Chair should have temporarily suspended study activities when doubt arose about who was responsible for the study and it became clear that the pilot phase of the project was to be initiated without a mental health professional in place to conduct needed call-backs.

Recommendations:

1. ORO recommends that the Principal Deputy Under Secretary for Health, as Institutional Official for the VA Central Office Human Research Protection Program:
 - a. Establish or designate a specific Institutional Review Board (IRB) for oversight of research conducted by VHA Program Offices.
 - b. Ensure that the leaders of VHA Program Offices conducting research are trained in the regulatory and policy requirements applicable to the conduct of research.
2. ORO recommends that OPH ensure that the PIs of all OPH studies are empowered to oversee the scientific, technical, and day-to-day management of the research, and to fulfill all PI responsibilities as required by VHA Handbook 1200.05. If OPH officials wish to exercise the authority to make final decisions on OPH studies, they must assume the title of the PI and be accountable for the conduct of the studies, including the protection of human subjects participating in the studies.

Allegation #10: Threats Against the Complainant

Conclusions:

1. ORO concluded that there was no evidence of physical threat to the Complainant from OPH officials.
2. ORO concluded that the legitimate efforts of OPH management to redirect the activities of the Complainant toward work dictated by OPH program priorities were perceived as threats by the Complainant.
3. ORO concluded that the proximity in time between the Complainant's efforts to suspend activities in the *Gulf War Follow-up Study* and the initiation of admonishment actions by OPH leadership created the appearance for the Complainant of a connection between these two events, irrespective of leadership's intention to admonish the Complainant solely for failing to follow direct instructions from the Chief Public Health Officer and acting disrespectfully toward the Chief Consultant for Post-Deployment Health.

4. ORO concluded that temporal proximity created the appearance for the Complainant of a connection between his strong disagreements with OPH leaders and the following statements by OPH leaders that he perceived as threatening to his career in VA:
 - a. An offer to be relieved as PI of the *Gulf War Follow-up Study*, even though the Complainant had not requested any such relief.
 - b. Offers of assistance from leadership relative to the Complainant's medical and emotional state, even though he never requested any such assistance or any reasonable accommodation.
 - c. The statement that one of four options open to the Complainant with regard to his performance plan was to seek employment elsewhere.

Recommendations:

1. ORO recommends that OPH leadership receive targeted human resources training regarding dispute resolution, reasonable accommodations, dealing with medical information in the workplace, and refresher supervisory training.
2. ORO also recommends that OPH leadership consult both the Office of Workforce Management and Consulting and the Office of General Counsel for advice prior to acting on difficult personnel matters.

Recommendation Regarding the Need for Additional Review

ORO was charged to make a recommendation to the USH regarding the need for a full scale official investigation of the allegations.

ORO believes that the allegations have been adequately addressed by this ORO Special Review and the recommendations above.

ORO does not recommend that a full scale official investigation be conducted.

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I. INTRODUCTION AND METHOD OF REVIEW

The Office of Research Oversight (ORO) serves as the primary Veterans Health Administration (VHA) office for advising the Under Secretary for Health (USH), and conducting compliance oversight, related to the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information protection, and research misconduct. ORO also oversees Governmentwide debarments for research impropriety and conducts education programs for facility Research Compliance Officers (RCOs).

ORO was charged (Appendix A) with conducting a special review of allegations related to research conducted by the VHA Office of Public Health (OPH) presented by a former OPH employee during a Hearing of the Subcommittee on Oversight and Investigations of the United States House of Representatives Committee on Veterans Affairs (*March 13, 2013, Gulf War: What Kind of Care are Veterans Receiving 20 Years Later?*).

The purpose of the review was to evaluate each allegation, make findings of fact, draw conclusions, and provide recommendations to the USH regarding the need for a full scale official investigation of the allegations.

ORO's review included individual interviews with the Complainant, OPH leadership and professional staff, and the Chair of the Institutional Review Board (IRB) with responsibility for oversight of the research (Appendix B) and an evaluation of over 3000 pages of relevant documentation, including research protocols, e-mail and other communications, and approximately 40 published articles (Appendix C). In addition, draft report findings were forwarded to the Complainant, OPH and the IRB Chair for factual corrections.

II. OVERVIEW – VHA OPH

The mission of OPH is to improve Veterans' health, including special populations of Veterans, through prevention and treatment, outreach, and surveillance. OPH serves as VHA's leader and authority in public health, a core element essential to serving and honoring America's Veterans. OPH is also responsible for managing programs to protect the safety and health of VHA employees.

The mission of OPH is implemented through four foundational components: surveillance and epidemiology; service to underserved populations; disease prevention, risk reduction, and health promotion; and public health policy and guidance. OPH is organized as follows:

- The Post-Deployment Health Group includes programs on environmental health, epidemiology, and the War-Related Illness and Injury Study Centers. The group is directed by the Chief Consultant for Post-Deployment Health and includes the Epidemiology Program in which the Complainant worked.
- The Clinical Public Health Group includes programs on HIV and hepatitis C, influenza, tobacco and health, health care quality, and surveillance and research.
- The Population Health Group works to improve Veteran health by identifying, assessing, and reporting on Veteran populations and the factors and interventions influencing their health.
- The Occupational Health Group covers issues from violence prevention to bloodborne pathogens and has major responsibility for VHA's Workers' Compensation Program.
- The Veterans Emergency Management Evaluation Center (VEMEC) identifies best practices to mitigate, prepare for and respond to national emergencies and natural disasters.

OPH and its employees conduct research related to its mission. The allegations presented at the House Veterans Affairs Subcommittee Hearing on March 13, 2013, involved three studies, all conducted by the OPH Post-Deployment Health group and all reviewed and approved by the IRB and the Research and Development Committee (R&DC) at the Washington, DC Veterans Affairs Medical Center (DCVAMC):

1. *National Health Survey of Persian Gulf Veterans and Their Families (VA Cooperative Studies Program (CSP) 458, DCVAMC IRB Protocol #0074); Principal Investigator (PI), 1996-2001, no longer employed by VA). The National Health Survey was conducted to determine the prevalence of a wide variety of symptoms and diseases, and to evaluate*

whether 15,000 deployed and 15,000 non-deployed Veterans and their family members experienced adverse health outcomes associated with the Persian Gulf War. A follow-up survey of this population was conducted in 2004-2005. The 1996 study included three Phases; Phases I and II (postal and telephonic survey data collection) were funded and performed by OPH. Phase III (the family portion) was funded and performed by the Office of Research and Development (ORD).

2. *Health Surveillance for a New Generation of US Veterans (sometimes referred to as the National Health Study for a New Generation of US Veterans, DCVAMC IRB Protocol #01167; PI, 2008-2009, no longer employed by VA; PI 2009-present, [Complainant's supervisor]).* The *New Generation Study* periodically assesses the health status of 30,000 deployed and 30,000 non-deployed Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) Veterans by comparing chronic medical conditions, post-traumatic stress disorder (PTSD) and other psychological conditions, general health perceptions, reproductive health, pregnancy outcomes, behavior risk factors, functional status, mortality, health care utilization, and VA disability compensation between these two Veterans populations.
3. *Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans (DCVAMC IRB Protocol #01366; PI, 2011-2012 [Complainant]; PI, 2013–present, [OPH professional staff]).* The *Follow-up Study* assesses the health status of Veterans of the 1991 Gulf War and Veterans who served during the same era but who were not deployed to the Persian Gulf, by comparing chronic medical conditions, PTSD and other psychological conditions, general health perceptions, functional status, mortality, health care utilization, and VA disability compensation between these two Veteran populations. Other objectives are to understand better the natural history of chronic fatigue syndrome-like (CFS-like) illness, unexplained chronic multisymptom illness (CMI), psychological disorders and other health conditions 20 years after deployment.

III. ALLEGATIONS AND FINDINGS

The USH directed ORO to review 10 specific allegations:

Allegation #1: Policy Bias

The Complainant alleged that OPH does not release studies that do not support its policy bias against a neurological basis for Gulf War illness (also see Allegation #2 regarding data availability).

Findings

The Complainant testified that “If the studies produce results that do not support OPH’s unwritten policy, they do not release them. This applies to data regarding adverse health consequences of environmental exposures, such as burn pits in Iraq and Afghanistan, and toxic exposures in the Gulf War.” He also testified that “On the rare occasions when embarrassing study results are released, data are manipulated to make them unintelligible.”

When interviewed by ORO, the Complainant re-affirmed his belief that OPH leadership selectively chooses to analyze and report data that support a psychiatric, rather than neurological, basis for Gulf War illness, which OPH and the Institute of Medicine (*IOM, Committee on Gulf War and Health: Treatment of Chronic Multisymptom Illness*) have labeled “Chronic Multisymptom Illness” (CMI). He expressed dismay at the lack of urgency within OPH about conducting meaningful analyses of the wealth of data that it holds related to environmental exposures among deployed Veterans.

ORO’s interviews with OPH leadership and professional staff revealed substantive scientific and programmatic disagreements with the Complainant regarding priorities for analyzing and reporting data from the second and third large surveillance studies listed above (see also Allegation #3 below). These disagreements appear to have arisen in part because no specific *a priori* plans for hypothesis testing and data analysis had been developed when the studies were originally designed and implemented. Rather, study teams generated ideas for analytic strategies and publication topics after data had been collected, subject to approval by Post-Deployment Health leadership.

OPH leadership stated that the overall hypothesis “tested in OPH’s large cohort studies is the null hypothesis that the health of deployed Veterans is no different than that of non-deployed Veterans. These studies are not designed to examine one exposure and one outcome (like a controlled trial), but are hypothesis generating studies.”

OPH leadership and professional staff uniformly denied the existence of a bias within OPH against the importance of neurological factors in CMI (i.e., Gulf War Illness). All maintained that neurological, environmental, and psychiatric factors all played an important role in the development of CMI.

As indicated above, OPH leadership pointed out that their large epidemiological studies are not designed to assess etiology of disease. They can establish associations, but not causation. The *Follow Up Study* includes items about diagnosed neurological conditions (questions 8a- 9e in survey instrument), as recommended by the Gulf War Illness Research Advisory Council (RAC) (see Allegation #6 below). There are no questions in the survey instrument that could address a neurological basis for Gulf War Illness

Additionally, OPH provided examples of publications to refute the Complainant's allegations. For example, an OPH study published in the Archives of Environmental Health in 2002 (*Kang HK et al., Evidence for a deployment-related Gulf War syndrome by factor analysis. Arch Environ Health 57: 61-68, 2002*) reported that although five of the factors analyzed were very similar in the Gulf War and non-Gulf War Veterans groups, one of the factors in the Gulf War group, but not the non-Gulf War group, contained a cluster of symptoms consistent with neurological impairment. Symptoms specific to this factor were blurred vision, loss of balance/dizziness, tremors/shaking, and speech difficulty. The Gulf War Veterans who had all of the aforementioned symptoms also reported exposures to putative risk factors such as nerve gas, depleted uranium, etc., at a rate of 3 or more times higher than the other Gulf War Veterans.

Likewise, an OPH study published in the American Journal of Industrial Medicine in 2009 (*Barth SK et al., Neurological mortality among US veterans of the Persian Gulf War: 13-year follow up. Am J Ind Med 52- 663-670, 2009*) reported that although the risk of death due to Parkinson's Disease, and brain cancers was not associated with Gulf War service in general, Gulf War Veterans potentially exposed to nerve gas at Khamsiya, Iraq, and oil well fire smoke had an increased risk of mortality due to brain cancer.

The Complainant, in response to ORO's request for factual corrections, stated on May 13, 2013, that his allegation was primarily directed toward the current OPH leadership at the Post-Deployment Health Group, not OPH as a whole, and pointed out that there had been no publications on the neurological basis of CMI by the current Chief Consultant and/or the Acting Director of the Epidemiology Program despite the fact that there had been a wealth of data in the *New Generation Study*.

Allegation #2: Data Availability

The Complainant alleged that OPH does not make OPH data available to qualified researchers, i.e., OPH lacks a mechanism to share its databases with qualified VA researchers.

Findings

ORO's interviews with OPH leadership and professional staff confirmed that OPH has no formal mechanism for sharing its research databases outside OPH. Rather, OPH shares data under a "collaboration authorship" model, whereby interested VA and non-VA researchers may propose collaborative studies using OPH data. The relevant OPH research team evaluates the proposed study and decides whether or not to undertake the collaboration.

OPH leadership expressed the philosophy that OPH data should be open and available to other investigators following a reasonable period for OPH analyses and reporting. However, OPH currently has no written procedures for formal implementation of this philosophy. ORO noted that there are no current VA requirements for such a data availability policy.

Note: Although the VHA Committee on Public Access to VA Research Data recommended in Fall 2012 that data sharing be required only for studies supported by large awards from Office of Research and Development (ORD), this recommendation is likely to be modified to comply with a recent policy memorandum from the Executive Office of the President, Office of Science and Technology Policy (*Memorandum for the Heads of Executive Departments and Agencies, February 23, 2013*).]

Allegation #3: Selective Data Release

The Complainant alleged that the *Health Surveillance for a New Generation of US Veterans* (Section II, Study #2) produced data on exposures to pesticides, oil well fires, and pyridostigmine bromide and on medication usage, but OPH has not released these data.

Findings

ORO's interviews with OPH leadership and professional staff confirmed that OPH has not yet performed exhaustive analyses of data from the *New Generation Study*, including detailed analyses related to pesticide exposure, oil well fires, pyridostigmine bromide and medications. OPH professional staff pointed out that the *New Generation Study* did not ask any specific questions on pyridostigmine bromide.

OPH leadership indicated that programmatic priorities dictated that initial analyses of the *New Generation* data should focus on the key objectives of the study, particularly traumatic brain injury and post traumatic stress disorder. OPH leadership stated that a number of data coding problems, particularly problems related to the coding of subjects' deployment status, needed to be resolved prior to conducting more detailed analyses, such as analyses of the relationships between environmental factors and various health outcomes.

OPH professional staff noted that large epidemiologic studies require extended periods of time for data collection, data cleaning and analysis, manuscript preparation, and publication. For

example, although the *National Health Survey of Persian Gulf Veterans and Their Families* (Section II, Study #1, above) began in 1996, substantive results from the study only began to be presented at international conferences and published in major peer reviewed journals in May 2000 and extended through December 2006. This was said to represent the natural period of time for conduct of a scientific survey of a nation-wide population-based sample of Veterans.

The Complainant discounted these considerations, maintaining that detailed analyses related to exposures to pesticides, oil well fires, and pyridostigmine bromide, and to medication usage deserved immediate attention. In response to ORO's request for factual corrections, the Complainant stated that the *New Generation Study* dataset contained meticulously coded data on current medications, which could be used to examine medications used by Veterans who served during the 1990-1991 Gulf War over 22 years ago and suffer from chronic fatigue syndrome, chronic multisymptom illness, and related conditions. This again illustrates the substantive scientific and programmatic disagreements between OPH leadership and the Complainant regarding the priorities for analyzing and reporting data.

Allegation #4: Selective Data Exclusion

The Complainant alleged that, as the co-author of a paper on findings from the *New Generation Study* on the relationship between exposure to burn pits and other inhalation hazards and asthma and bronchitis in OEF/OIF, he was not permitted to include hospitalizations and doctors' visits, thus obscuring important associations.

Findings

ORO's interviews with OPH leadership and professional staff confirmed that leadership of the Post-Deployment Health group determined that the initial *New Generation* paper (*Barth S et al., Prevalence of Respiratory Diseases among Veterans of Operation Enduring Freedom and Operation Iraqi Freedom: Results from the National Health Study for a New Generation of U.S. Veterans*) would consist of a straightforward analysis of respiratory health conditions, although later papers could examine more detailed relationships requiring more complex analyses of "New Generation" data including hospitalizations and doctors' visits. The Complainant disagreed with this leadership decision. (See Chronology for Allegation #10, November 23-28, 2012.)

Leadership of the OPH Post-Deployment Health Group disputed the allegation that the decision to limit the scope of the first *New Generation* respiratory health paper was made to obscure important associations or preclude subsequent investigations of more subtle relationships in the data. Rather, leadership believed that the respiratory exposure analyses were too complicated to interpret without additional data cleaning and analysis.

In another example of continuing substantive scientific and programmatic disagreements with OPH leadership, the Complainant requested that his name be removed as co-author of a poster

presentation on findings from the *New Generation* study (Schneiderman A et al., *Population Prevalence Estimates of Screening Positive for TBI and PTSD: Results from the National Study of a New Generation of U.S. Veterans*). In response to the first author's request for the reason to remove his name from the poster, the Complainant stated that "the abstract for the poster presentation was submitted to the conference organizers without my knowledge, the materials for the poster were submitted for OPH clearance without my knowledge . . . My comments about deployment status are not reflected in the Discussion section of the poster. The focus of the poster is more on patient-level factors (e.g., obesity than societal problems like homelessness and unemployment."

On the other hand, when other OPH professional staff commented on one of the Complainant's manuscripts (Coughlin SS et al., *The Effectiveness of Monetary Incentive on Response Rates in a Survey of Recent U.S. Veterans*), the Complainant responded in a December 7, 2010, e-mail message that ". . . if your current perspective is that the paper has this many problems, I'm not sure how to respond. I am more familiar with the approach that all coauthors send an email to the first author indicating that they have read the article and agree with submission to the journal." In response to ORO's request for factual corrections, the Complainant pointed out that all the coauthors "had opportunities to provide comments over time as the article went through successive iterations" and that, a final consensus was obtained before the manuscript was submitted and published.

Allegation #5: Gulf War Family Registry Data

The Complainant alleged that "Another example of important data that has never been released are the results of the Gulf War Family Registry mandated by Congress. These were physical examinations provided at no charge to Gulf War veterans' family members. I have been advised that these results have been permanently lost."

During his interview, the Complainant clarified that the Gulf War Family Registry data to which he referred was the data derived from the *Persian Gulf Spouse and Children Examination Program*, not the data from Phase III of the *National Health Survey of Persian Gulf Veterans and Their Families*.

Findings

The *Persian Gulf Spouse and Children Examination Program* was mandated under section 107 of the 1994 Persian Gulf War Veterans Benefits Act (Public Law (PL) 103-466) which directed the Secretary of Veterans Affairs "to conduct a study to evaluate the health status of spouses and children of Persian Gulf War" Veterans and to provide diagnostic testing and medical examinations "to determine the nature and extent of the association, if any, between illness or disorder of the spouse or child and the illness of the Veteran." Results were to "be entered into the Persian Gulf War Veterans Health Registry."

The Program began in April 1996 (*Persian Gulf Dependents' Medical Exam Program Ineffectively Carried Out, US General Accounting Office, March 1998, GAO/HEHS-98-108*) and was extended (PL 104-262 section 352 and PL 105-368 section 107) at least through December 1999. VA and the Department of Defense reported in September 2002 that "The clinical evaluation protocol" included "a detailed medical history, physical examination, and laboratory testing as clinically required" for 434 spouses and 686 children of Gulf War Veterans (*Combined Analysis of the VA and DoD Gulf War Clinical Evaluation Programs, A Study of the Clinical Findings from Systematic Medical Evaluations of 100,339 US Gulf War Veterans*).

In interviews with ORO, the Chief Public Health Officer stated that she had never heard the Complainant expressing interest or concern about the Gulf War Family Registry data until the Complainant presented this allegation at the Hearing on March 13, 2013. OPH leadership indicated that attempts to locate the data had been unsuccessful as of the date of their interviews with ORO, but that discussions had been initiated with staff at the VA Austin Data Center to determine if the Data Center has any records from this program.

Subsequent to their interviews with ORO, OPH senior staff had discussed this issue with former OPH staff who had worked on the Family Registry program. The former staff provided information about the program and indicated that any medical records specific to individual family members would have been kept at the VA medical centers or fee basis locations where the family registry exams were conducted. Former OPH staff further stated that staff (and former staff) at the VA Austin Data Center indicated that records for the Family Registry were not moved to a new server when they upgraded their systems around 2005.

The Complainant, in response to ORO's request for factual corrections, provided ORO on May 15, 2013, with documentation indicating that one OPH Official, i.e., Acting Director, Epidemiology Program, knew about the existence and loss of the *Persian Gulf Spouse and Children Examination Program registry* data in 2011. Specifically, he was aware that the program lasted until 2005 and when he was informed by VA Austin Data Center that there was no longer any data available of the terminated "PGD" registry, he responded on November 17, 2011, that "This registry represents significant effort over a period of years and addresses a scientifically and politically important topic. Any idea about how to track this down?"

NOTE: The *Persian Gulf Spouse and Children Examination Program* (above) is to be distinguished from Phase III of the *National Health Survey of Persian Gulf Veterans and Their Families* (1998 – 2001) (Section II, Study #1), which was a research study that included physical examinations of 2,000 selected Gulf War Veterans and their family members (*Eisen, S.A., et al., Spouses of Persian Gulf War I Veterans: Medical Examination of a US Cohort, Military Medicine, 171: 613, 2006*). OPH leadership reported that all data from this study remain intact at ORD's Cooperative Studies Program Office at Hines, IL.

Allegation #6: Gulf War Illness Research Advisory Committee (RAC) Recommendations

The Complainant alleged that OPH failed to accept constructive recommendations from the RAC regarding the *Follow-up Study of a National Cohort of Gulf War and Gulf War Era Veterans* (see Section II, Study #3).

Findings

Interviews with the Complainant and OPH leadership and review of written documents established that OPH had accepted some, but not all, of the RAC's public recommendations on the *Gulf War Follow-up Study*. For example, the Complainant indicated that the number of questions about psychological conditions was reduced to provide room for questions on neurological conditions and that prompts were added throughout the survey to elicit additional information in narrative form as recommended by the RAC. Although he did not control the final version, the Complainant acknowledged that he had drafted substantial portions of the OPH response to the RAC recommendations. OPH made the following observations in its response to the RAC recommendations:

- OPH investigators are actively addressing many of the RAC's concerns, such as the need for comprehensive data on diagnosed medical conditions and information on use of health care services and treatments. All questions pertaining to diagnosed medical conditions and symptoms associated with Gulf War service have been retained, as have questions to assess the persistence of symptoms over time and the incidence and prevalence of major medical conditions.
- OPH published detailed pregnancy outcome data in 2001 and a validation study of reported birth defects is ongoing. Because many Veterans in this study panel are beyond their reproductive years or have adult children, the health of family members would be addressed more effectively in a separate study.
- OPH has developed a separate study to examine neurological mortality in Gulf War Veterans to focus on Parkinson's Disease, Amyotrophic lateral sclerosis, Multiple Sclerosis, and Brain Cancer.
- OPH researchers are active members of a Planning Committee for the VA CSP's large-scale genomics study and biorepository for Gulf War Veterans.

Allegation #7: Scientific Review of RAC Recommendations

The Complainant alleged that OPH officials failed to obtain an objective scientific review of, and made false statements to, the VA Chief of Staff regarding, the RAC recommendations regarding

the *Follow-up Study of a National Cohort of Gulf War and Gulf War Era Veterans* (see Section II, Study #3).

Findings

Interviews with the Complainant and OPH leadership established that the VA Chief of Staff (COSVA) requested that OPH obtain an objective scientific review of the RAC recommendations on the *Follow-up Study*.

The Complainant alleged that (i) the Chief Consultant for Post-Deployment Health contacted a friend, the Dean of a School of Public Health, who identified a faculty colleague with no background in Gulf War health research to conduct the review; (ii) the reviewer was told that the RAC's recommendations were politically motivated; and (iii) OPH leadership made false statements to the COSVA suggesting that modifying the survey to incorporate the RAC's recommendations would cost approximately \$1 million, delay the study one year, and possibly result in contract default.

In his interview with ORO, the leader of the Post-Deployment Health Group maintained that: (i) the Dean referenced above was not a personal friend but a professional acquaintance with whom he had not interacted substantively in over 20 years; (ii) the reviewer, an Air Force Veteran, was a full professor and the director of the Institute for Evaluation Science in Community Health at a respected university graduate school of public health who has conducted national health surveys for 40 years; (iii) he had no contact with the reviewer during the conduct of the review; (iv) it was the reviewer, not OPH personnel, who after completing the review, suggested that some of the RAC comments could have been motivated by non-scientific concerns; and (v) it was the VA Contracting Officer, not OPH staff, who provided the cost estimate of \$1 million and described the contracting issues that would result from halting the study for the 6 to 12 months that OPH professional staff estimated would be required to incorporate additional changes into the study.

ORO noted that one OPH official (i.e., the Acting Director of the Epidemiology Program) did call the Reviewer in the presence of the Complainant regarding logistics of the review after the Reviewer agreed to provide the review. The Complainant informed ORO that during the telephone conversation, the OPH official told the reviewer that the RAC's recommendations were politically motivated. However, the OPH official denied that he had ever made such a statement. As there were no other parties present during the telephone conversation, ORO was unable to obtain independent verification of their statements.

Allegation #8: Institute of Medicine (IOM) study

The Complainant alleged that OPH officials chose witnesses biased in favor of psychiatric causes for a Congressionally mandated IOM study of treatments for CMI in Gulf War Veterans.

Findings

The IOM is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public. Established in 1970, the IOM is the health arm of the National Academy of Sciences (see IOM website at <http://iom.edu/About-IOM.aspx>). The IOM secures the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public.

The committee responsible for the IOM report on *Gulf War and Health: Treatment for Chronic Multisymptom Illness* published January 23, 2013, was comprised of 15 independent experts from prestigious US medical facilities and universities. In developing its report, the committee conducted a systematic review to evaluate the scientific literature, commissioned an analysis of social media to understand better the experiences of veterans who have CMI, and held three public meetings to hear from invited speakers. Presentation topics included general information on CMI, current practices and capabilities in the Veterans Health Administration, current understanding of the underlying mechanism of CMI, treatments for CMI, and how health information technology is being used in managing chronic conditions. Members of the public were given the opportunity to share information and experiences with the committee at the public meetings. Written materials submitted by the public also were considered by the committee. Two senior health care experts, appointed by the National Research Council and the Institute of Medicine, were responsible for making certain that an independent review of the report was carried out in accordance with institutional procedures and that all review comments were carefully considered. (See report at <http://www.iom.edu/Reports/2013/Gulf-War-and-HealthTreatment-for-Chronic-Multisymptom-Illness.aspx>).

OPH leadership uniformly maintained that its personnel did not interfere in any way with the independent IOM review process. The IOM study chairman verified this in his Congressional testimony and stated that VA had no authority to appoint IOM panel members or call witnesses. ORO identified no credible information to the contrary.

Allegation #9: Follow-up of Suicidal Ideation

The Complainant alleged that OPH officials failed to provide adequate follow-up of Veterans who self-reported recent thoughts that they would be better off dead (i.e., suicidal ideation) in (a) the *Health Surveillance for a New Generation of US Veterans* study (Section II, Study #2) and (b) the *Follow-Up Study of a National Cohort of Gulf War and Gulf Era Veterans* (Section II, Study #3)

Findings

New Generation Study (Section II, Study #2).

Document reviews and interviews established that the original plan for the *New Generation Study* did not describe any procedures for contacting Veterans who self-reported suicidal ideation on the on-line and paper-and-pencil (i.e., mail) surveys that they filled out, although an information sheet and a contact number for the VA Suicide/Crisis Hotline was provided in case survey questions precipitated undue stress for the Veteran.

However, a plan was developed to follow-up with Veterans who participated in the study through Computer Assisted Telephone Interviews (CATI) and provided a positive response to thoughts of self-harm or made comments that raised concerns of the telephone interviewers. CATI calls began on March 9, 2010, and ended on May 2, 2010. Of the 1360 completed CATI interviews, 92 Veterans (14.8%) required a follow-up call from a study team clinician. A study team clinician spoke to 52 of these 92 Veterans (56.5 %) and left at least one voice mail message with an additional 36 Veterans (39.1%). The clinician was unable to leave a message for the four remaining Veterans (4.3%). (Memorandum from PI to IRB, November 23, 2010)

ORO's interview with the Chairperson of the DCVAMC IRB, which had oversight responsibility for the *New Generation Study*, revealed that the IRB's expectations for follow-up of suicidal ideation expressed in survey research has evolved in the period from 2008, when the *New Generation Study* began, to the present. The Chair stated that while the IRB had previously focused on requiring mental health personnel call backs for the CATI subjects and maintaining the confidentiality of responses to online and paper-and-pencil surveys, the IRB has begun to focus increasingly on the need for active follow-up of suicidal ideation appearing in the online and paper-and-pencil surveys.

Thus, lack of active follow-up for suicidal ideation in the on-line and paper-and-pencil surveys from the *New Generation Study* was not considered problematic by the IRB at the time the study was conducted, and the approximately 2000 Veterans who expressed suicidal ideation in their on-line and paper-and-pencil surveys were not at that time considered by the IRB to be at undue risk.

In his interview with ORO, the Complainant maintained that in 2012, he drafted a manuscript (*Post-Traumatic Stress Disorder and Other Predictors of Total Mortality in a Longitudinal Study of US Veterans Who Served During the 1990-1991 Gulf War or During the Same Era, unpublished*) demonstrating that PTSD and major depression in the 2004-2005 follow-up of the *National Health Survey of Persian Gulf Veterans and Their Families* (Section II, Study #1) were predictors of participant mortality through February 2012. He claimed that his supervisor would not review the manuscript and never advanced it for OPH clearance. He asserted that the predictive relationship described in the manuscript demonstrated the critical need for clinical

follow-up of Veterans displaying suicidal ideation in the *New Generations Study and the Gulf War Follow-up Study (below)*.

E-mail correspondence from the Complainant’s supervisor (dated October 16, 2012) cited recently discovered limitations/problems with death data from the VA Beneficiary Identification and Records Locator Subsystem (BIRLS) and the Social Security Administration (SSA), which were the basis for the Complainant’s analysis in the manuscript, and expressed a need to utilize the more reliable National Death Index (NDI) compiled by the Centers for Disease Control and Prevention (CDC). OPH leadership indicated to ORO that NDI data are not yet available for Veterans in the *New Generation Study*.

E-mail correspondence from the Complainant to his supervisor (dated November 20, 2012) reported the following analyses of self-reported suicide attempts in the *New Generation Study* data set: “Of 18, 696 Veterans who responded to the question about hospitalizations, 17 (0.1%) self-reported that they had been hospitalized for the past 12 months for a suicide attempt. Among the 17 Veterans, the number of hospitalization for suicide attempts ranged from 1 to 6 in the past 12 months . . . only 7 of the 17 had ever received VA health care services. A total of 13 of the 17 Veterans (76.5%) had probable PTSD . . . About 75% of the 17 Veterans had probable major depression . . . On the draft paper on major depression for the [*New Generation Study*], which I prepared in September, I have received comments from . . . but not from [the Complainant’s supervisor]. A major reason that paper has not moved forward is I don’t have the sampling weights for the final deployment status variable.”

Gulf War Follow-up Study (Section II, Study #3)

ORO developed the following chronology of events based on document reviews and interviews.

- 11/14/2011 The IRB granted initial approval of the *Gulf War Follow-up Study*. Like the *New Generation Study*, the approved protocol included call back procedures for CATI subjects who might express emotional distress due to the interview. However, it did not contain procedures for contacting Veterans who self-reported suicidal ideation on their online and paper-and-pencil surveys, although an information sheet and the telephone number for the VA Suicide/Crisis Hotline was provided with each survey.
- 05/21/2012 Advance letters signed by the Secretary of Veterans Affairs were sent to Veterans for participation in the pilot phase of the *Gulf War Follow-up Study*.
- 05/25/2012 In follow-up to a February 2012 discussion between the Complainant (as study PI) and the IRB Chair, the Complainant, his supervisor, and a member of the study team met with the IRB Chair and the IRB Coordinator to discuss a plan to identify Veterans displaying suicidal ideation or distress (i.e., “Hot Comments”) on their on-line and paper-and-pencil surveys. The plan called for these three

individuals (two epidemiologists without clinical training and a nurse) to telephone the identified “Hot Comment” Veterans and, if the Veteran agreed, perform a “warm transfer” to the VA Suicide/Crisis Hotline. During this meeting, the IRB Chair indicated that OPH needed to identify mental health clinicians to perform these call-backs. The IRB Chair stated during his interview with ORO that he left the meeting with the impression that OPH would proceed to do so.

06/01/2012 The IRB approved an amendment adding the following statement to the informed consent document for the *Gulf War Follow-up Study*: “If your answers indicate that you plan to harm yourself or someone else, VA may directly contact you and others who can provide you with assistance.”

06/11/2012 The Complainant submitted an amendment, approved by his supervisor, to the IRB office under which study personnel would telephone Veterans who displayed “Hot Comments” on their on-line and paper-and-pencil surveys and, if the Veteran agreed, perform a “warm transfer” to the VA Suicide/Crisis Hotline.

The protocol amendment contained procedures for the survey contractor to identify on-line or paper-and-pencil survey responses that indicated the potential to harm or threaten self or others, and included a list of approximately 100 words or phrases that signaled such potential,

The Complainant’s supervisor approved the submission of the “Hot Comments” amendment on June 8, 2012. However, the Complainant notified his supervisor that he had modified the language of the amendment prior to submitting to the IRB on June 11, 2012, to include all three study personnel, i.e., the Complainant (PI), his supervisor (a nurse), and one non-clinical professional staff, to conduct the call backs. The Complainant’s supervisor immediately expressed reservations to the Complainant about research personnel being responsible for all the call backs. The Complainant offered to withdraw the amendment, but did not do so. Later that day the Supervisor informed the Complainant that he could not accept responsibility, as the study team’s only clinician, for the large number of call-backs that would be needed under the amendment.

06/12/2012 At 9:00 am, the Complainant met with the Post-Deployment Health Group’s Administrative Officer (AO), the Chief Consultant for Post-Deployment Health, his supervisor, professional staff for the *Gulf War Follow-up Study* to report that there was inadequate staffing to support and complete the study, and that he was the only person available to conduct call-backs to study participants who expressed an intention to harm themselves or were in psychological distress. The Chief Consultant directed that the “Hot Comments” plan be sent to the Office of General Counsel (OGC) for review, thinking that the information sheet and VA

Suicide/Crisis Hotline information provided to study participants were sufficient, and that it was not immediately necessary to identify clinical staff for the study.

At 10:00 am, the Chief Consultant and other senior OPH leaders convened for their weekly meeting, during which the Chief Public Health Officer directed that the Complainant be instructed to withdraw the “Hot Comments” amendment, evaluate data from the study’s pilot phase to determine the appropriate course of action, prepare a plan for handling his concerns accordingly, and defer review by OGC until these actions were accomplished.

At 12:01 pm, the Complainant’s supervisor directed him by e-mail to withdraw the call-back provisions of the “Hot Comments” amendment pending an evaluation of need and to prepare a “clinical plan” with criteria for triggering follow-up telephone calls.

At 12:56 pm, the Complainant e-mailed the IRB Chair requesting suspension of IRB approval of the *Gulf War Follow-up Study* due to inadequate staffing, including a lack of “trained psychologists or psychiatrists to join the research team in order to help refine and implement the procedures for protection of human subjects.” The complainant expressed that he was unable “in good conscience to mail out 500 PI letters and gather information” from Veterans without the ability to make follow-up calls to Veterans reporting psychological distress.

At 1:55 pm, the IRB Chair replied that, rather than having the IRB suspend study approval, the Complainant (as study PI) should send the IRB a protocol modification suspending study activities pending resolution of the staffing issues. The Complainant replied that he would prepare such a modification but doubted that it would be approved for delivery by his supervisor.

At 3:20 pm, the Chief Consultant for Post-Deployment e-mailed the Chief Public Health Officer, forwarding the Complainant’s 12:56 e-mail to the IRB Chair and commented: “I spoke with [the Complainant] a few minutes ago in his office and told him that was not what he was asked to do. He indicated that it was his responsibility as PI to do so. I informed him that wasn’t his decision to make without first discussing such a decision with [his supervisor] and me. He then stood up and indicated that he was going to talk to you and get the number for the IG. While I was talking to him, he turned his back on me in his office and walked out his door. I consider this insubordination and would like to set up a meeting with you and [the Complainant’s supervisor], [the Complainant] and me.

At 3:15 pm, the Complainant approached the Office of Inspector General (OIG) for assistance in dealing with three concerns: (i) notification to the IRB of

insufficient resources to conduct the *Gulf War Follow-up Study* with adequate protections for human subjects; (ii) direction from OPH leadership to retract the notification to the IRB; and (iii) workplace hostility and increased scrutiny after raising these concerns.

At 4:49 pm, the Complainant e-mailed the IRB Chair that the Chief Public Health Officer had indicated that a “clinically trained psychologist or psychiatrist” would likely be identified “in the next week or so to join the study to facilitate refinement of the clinical procedures.” This was contrary to the OPH Leadership determination that the call-back provisions of the “Hot Comments” protocol amendment must be withdrawn and a new protocol be submitted that included “clinical triggers” for making callbacks by appropriately trained personnel and that the protocol define data collection and analysis parameters so that OPH could learn about opportunities for intervention in survey respondents who express suicidal ideation or other mental health issues.

06/13/2012 At 8:28 am, the Complainant’s supervisor e-mailed the IRB Chair indicating that OPH leadership had met the previous day “to resolve the issues regarding safety of research subjects addressed in earlier email and to develop a resolution and plan. The plan includes requesting the retraction of the amendment to consider [the] “hot comments” protocol until we can evaluate the pilot results, gauge demand for enhanced response to actionable comments, develop a clinical plan to adequately and safely respond to research subjects, and engage personnel with appropriate professional credentials to support this response. The proposed protocol enhancements are understood to be a positive advance in the protection of research subjects; OPH leadership is in agreement with the study team that an intervention of this nature is the right thing to do. However it must be done responsibly to assure successful protection for research subjects. We plan to put this in place as quickly as possible.”

At 8:42 am, the Complainant e-mailed the IRB Chair: “By raising these concerns, I have been exposed to pronounced hostility in the workplace, questions about my willingness or ability to continue to serve as principal investigator of the Follow-up Study of a National cohort of Gulf War and Gulf War Era Veterans, and most recently, questions about my own mental health . . . As noted, the concern is over U.S. Veterans in this large panel who may report suicidal ideation or other pronounced psychological distress and the timeliness of a response from VHA. Yesterday I was asked by OPH to retract my email to the IRB Office and to [OIG] but declined.” In responding to ORO’s request for factual corrections, OPH officials stated that they have never asked the Complainant to retract his e-mail to OIG.

At 2:36 pm, OIG e-mailed the Complainant recommending that he pursue “established channels of relief” as follows: ORO regarding human subject protection concerns; Human Resources Management or the VA Resolution Support Center regarding workplace conflict; and the Office of Special Counsel regarding alleged whistleblower reprisal.

06/15/2012 The Chief Public Health Officer e-mailed the ORO Chief Officer: “One of my staff members, the study PI, has become concerned that a research study using survey methodology (IRB-approved; OMB approved) we’re sending to Veterans does not include adequate safeguards if the survey should identify Veterans at risk for suicide or other extreme behaviors. The PI asked the IRB to stop the study; the IRB Chair responded that the PI should stop the study. The PI asked the OIG to review the study; the OIG referred the PI to ORO. The PI’s supervisor and I want to keep the study going for several reasons. I don’t agree that taking the survey either places Veterans at risk for destructive behaviors or fails to provide safeguards should mental health issues be identified in respondents (e.g., printed survey refers Veterans to the crisis hotline in several places; telephone interviews have similar instructions). But I realize standards may have changed and I think we may want another set of eyes on this protocol for appropriate human subjects use – would ORO review the study?”

The ORO Chief Officer replied: “1. The PI has an obligation to (a) remain informed about the current state of scientific knowledge relevant to the study (e.g., by keeping up with the scientific literature and/or seeking input from subject matter experts as warranted); (b) inform the IRB (in writing) if the PI identifies new risks or risks that were not originally evaluated; and (c) propose modifications to address such risks. 2. If the PI genuinely believes that the study places subjects at undue risk, then the PI should voluntarily suspend enrollments pending the IRB’s review and its determination that the study can continue, either under the existing protocol or under an amended protocol. 3. Whether or not the PI believes suspension of enrollments is warranted, the IRB has an obligation to evaluate the newly identified risks and proposed modifications that the PI has identified. If the IRB’s members lack the scientific expertise to evaluate these risks, the IRB is required [to] obtain that expertise through the use of ad hoc consultants. Hope this helps – we can discuss if needed.”

06/25/2012 Survey packets soliciting participation in the *Gulf War Follow-up Study* were mailed to a total of 500 Veterans, randomly sampled from the overall panel, for the pilot phase of the study (Source: OPH Data Collection Progress Report). OPH staff indicated that the survey packet included the informed consent document approved by the IRB on June 1, 2012.

- 06/28/2012 In an e-mail to the Complainant's supervisor (the Complainant was on leave), the IRB Chair clarified that the current status of the *Gulf War Follow-up Study* was that "the IRB did not suspend the study when informed that staffing might become inadequate. We suggested that the PI himself could restrict the activity until he could predict the future course . . . the ball is still in your court."
- 07/17/2012 In response to a query from the Complainant's supervisor, the Director of a Veterans Integrated Health Service Network (VISN) Mental Illness Research, Education, and Clinical Center (MIRECC) indicated that there was no scientific evidence to support the predictive validity of free-text survey comments and no data "to support which if any text would predict future dangerous behavior." She maintained that investigators "are always dealing with the tension between protecting the safety and privacy of participants" and noted that "many of our IRB protocols include safety procedures which require breaches of privacy only in the case of imminent risk."
- 07/27/2012 The Complainant's supervisor invited the Director of the War-Related Illness and Injury Study Center (WRIISC) at the District of Columbia (DC) VA Medical Center to assist in developing the safety plan for the study.
- 07/31/2012 The DC WRIISC Director stated the following in response to a query from the Chief Consultant for Post-Deployment Health: "If someone is in enough crisis/depression/pain to write in free text space that they are considering harming themselves, I think we need to call that person immediately . . . In terms of the paper copy of the questionnaire . . . question 28i asks about "thoughts that you would be better off dead or of hurting yourself in some way" . . . I think it is best to reach out to a Veteran who might be in need . . . can you answer why it is you asked questions about suicide, got an answer, but never reached out to the Veteran . . . However, keep in mind, if even 1% of 30K people acknowledge anything other than "not at all" you are looking at 300 phone calls . . . it might be worthwhile to think this through some more. You might need a contractor (or I can work after hours for you if need be . . .)."
- 08/01/2012 The DC WRIISC Director initiated call-backs to Veterans in the pilot phase of the study. The OPH Data Collection Progress Report shows that 167 Veterans had participated in the study (50 via the web, and 117 through paper-and-pencil surveys) between May 29 and July 31, 2012. Of these 167 Veterans, call-backs were made to the 6 participants (3.6%) who responded that they had "thoughts that you would be better off dead or of hurting yourself in some way" more than half the days or nearly every day in the past two weeks.
- 09/10/2012 Letters and survey packets were sent to Veterans for participation in the main phase of the *Gulf War Follow-up Study*. For the main phase of the study, the call-

back plan was expanded to include any positive response to having “thoughts that you would be better off dead or of hurting yourself in some way” within the past 2 weeks.

- 01/01/2013 As of this date, a team of licensed clinical social workers and psychologists had completed 1,331 calls to *Gulf War Follow-up Study* Veterans.
- 01/31/2013 As of this date VHA clinical personnel had been able to contact 984 of these 1,331 Veterans directly, 48 of whom were referred to the VA Suicide/Crisis Hotline for immediate assistance.

In their interviews with ORO, OPH leadership emphasized their belief, based on past experience and the original IRB approval of the study without follow-up of suicidal ideation, that the pilot phase of the study did not put the 500 eligible participants at undue risk. They also expressed strong reservations that call-backs to study participants could be viewed by Veterans as a violation of longstanding privacy and confidentiality guarantees and thereby undermine Veterans’ trust in future OPH surveys.

In the view of OPH leadership, a plan for follow-up of suicidal innovation represented a desirable innovation, rather than an immediate need, and believed that such a plan could await an evaluation of pilot results, identification of appropriate clinical indicators, and arrangements to involve mental health professionals for call-backs. They indicated that the study had already been delayed and OPH felt pressure to initiate and complete the study’s pilot phase. OPH leadership stressed that the Complainant was directed in June 2012 to develop a specific “clinical plan” for follow-up telephone calls but that he failed to produce such a plan.

The Complainant, on the other hand, emphasized his frustration at what he considered to be resistance from OPH leadership in the face of an immediate need to ensure the safety of Veterans in the *Gulf War Follow-up Study*. He pointed out that the *New Generation Study* had successfully implemented a follow-up procedure for Veterans participating via live interviews (CATI) and that many of those Veterans had required a follow-up call from a study team clinician.

The Complainant also noted the involvement of his supervisor in the May 2012 meeting with the IRB Chair to discuss follow-up procedures for Veterans displaying suicidal ideation and the June 2012 approval by his supervisor of the “hot comments” IRB protocol amendment, which included detailed procedures for follow-up calls, but which OPH leadership directed him to withdraw. He suggested that concerns that call-backs would violate the privacy of survey participants, expressed by OPH leadership as late at July 2012, were unfounded because the informed consent document for the study had been modified in early June 2012 to provide for direct contact with Veterans if their responses suggested plans to harm themselves or others.

In response to ORO's request for factual corrections, the Complainant provided documentation demonstrating that he began to address leadership's direction to develop a specific "clinical plan" for follow-up telephone calls by identifying existing clinical plans posted on the VA website and sending that information to OPH officials. The Complainant stated that he then went on a scheduled vacation and, upon his return, received an e-mail from his supervisor indicating that the clinical follow-up plan had been developed in his absence. However, the Complainant felt that the leadership plan did little to assist suicidal research participants enrolled in the study.

As indicated previously, the IRB Chair stated during his interview with ORO that the IRB's expectations for follow-up of suicidal ideation in survey research have evolved over the past several years such that while the IRB had previously required mental health personnel call backs for only the CATI subjects, the IRB has begun to focus increasingly on the need for active follow-up of suicidal ideation appearing in the online and paper-and-pencil surveys.

In e-mails to ORO on April 17 and April 23, 2013, the IRB Chair reiterated his belief that their meeting on May 5, 2012, had resulted in a commitment by OPH "to the new process for monitoring potential adverse emotional events" of the online and paper-and-pencil surveys in the *Gulf War Follow-up Study*. He indicated that this was apparently not the case, as multiple e-mails on June 12-13, 2012, suggested that the issue was being revisited by OPH leadership and that there was "no one spokesperson for the protocol." From the IRB's point of view, "the bottom line was that we did not understand why or whether they wanted to eliminate a process which apparently they had endorsed."

The IRB Chair suggested that he is just now realizing "an important reality" in dealing with VA Program Offices that wish to use the DCVAMC IRB; specifically, that the IRB could no longer assume that the research of Program Office employees was self-initiated and self-contained and that the study PI "had all of the responsibilities and authority implicit in that designation." This reality began to become apparent to him only when the Complainant "indicated that he was not empowered to temporarily suspend his research without ratification by the OPH leadership." He further stated that "the older model is no longer tenable if the true PI is the VACO staff and the designated PI takes a role akin to that of the local site investigator in a cooperative study. Of equal importance is the apparent change in the goal of the research to those immediately relevant to the programmatic functions of the VA office involved."

Allegation #10: Threats against the Complainant

The Complainant alleged that OPH officials threatened the complainant (a) when he wanted to include hospitalizations and doctors' visits in the initial *New Generation* paper (*Barth et al.*, see Allegation #4) and (b) when he reported to the IRB and OIG the need for follow-up of Veterans reporting suicidal ideation in the *Gulf War Follow-up Study* (see Allegation #9).

Findings

In addition to the chronology provided for Allegation #9, above, ORO identified the following events, based on document reviews and interviews, relevant to Allegation #10.

07/26/2011 The Complainant received an e-mail from his supervisor regarding his behavior during a group meeting: "I felt your behavior this morning during the [*New Generation Study*] meeting was inappropriate abrupt and rude. You were describing . . . a point which I do not find fault. When I was trying to raise another related point, you interrupted me . . . I tried to continue and in an effort to get you to yield the floor back to me said "chill" because it seemed that you were talking and unwilling to listen – I hope to continue with "please let me finish". However you stood and said something to the effect of "I have other things to do" and left the meeting room. This was not respectful or appropriate of anyone in the room. I think everyone has the right to be heard and must be willing to take feedback as well."

In response to ORO's request for factual corrections, the Complainant stated the following on May 13, 2013, but did not provide supportive documents (even after ORO requested such on May 14, 2013):

What actually happened is that I wrote a letter to the Editor of the *New England Journal of Medicine* that was coauthored by [the Chief Consultant and the Deputy Chief Consultant]. When [my supervisor] found out, he became agitated and treated me in a disrespectful way in front of coworkers. I left the room at the end of the scheduled meeting and sent an email to him, cc'd my email to [the Chief Consultant and the Deputy Chief Consultant] and asked [my supervisor] to please not berate me in front of coworkers. He then drafted the email that you received a copy of from OPH. My letter to the Editor of the *New England Journal of Medicine* was not cleared for submission to the journal, even after I substantially revised it to address [my supervisor's] concerns.

08/05/2011 The Complainant received an e-mail from his supervisor reminding him of the importance of Program priorities: "I really need you to apply your analytic and creative energy to developing the [*New Generation Study*] data we have into papers. I have recently sent the prioritized list agreed upon by [the Chief Consultant for Post-Deployment Health]. I know you have many ideas that will begin to satisfy the important topic areas included on the list and can generate important publications."

09/13/2011 The Complainant received an e-mail from his supervisor reminding him of the importance of Program priorities: “Please understand that the Service Directed Research Efforts of [the Post Deployment Health Epidemiology] Program remain the priority, regardless of other investigator initiated projects that may be developed.”

06/11/2012 See Chronology for Allegation #9.

06/12/2012 See Chronology for Allegation #9.

In a memorandum to the record, the Chief Public Health Officer stated that she had met privately with the Complainant on the afternoon of June 12, 2012, to express “concern for him personally, to ask whether he was well and whether he is feeling strong enough to be taking on a difficult workload as PI of a study. He stated that he is well, is happy to be PI . . . “

06/13/2012 See Chronology for Allegation #9.

06/15/2012: The Complainant e-mailed the Special Advisor to the Secretary of Veterans Affairs requesting administrative reassignment due to workplace hostility.

07/09/2012 A Letter of Admonishment to the Complainant from the Complainant’s supervisor detailed the following:

Charge 1. Failure to Follow Instructions.

Specification 1: “ . . . you received written instruction . . . to . . . notify the IRB we would like to withdraw the portion of the hot comments protocol that results in a direct response’ . . . in connection with an important national health study of Gulf War and Gulf War Era Veterans. You were also specifically informed in writing that ‘there should be no reason to alter the consent at this time – everything should be able to proceed, except implementation of follow-up calls by OPH. Despite receiving these instructions, you contacted the IRB and requested that the IRB suspend approval for” the *Gulf War Follow-up Study*.

Specification 2: “ . . . you received verbal instructions from [the Chief Public Health Officer] to notify the IRB indicating that the amendment is withdrawn until further notice and that the study, as approved by the IRB, should continue. Despite receiving these instructions, you contacted the IRB Chair and informed him that” you had been asked by [the Chief Public Health Officer] to inform him that “it is a likely that a clinically trained psychologist or psychiatrist will be identified in the next week or so to join the study to facilitate refinement of the clinical procedures.”

Charge 2. Disrespectful Conduct:

Specification: While [the Chief Consultant for Post-Deployment Health “was speaking to you in your office, you stood up, turned your back on [him], and walked out of your office.”

- 07/16/2012 The Complainant received the above letter of admonishment upon his return to the office from vacation.
- 08/13/2012 Following the Complainant’s appeal of the admonishment on July 20, his e-mail expressing an informal grievance on July 23, and a meeting with his supervisor on July 24, the Complainant’s supervisor notified him by letter that the admonishment would stand “without alteration.” The Complainant thereupon submitted a formal grievance to the VHA Deputy Under Secretary for Health for Policy and Services (DUSHPS).
- 09/20/2012 The Complainant received an e-mail from his supervisor summarizing their meeting on the previous day: “During the meeting I described the importance of focusing your efforts on topics that are directly relevant to the mission of the Post-Deployment Health Group/Epi Program and veteran-centric topics. I reiterated that we had talked about the need to focus on veteran-centric topics in the past. This message comes after multiple self-initiated work products that are outside the post deployment health group mission or tangential to Veterans. I requested that you focus on developing papers and using data already in place in EPI/PDHG. Especially important are papers that fully explore the [Gulf War] longitudinal data that are describing and investigating the course of health based on data points we have collected . . . During the discussion of topics below you brought up your concern about a need for analyst or statistician support and we talked about possible ways to satisfy this.
- 09/21/2012 The Complainant responded to the above e-mail from his supervisor: “My written employee performance plan requires me to write 2 manuscripts a year. I wrote 14 in the past year . . . You did say during our mtg yesterday that you ‘may wish to re-assign the [Gulf War Follow-up Study] to someone else who needs the experience.’ My reading on that is that is clear evidence of further retaliation for blowing the whistle to VA Leadership.”
- 09/27/2012 The Chief Public Health Officer in an e-mail sent to the Chief Consultant for Post-Deployment Health raised the possibility of requesting, through Human Resources, a “fitness for duty” examination for the Complainant to determine if his working situation is appropriate to his health and wellbeing and “to help his leadership determine how best to tailor his work and working situation to meet his needs as well as those of the office.”

- 10/02/2012 A memorandum from the Assistant DUSHPS offered, and the Complainant accepted, a resolution of his formal grievance through acceptance, in lieu of the admonishment, of written counseling that recognized the motivation for the Complainant's actions.
- 11/23/2012 At 10:00 am, the Complainant sent an e-mail to members of the Post-Deployment Health group suggesting that a number of additional analyses related to asthma and emphysema be included in the first respiratory paper based on the *New Generation Study*: "I recommend [extension of] logistic models (for asthma, bronchitis, sinusitis) and [including] design variables for number of deployments (not an ordinal variable like 0, 1, 2, 3 but rather 3 design variables indicating whether they were deployed to OEF/OIF once, twice, three or more times, or not at all."
- At 11:28 am, the Complainant's supervisor responded: "Some of the work that was previously done [by other members of the Post-Deployment Health Group] had looked at deployment, number of episodes and other parameters associated with exposure. The decision was made to proceed initially with a straight forward analysis. As I stated in my earlier message, subsequent analyses can be considered, but direction of the first respiratory paper is set and will proceed. There are other high priority analyses that can go forward with the final dataset now available. This email dialogue should come to a close for the time being.
- At 11:43 am, the Complainant replied to his supervisor, copying OPH Leadership and members of the Post-Deployment Health Group: "Ok, then I wish to step down as a coinvestigator on the *National Health Study for a New Generation of U.S. Veterans*. Please notify [the IRB administrator] to remove me from the list of collaborators. I will ask [the Chief Consultant] to assign some other work for me to do in the Office of Post-Deployment Health."
- 11/28/2012 Following the above disagreement about analyses of data from the *New Generation Study*, the Complainant's supervisor e-mailed the Complainant: "As a member of the Epidemiology Program staff and Senior Epidemiologist, it is expected that you will perform the work of the Program which is both assigned to you and included in your performance plan. In the attached email, I have affirmed, at your request, the order in which some of these previously assigned tasks should be tackled. I cannot honor your request to remove you as co-investigator of the *New Generation Study*."
- 12/04/2012 The Complainant filed a claim for compensation for injury describing a shattered tooth resulting from the stress caused by "interrogation and threat" on the part of his supervisor on November 29. The Claim was denied by the Office of

Worker's Compensation Program in the US Department of Labor due to insufficient evidence.

12/20/2012 A memorandum for the record from the Post-Deployment Health Deputy Chief Consultant documented her meeting with the Complainant and his supervisor concerning the Complainant's Fiscal Year (FY2013) Performance Plan: (1) The Complainant "wishes to be a consultant rather than a co-investigator on the *New Generation Study* . . . [he] has been told numerous time that he will not be relieved of his duties as the study co-investigator. (2) The meeting was conducted in a professional manner . . . at no point were there any raised voices. [The Complainant's supervisor] led a discussion about contact with HR personnel regarding the legality of assigning tasks to a subordinate in a performance plan . . . (3) I informed [the Complainant] that his continued assignment as the study co-investigator was legal and appropriate. I apprised him of his choices which included the following: (a) Sign the performance plan and accept his continued assignment as a co-investigator. His performance as co-investigator would be part of his yearly evaluation. (b) He could refuse to sign the performance plan but he would still be responsible and be evaluated as the co-investigator. (c) He could either sign or not sign and refuse to do the assigned duties [and] this could possibly have an adverse effect on his performance rating. (d) Lastly if these duties were impossible for him to continue to do, he could seek employment elsewhere. [The Complainant] wanted to talk about his EEO issues and previous Complainants from another study. I told him that we were here to only discuss his performance plan going forward. [He] was obviously unhappy but signed his performance plan and annotated that [it] was signed under duress. I reiterated that he did not have to sign as detailed above in paragraph 3. The meeting took approximately 10 minutes and was conducted on December 20, 2012.

At 6:36 pm, the Complainant's supervisor responded by e-mail to a request for additional data entry support for the *Gulf War Follow-up Study*: "I am okay with this if it is needed. However, I am unclear where [the Complainant's] data entry ends and this [Research Assistant] data entry begins . . . I have not received a report from [the Complainant] about his progress. Did he not complete the data entry that was backlogged? Is he not going to continue? I guess I just need some awareness of where the entire scheme stands."

12/21/2012 At 8:07 am, the Complainant sent the following single sentence e-mail reply to his supervisor: "This is a hostile work environment."

At 11:47 am, the Chief Public Health Officer sent an e-mail to the DUSHPS and the VHA Chief of Staff regarding the Complainant: "Lately his supervisor has been working with him to get him to do the work we need done as opposed to work he wants to do. Yesterday he was very upset after a meeting about his

2013 performance plan (he did not like the plan). Today he asked for a research assistant to help manage data on a study he leads and his supervisor questioned the need (reasonably, by an email). He claimed (by email) that this is a hostile work environment, then sent a note that he was resigning to some of his study team members and our HR specialist. Since we heard he was angry . . . Dr. Terry Walters and I spoke with him to assess his intentions . . . He refused to take the number of Employee Assistance. We had spoken to security to get them ready in case we needed their help as he leaves and to ensure that they would take steps to remove his access to this and other VA buildings. He has turned in his IDs (VACO and DC VA) and government travel card and signed clearance documents and left the building with his belongings. VA security has told us they are taking care of the larger and ongoing security issues (like making sure our own building security has his photo and does not let him back in). I have informed staff in his group and we'll handle their concerns individually."

In his interview with ORO, the Complainant maintained that he had been yelled at and threatened by his supervisor and by the Chief Consultant for Post-Deployment Health for disagreeing with their scientific decisions and over the immediate need for call-backs to Veterans displaying suicidal ideation in OPH surveys. For example, the Complainant asserted that the Chief Consultant had "yelled" at him and "jabbed at him in a physically threatening way" for contacting the IRB regarding the *Gulf War Follow-up Study*. The Complainant stated that his reaction to this threatening behavior was to leave the area quietly. The Complainant also asserted that his supervisor interrogated and threatened him, waving his hands in the air and yelling "You know what will happen," when the Complainant stated that he did not want to continue as co-investigator of the *New Generation Study*. He stated that on other occasions, his supervisor threatened to take administrative action against him.

In respect to the Complainant's assertion that on July 12, 2012, the Chief Consultant had "yelled" at him and "jabbed at him in a physically threatening way" for contacting the IRB regarding the *Gulf War Follow-up Study*, two OPH professional staff who witnessed the incident stated in e-mail messages dated July 24, 2012, that "[The Chief Consultant] didn't raise his voice or act inappropriately in any way" and "I don't recall hearing any yelling or confrontations coming from [the Complainant's] office on that day."

In his interview with ORO, the Complainant's supervisor indicated that the Complainant did not understand the difference between traditional investigator-directed research and the service-directed research that was the mission of OPH. He described the latter as policy research prioritized by program needs, and emphasized that all such research needed to demonstrate the best possible science. He emphasized the collaborative team approach that was necessary to ensure this outcome, and stated that the Complainant "repeatedly chafed" when research group or management decisions did not support his point of view. The supervisor stated that he often had to remind the Complainant of the need to follow program priorities and clear his research ideas with management. The Complainant's supervisor maintained that he was careful to maintain a calm quiet voice and demeanor during such discussions.

In reference to the admonishment of the Complainant, the Chief Consultant for Post-Deployment Health emphasized that he had heard the Chief Public Health Officer tell the Complainant at least five times on June 12, 2012, to contact the IRB to withdraw the "Hot Comments" amendment. Instead, the Chief Consultant stated, the Complainant directly disobeyed the Chief Officer's instructions. The Chief Consultant went on to state that the Complainant acted disrespectfully when the Chief Consultant later confronted the Complainant about his failure to follow the Chief Officer's instructions.

The Chief Public Health Officer characterized the Complainant as an intelligent researcher who had been permitted to work on lots of projects not directly related to the mission of OPH prior to 2011. She stated that when a new supervisor took over the Epidemiology Group and began to manage his activities more closely, the Complainant began to demonstrate difficulties working within his group's collaborative team-oriented approach and increasingly insisted on pursuing his own agenda rather than his assigned work. The Chief Public Health Officer indicated that these problems peaked with disagreements over suicidal ideation call-backs for the pilot phase of the *Gulf War Follow-up Survey*; his failure to follow management's decision to withdraw the "Hot Comments" IRB protocol amendment; his request, without management approval, that the IRB suspend the study; and serious disagreements in December 2012 about his FY2013 Performance Plan.

The Post-Deployment Health Group Deputy Chief Consultant confirmed the content of her Memorandum to the Record, dated December 20, 2012.

In response to ORO's request for factual corrections, the Complainant stated on May 13, 2013, that he followed written work plans, revised once a year with assistance from his supervisor, and received "Outstanding" performance evaluations for 4 years in a row. Then in 2012, after I contacted the IRB Chair and VA Office of Inspector General out of concern for the lack of follow-up care for research participants who self-report suicide ideation, my annual performance evaluation was reduced to "Satisfactory."

On May 15, 2013, the Complainant provided ORO with a list of publications (journals, book chapters, and commentaries) to illustrate that he had been productive professionally and had collaborated successfully during the past four years with various OPH and other VA colleagues. Topics of these publications included unexplained CMI, monetary incentives in surveys of US Veterans, PTSD, suicidal behavior and neurological illnesses, and epidemiologic methodology.

IV. CONCLUSIONS AND RECOMMENDATIONS

Based on the above findings, the ORO Review Team made the following conclusions and recommendations:

Allegation #1: Policy Bias

Conclusion: ORO concluded that OPH does not maintain a policy bias against neurological causes for Gulf War illness (or CMI), CFS-like illness, etc. ORO noted that OPH surveys are not designed to identify cause and effect relationships.

Recommendation: ORO recommends that OPH analyze and publish as soon as possible the available data from the *New Generation Study* and the *Gulf War Follow-up Study*, including any data suggesting potential neurological bases for CMI.

Allegation #2: Data Availability

Conclusion: ORO concluded that VA policy does not require that OPH provide its study data to other VA researchers or to researchers outside VA.

Recommendation: Once the VA Policy on Public Access to VA Research Data is finalized, ORO recommends that OPH implement the Policy as quickly as possible.

Allegation #3: Selective Data Release

Conclusion: ORO concluded that profound scientific and programmatic disagreements between OPH leadership and the Complainant regarding the priorities for analyzing and reporting data from the *New Generation Study*, combined with the fact that OPH has not yet completed exhaustive analyses of these data, resulted in intense frustration and distrust on the part of the Complainant. Despite the Complainant's passionate commitment to the belief that analyses of data related to environmental exposures warranted the highest priority, ORO concluded that OPH leadership had both the authority and the responsibility to set program priorities, even if OPH staff disagreed.

Recommendation: ORO recommends that OPH complete the analyses of data from the *New Generation Study* as expeditiously as possible.

Allegation #4: Selective Data Exclusion

Conclusion: As in Allegation #3 above, ORO concluded that despite profound scientific and programmatic disagreements between OPH leadership and the Complainant, OPH leadership had both the authority and the responsibility to set program priorities.

However, submission of an abstract that listed the Complainant as an author without the Complainant's explicit prior approval was clearly inappropriate and violated widely-accepted standards within the scientific community.

Recommendation: OPH should implement policy and procedures to prohibit the practice of including any individual's name in any publications (i.e., abstracts, poster presentations, or manuscripts) without the explicit approval of the individual.

Allegation #5: Gulf War Family Registry Data

Conclusion: ORO concluded that Gulf War Family Registry data appeared to have been lost when the Austin Data Center upgraded its systems in 2005. Loss of the Registry data was not attributable to current OPH leaders or personnel. ORO noted that OPH staff who had responsibility for the Registry are no longer employed by VA, and current OPH staff had little knowledge of the Registry's use or history. ORO found no approved Record Control Schedule that would have permitted destruction of these data.

Recommendation: OPH should establish policy and procedures to ensure that research data are retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Record Control Schedule (RCS 10-1) as required by VHA Handbook 1200.05 §26.h.

Allegation #6: Gulf War Illness Research Advisory Committee (RAC) Recommendations

Conclusion: ORO concluded that OPH considered the recommendations of the Gulf War Illness RAC and accepted those that it considered constructive and practicable. ORO concluded that OPH leadership had both the authority and the responsibility to use its own professional judgment in evaluating the RAC's recommendations.

Recommendations: None

Allegation #7: Scientific Review of RAC Recommendations

Conclusion: ORO concluded that the scientific review of RAC recommendations requested by the VA Chief of Staff was conducted in an objective and professional manner. ORO found no evidence that OPH officials made false statements to Chief of Staff related to his request.

Recommendation: None

Allegation #8: Institute of Medicine (IOM) Study

Conclusion: ORO concluded that the IOM study, *Gulf War and Health: Treatment for Chronic Multisymptom Illness*, was conducted in an objective and professional manner in accordance with IOM standards. ORO found no evidence that OPH officials chose, or inappropriately influenced the selection of, panel members or witnesses for the IOM study.

Recommendation: None

Allegation #9: Follow-up of Suicidal Ideation**Conclusions:**

1. ORO concluded that OPH provided adequate protections for subjects in the *New Generations Study*, given prevailing standards at the time the study was conducted and the evidence available to OPH when the Complainant later raised the possibility of contacting Veterans who had participated in the study.
2. ORO concluded that in delaying implementation of “Hot Comment” call-backs in the pilot phase of the *Gulf War Follow-up Study* from June 11 through July 31, 2012, OPH fell short of the requirement to minimize risks to study subjects under VA regulations at 38 CFR 16.111(a)(1) and VHA policy (VHA Handbook 1200.05 §10.d and §17.a).

ORO did not find OPH’s rationale for this delay to be persuasive.

- a. Relative to the belief that call-backs could undermine Veterans’ trust in OPH privacy and confidentiality guarantees, ORO noted that changes to the study’s informed consent document to provide for such call-backs had been approved by the IRB on June 1, 2012. Paper-and-pencil survey questionnaires were first mailed to the 500 potential pilot phase participants on June 25, 2012, and included the revised consent document. Prior to the June 25 mailing, only five “preliminary” *Gulf War Follow-up Study* pilot phase participants had completed the survey. All five participated in the on-line version of the study.

- b. Relative to the decision that the need for call-backs required an evaluation prior to implementation, ORO noted that implementation of call-backs during the pilot phase of the *Gulf War Follow-up Study* not only would have permitted evaluation of the need for call-backs, but also would have permitted evaluation of the call-back procedure itself (as described in the “Hot Comments” protocol amendment submitted to the IRB by the Complainant) prior to initiation of the main phase of the study.
- c. ORO further noted that the number of call-backs needed for the 500 *Gulf War Study* pilot phase participants could have been anticipated to be quite modest and, therefore, practicable to implement.

The overall response rate for the *New Generation Study* (Barth et al.) was 34% (20,563 of 60,000), including the 1360 CATI subjects (who were the only subjects eligible for call-backs). Of those 1360 subjects, 92 (7%) required call-backs. Thus, it would have been reasonable to estimate that if 40% (200) of the *Gulf War Follow-up Study* pilot phase participants completed surveys, roughly 20 (10% of 200) would need call-backs. [Note: In reality, 167 Veterans completed surveys by the time call-backs began on August 1, 2012, and 6 of those Veterans (4% of 167) required call-backs; a total of 211 Veterans completed surveys prior to initiation of the main phase of the *Gulf War Follow-up Study* on September 10, 2012.]

Thus, OPH should either have arranged for a mental health professional to conduct the call-backs for the pilot phase of the study when it began on June 25, 2012, or postponed the beginning of the pilot phase until a mental health professional could be found to conduct the call-backs.

3. ORO concluded that the Complainant, as PI of the *Gulf War Follow-up Study*, had both the authority and the responsibility to report to the IRB his concerns about minimizing risks to subjects who demonstrated suicidal ideation in their on-line and paper-and-pencil survey responses.

VHA Handbook 1200.05 §3.ss(2) defines the PI as a qualified person designated to direct a research project or program. The PI oversees scientific, technical, and day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of that team. VHA Handbook 1200.05 §9.b and §9.r further define the PI’s responsibilities, respectively, to include ensuring that “there are adequate resources to carry out the research safely” and “reporting all unanticipated problems involving risks to subjects” to the IRB.

ORO found that OPH officials, both in their actions relative to the *Gulf War Follow-up Study* and in their statements to ORO, demonstrated an inadequate understanding of

the PI's authorities and responsibilities under VHA policy. As a result, these authorities and responsibilities were compromised.

4. ORO concluded that the Chair of the IRB responsible for oversight of the *Gulf War Follow-up Study* was slow to address the possible need for additional protections for participants in the pilot phase of the study because he was initially unaware of the limitations being placed on the PI's authority by OPH leadership and later unclear about who in OPH was actually responsible for the conduct of the study.

ORO found that the IRB Chair should have temporarily suspended study activities when doubt arose about who was responsible for the study and it became clear that the pilot phase of the study was to be initiated without a mental health professional in place to conduct needed call-backs.

Recommendations:

1. ORO recommends that the Principal Deputy Under Secretary for Health, as Institutional Official for the VA Central Office Human Research Protection Program:
 - a. Establish or designate a specific Institutional Review Board (IRB) for oversight of research conducted by VHA Program Offices.
 - b. Ensure that the leaders of VHA Program Offices conducting research are trained in the regulatory and policy requirements applicable to the conduct of research.
2. ORO recommends that OPH ensure that the PIs of all OPH studies are empowered to oversee the scientific, technical, and day-to-day management of the research, and to fulfill all PI responsibilities as required by VHA Handbook 1200.05. If OPH officials wish to exercise the authority to make final decisions on OPH studies, they must assume the title of the PI and be accountable for the conduct of the studies, including the protection of human subjects participating in the studies.

Allegation #10: Threats Against the Complainant

Conclusions:

1. ORO concluded that there was no evidence of physical threat to the Complainant from OPH officials.
2. ORO concluded that the legitimate efforts of OPH management to redirect the activities of the Complainant toward work dictated by OPH program priorities were perceived as threats by the Complainant.

3. ORO concluded that the proximity in time between the Complainant's efforts to suspend activities in the *Gulf War Follow-up Study* and the initiation of admonishment actions by OPH leadership created the appearance for the Complainant of a connection between these two events, irrespective of leadership's intention to admonish the Complainant solely for failing to follow direct instructions from the Chief Public Health Officer and acting disrespectfully toward the Chief Consultant for Post-Deployment Health.
4. ORO concluded that temporal proximity created the appearance for the Complainant of a connection between his strong disagreements with OPH leaders and the following statements by OPH leaders that he perceived as threatening to his career in VA:
 - a. An offer to be relieved as PI of the *Gulf War Follow-up Study*, even though the Complainant had not requested any such relief.
 - b. Offers of assistance from leadership relative to the Complainant's medical and emotional state, even though he never requested any such assistance or any reasonable accommodation.
 - c. The statement that one of four options open to the Complainant with regard to his performance plan was to seek employment elsewhere.

Recommendations:

1. ORO recommends that OPH leadership receive targeted human resources training regarding dispute resolution, reasonable accommodations, dealing with medical information in the workplace, and refresher supervisory training.
2. ORO also recommends that OPH leadership consult both the Office of Workforce Management and Consulting and the Office of General Counsel for advice prior to acting on difficult personnel matters.

Recommendation Regarding the Need for Additional Review

ORO was charged to make a recommendation to the USH regarding the need for a full scale official investigation of the allegations.

ORO believes that the allegations have been adequately addressed by this ORO Special Review and the recommendations above.

ORO does not recommend that a full scale official investigation be conducted.

OFFICE OF RESEARCH OVERSIGHT



A handwritten signature in black ink that reads "Michael Ban".

Deputy Chief Officer, ORO

Date: July 5, 2013

A handwritten signature in blue ink that reads "John Pylis".

Date: July 5, 2013

APPENDIX A
UNDER SECRETARY FOR HEALTH CHARGE MEMO

**Department of
Veterans Affairs**

Memorandum

Date: MAR 25 2013
From: Under Secretary for Health (10)
Subj: Charge to Review Allegations Made by Dr. Coughlin
To: Chief Officer, VHA Office of Research Oversight (10R)

1. You are charged with reviewing allegations made by Dr. Coughlin at the hearing of the House Veterans Affairs Committee, "Gulf War: What Kind of Care are Veterans Receiving 20 Years Later?" on March 13, 2013.
2. The review will include interviews of experts and witnesses including: Dr. Steven S. Coughlin, Dr. Victoria Davey, and others as required, as well as a complete review of all applicable documents including: protocols, consent forms, Institutional Review Board Records, and applicable published studies.
3. The review will include specific review of allegations including:
 - a. The VHA Office of Public Health (OPH) does not release studies that do not support its policy bias against a neurological basis for Gulf War illness and does not make OPH data available to qualified researchers.
 - b. The 2009-2010 National Health Study of New Generation US Veterans produced data on pesticide exposure, oil well fires, pyridostigmine bromide, and medications, but OPH has not released these data.
 - c. As co-author of a paper on findings from the New Generation study on the relationship between exposure to burn pits and other inhalation hazards and asthma and bronchitis, Dr. Coughlin was not permitted to include hospitalizations and doctors' visits, thus obscuring important associations.
 - d. The Gulf War Family Registry data have been permanently lost.
 - e. OPH failed to accept constructive recommendations from the Research Advisory Committee on Gulf War Illness (RAC) regarding the Follow-up Study of a National Cohort of Gulf War and Gulf War Era Veterans.
 - f. OPH officials failed to obtain an objective scientific review of, and made false statements to the VA Chief of Staff regarding the RAC recommendations on the follow-up study.

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Charge to Review Allegations Made by Dr. Coughlin

- g. OPH lacks a mechanism to share its databases with qualified VA researchers.
- h. OPH officials chose witnesses biased in favor of psychiatric causes for a Congressionally mandated IOM study of treatments for Chronic Multi-Symptom Illness (CMI) in Gulf War Veterans.
- i. OPH officials failed to address the need for mental health follow-up of approximately 2000 participants from the New Generation survey who self-reported recent thoughts that they would be better off dead.
- j. OPH officials threatened Dr. Coughlin:
 - (1) In reference to including hospitalizations and doctors' visits;
 - (2) When he reported to the Institutional Review Board (IRB) and the Office of Inspector General (OIG) the need for mental health follow-up of Gulf War Veteran participants experiencing suicidal ideation.

3. While preparations for this review began on March 14, 2013, this memorandum officially authorizes you to inquire into all aspects of these matters; to require VA employees to cooperate with you; and to gather other information that you determine is necessary and relevant.

4. Please provide an interim report on the status of your review by April 25, 2013, and a final report by May 28, 2013.

5. Your report should specifically include findings of fact and conclusions. You are also invited to provide recommendations relative to your conclusions. Based upon your review, recommend if you believe a full scale official investigation is warranted.

6. Please contact Dr. Lisa Thomas, VHA Chief of Staff, 202-461-7016, if you have any questions.



Robert A. Petzel, M.D.

APPENDIX B
ORO REVIEW TEAM AND PERSONNEL INTERVIEWED

A. ORO Review Team

Min-Fu Tsan, M.D., Ph.D.	Leader, ORO Special Review Team
James F. Burris, M.D.	Deputy Chief Officer, ORO
Cynthia Kerenyi, M.A.M	Associate Director for Policy and Planning ORO
Terrilynn Carlton, M.P.H.	Health Science Specialist ORO Western Regional Office
Derwood J. Haskell, J.D.	Health Science Specialist ORO Southern Regional Office
Sylma Vargas, J.D.	Specialty Team Advising Research Office of General Counsel
Thomas Puglisi, Ph.D.	Human Resources Consultant Office of Workforce Management & Consulting Chief Officer ORO
Dee Dee S. Chavers	Staff Assistant, ORO

B. Personnel Interviewed

April 16, 2013

Steven S. Coughlin, Ph.D.	Complainant
James Finkelstein, M.D.	Chair, Institutional Review Board (IRB), VA Medical Center, Washington, DC
Aaron Schneiderman, R.N., Ph.D.	Acting Director, Epidemiology Program, Office of Public Health (OPH)
Michael Peterson, D.V.M, M.P.H., Dr.P.H.	Chief Consultant, Post Deployment Health, OPH

April 17, 2013

Victoria Davey, Ph.D., M.P.H.	Chief Officer OPH
Terry Walters, M.D., M.P.H	Deputy Chief Consultant Post Deployment Health, OPH
Erin Dursa, Ph.D., M.P.H.	Health Science Specialist Epidemiology Program, OPH

**APPENDIX C
DOCUMENTS REVIEWED**

- A. Charge to Review Allegations Made by Dr. Coughlin, Memo from the Under Secretary for Health to ORO Chief Officer dated March 25, 2013
- B. Statement of Steven S. Coughlin, Ph.D., U. S. House of Representatives Committee on Veterans' Affairs Oversight and Investigations Subcommittee, March 13, 2013
- C. Statement of Victoria J. Davey, Ph.D., M.P.H, R.N., Chief Officer, Public Health, Veterans Health Administration (VHA), Department of Veterans Affairs, before the House Committee on Veterans' Affairs Oversight and Investigations Subcommittee, March 13, 2013
- D. Gulf War and Health: Treatment for Chronic Multisymptom Illness, written statement of Bernard Rosof, M.D., Chair, Committee on Gulf War and Health: Treatment for Chronic Multisymptom Illness, Institute of Medicine of the National Academies, before the Subcommittee on oversight and Investigations, Committee on Veterans' Affairs, U.S. House of Representatives, March 13, 2013
- E. E-mail Correspondence between OPH and ORO, subject "Research Situation" dated June 19, 2012
- F. Researcher alleges VA covered up adverse consequences to toxic exposures, Steve Vogel, The Washington Post, March 13, 2013
- G. Public Law 103-446 Sec 107. Evaluation of Health Status of Spouse and Children of Persian Gulf War veterans, November 2, 1994
- H. Documents provided by Dr. Steven S. Coughlin:
 - 1) ORO Investigation/Retaliation against VA Whistleblower, Steven Coughlin, dated March 22, 2013
 - 2) National Health Study for a New Generation of US Veterans/ORO investigation, Steven Coughlin, dated March 30, 2013
 - 3) Factual corrections/comments on Draft ORO Special Report Findings, Steven Coughlin, dated May 13 and 15, 2013
- I. Documents from Institutional Review Board (IRB), VA Medical Center, Washington, DC:
 - 1) Protocol MIRB # 00074 (VA CSP 458): National Health Survey of Persian Gulf Veterans and their Families
 - 2) IRB Protocol MIRB # 01167: Health Surveillance for a New Generation of U.S. Veterans
 - 3) Protocol MIRB # 01366: Follow Up Study of a National Cohort of Gulf War and Gulf Era Veterans

- 4) IRB Protocol MIRB #01593: Gulf Era Twin Registry
- 5) CSP 585, VA CIRB #11-09: Pilot Study: Gulf War Era cohort and Biorepository
- 6) IRB meeting minutes dated June 4, 2012, June 25, 2012, July 12, 2012, and August 13, 2012.
- 7) E-mail Correspondence, subject "Re: ID 01366 Follow Up Study of a National Cohort of Gulf War and Gulf Era Veterans CLARIFICATION
- 8) E-mail messages "Some additional thoughts" from IRB Chair dated April 17, 2013
- 9) Factual corrections/comments on Draft ORO Special Report Findings, IRB Chair, dated May 16, 2013

J. Documents from the Office of Public Health (OPH):

- 1) E-mail Correspondence, subject "Fw: ORO Review," dated March 22, 2013, with 4 attachments:
 - i) Follow up Meeting with Marc Blackman, dated September 13, 2011
 - ii) Draft Editorial Addressing PTSD & HIV, dated August 5, 2011
 - iii) Note Regarding Meeting, July 26, 2011
 - iv) Idea For a Collaborative Research Article, dated July 7, 2011

- 2) E-mail Correspondence, subject "Fw: ORO Review - Suicidal Ideation Data From New Gen Survey" dated March 20, 2013, with 5 attachments:
 - i) Safety Plan, undated
 - ii) SRBI Staff Case Report Form (Blank), undated; VA Clinician or VA Staff Case Report Form, undated
 - iii) Amendment Memorandum of Understanding/Agreement for Mental Health Telephone Care Services between the VA National Suicide Prevention Hotline and the Department of Veterans Affairs (VA) Office of Public Health and Environmental Hazards Environmental Epidemiology Service, its Contractors HMS Technologies, Inc. and SRBI, and VA Clinicians Affiliated with the Study, final dated April 6, 2012
 - iv) Memorandum- subject: Health Surveillance for a New Generation of U.S. Veterans (MIRB) #1167) – Overview of Follow-Up for Study Participants who Expressed Past Intent to Self-Harm or Suicidal Ideation, dated June 12, 2012
 - v) Attachment to Miscellaneous Submission (Description of codes found on last page, dated May 20, 2013)

- 3) E-mail Correspondence, subject "ORO Review - Coughlin Admonishment," dated March 20, 2013, with 10 attachments:
 - i) Concerns, undated

- ii) OPH Memorandum for Record, subject “Meeting to Discuss Current Staffing of Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans,” dated June 12, 2012
 - iii) E-mail Correspondence, subject “FW: ID 01366 – Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans,” dated June 12, 2012
 - iv) OPH Memorandum for Record, subject “Meeting called by Dr. Davey to discuss Dr. Coughlin’s direction to the IRB,” dated June 14, 2012
 - v) Memorandum to the Record, no subject, dated June 12, 2012, 0900-1000, OPH
 - vi) E-mail Correspondence, subject “FW: ID 01366 – Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans CLARIFICATION,” dated June 13, 2012
 - vii) E-mail Correspondence, subject “IRB Communications,” dated June 14, 2012
 - viii) OPH Memorandum for the Record, subject “Meeting between Dr. Coughlin and senior staff of the Office of Public Health on June 12, 2012,” dated June 14, 2012
 - ix) OPH Memorandum for the Record, subject “Events related to meetings on June 12, 2012 with Dr. Steven Coughlin,” dated June 14, 2012
 - x) E-mail Correspondence, subject “FW: ID 01366 – Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans CLARIFICATION, dated June 15, 2012
- 4) E-mail Correspondence, subject “ ORO Review: New Generation Survey Instrument,” dated March 22, 2013, containing copy of “National Health Study for a New Generation of U.S. Veterans Questionnaire” (OBM 2900-0722)
- 5) E-mail Correspondence, subject “Fw: ORO Review: Notes from New Gen analysis meeting (March 7, 2013)” dated March 22, 2013
- 6) E-mail Correspondence, subject “Fw: ORO Review: Gulf War Publications,” dated March 21, 2013, Schneiderman A, et al., Variations in Health Communication Needs Among Combat Veterans. Am J Public Health 94: 2074-2076, 2004
- 7) E-mail Correspondence, subject “Fw: ORO Review: Gulf War Study E-mails,” dated March 22, 2013, with 21 attachments:
- i) Hot Comments Protocol (Paper Questionnaire) dated June 11, 2012
 - ii) How Are Missing Values Treated FW: Manuscripts for Comment
 - iii) FW: ID 01366 - Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans, dated June 12, 2012
 - iv) FW: Journal of Military and Veterans Health Manuscript, dated January 29, 2013
 - v) Draft Methodologic Issues in Epidemiologic Studies of Medically Unexplained Symptom-based Conditions in Veterans, dated January 28, 2013
 - vi) E-mail Correspondence, subject “Journal of Military and Veterans’ Health” dated January 17, 2013
 - vii) E-mail Correspondence, “IRB Continuation,” dated December 5, 3012
 - viii) Recent Journal Articles, Review Articles, and Encyclopedia Entries, undated

- ix) E-mail Correspondence, subject "Reply RE: Competing Risk Analysis, FW: Manuscripts for Comment Gulf War Panel Mortality," dated October 16, 2012
 - x) E-mail Correspondence, subject "RE: Competing Risk Analysis FW: Manuscripts for Comment Gulf War Panel Mortality" dated October 16, 2012
 - xi) E-mail Correspondence, subject "Competing Risk Analysis FW: Manuscripts for Comment Gulf War Panel Mortality" dated October 16, 2012
 - xii) E-mail Correspondence, subject "How Are Missing Values Treated FW: Manuscripts for Comment," dated October 16, 2012
 - xiii) E-mail Correspondence, subject "RE: Congressional Deliverable-Health Studies," dated October 10, 2012
 - xiv) OPH Memorandum subject "Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans (ID 01366) Update Regarding Patient Safety Monitoring Procedures," dated October 4, 2012
 - xv) E-mail Correspondence, subject "RE: First Draft of New Gen Study Depression Paper w/ Table Shells" dated October 1, 2012
 - xvi) E-mail Correspondence, subject "RE: GW Follow-up Study - Veterans With Psychological Distress," dated September 25, 2012
 - xvii) E-mail Correspondence, subject "FW: Journal of Military and Veterans' Health - Manuscript ID JMVH-2012-0032, dated "August 31, 2012
 - xviii) Draft Methodologic Issues in Epidemiologic Studies of Medically Unexplained Symptom-based Conditions in Veterans, dated August 30, 2012
 - xix) E-mail Correspondence, subject FW: Annals of Epidemiology: Submission Confirmation, dated August 17, 2012
 - xx) Letter, subject Re" Methodologic Issues in Epidemiologic Studies of Medically Unexplained Symptom-based Conditions," dated August 17, 2012
 - xxi) Draft " Methodologic Issues in Epidemiologic Studies of Medically Unexplained Symptom-based Conditions," dated June 8, 2012
- 8) E-mail Correspondence, subject "Fw: ORO Review: Gulf War Study Publications #1," dated March 21, 2013, with 7 publications:
- i) Miller RN, et al., Patterns of Health Care Seeking of Gulf War Registry Members Prior to Deployment. *Military Medicine* 171: 370-375, 2006.
 - ii) Kang HK, et al., Evidence for a Deployment-Related Gulf War Syndrome by Factor Analysis. *Arch Environ Health* 57: 61-68, 2002.
 - iii) Karlinsky JB, et al., Late Prevalence of Respiratory Symptoms and Pulmonary Function Abnormalities in Gulf War I Veterans. *Arch Intern Med* 164: 2488-2491, 2004.
 - iv) Li B., et al., Longitudinal Health Study of US 1991 Gulf War Veterans: Changes in Health Status at 10-Year Follow-up. *Am J Epidemiol* 1-8, 2011.
 - v) Lincoln AE, et al., The War-Related Illness and Injury Study Centers: A Resource for Deployment-Related Health Concerns. *Military Medicine* 171: 577-585, 2006.

- vi) Lincoln AE, et al., Motor Vehicle Fatalities Among Gulf War Era Veterans: Characteristics, Mechanism, and Circumstances. *Traffic Injury Prevention* 7: 31-37, 2006.
 - vii) Mahan CM, et al., Anthrax Vaccination and Self-reported Symptoms, Functional Status and Medical Conditions in the National Health Survey of Gulf War Era Veterans and Their Families. *Ann Epidemiol* 14: 81-88, 2004.
- 9) E-mail Correspondence, subject "Fw: ORO Review: Gulf War Study Publications #2," dated March 21, 2013, with 5 publications:
- i) Young HA, et al., Factor Analysis of Fatiguing Syndrome in Gulf War Era Veterans: Implications for Etiology and Pathogenesis. *J Occup Environ Med* 45: 1268-1273, 2003.
 - ii) Smith T, et al., The Postwar Hospitalization Experience of Gulf War Veterans Participating in U.S. Health Registries. *J Occup Environ Med* 46: 386-397, 2004.
 - iii) Toomey R, et al., Mental health of US Gulf War veterans 10 years after the war," *Brit J Psychiat* 190: 385-393, 2007.
 - iv) Wallin M, et al., Neuropsychologic Assessment of a Population-based Sample of Gulf War Veterans. *Cog Behav Neurol* 22: 155-166, 2009.
 - v) Young HA, et al., Investigating the Risk of Cancer in 1990-1991 US Gulf War Veterans With the Use of State Cancer Registry Data. *Ann Epidemiol* 20: 265-272, 2010.
- 10) E-mail Correspondence, subject "Fw: ORO Review: Gulf War Study Publications #3," dated March 21, 2013, with 16 publications:
- i) Kang HK and Bullman TA. Mortality among US Veterans of the Persian Gulf War: 7-Year Follow-up. *Am J Epidemiol* 154: 399-405, 2001.
 - ii) Gackstetter GD, et al., Fatal Motor Vehicle Crashes Among Veterans of the 1991 Gulf War and Exposure to Munitions Demolitions at Khamisiyah: A Nested Case-Control Study. *Am J Indust Med* 49: 261-270, 2006.
 - iii) Gray GC, et al., After More than 10 Years of Gulf War Veteran Medical Evaluations, What Have We Learned? *Am J Prev Med* 26: 443-452, 2004.
 - iv) Gray GC and Kang HK. Healthcare utilization and mortality among Veterans of the Gulf War. *Phil Trans R Soc B* 361: 553-569, 2006.
 - v) Gray GC, et al., The Postwar Hospitalization Experience of U.S. Veterans of the Persian Gulf War *N Engl J Med* 335: 1505-1513, 1996.
 - vi) Gray GC, et al., Gulf War Veterans' Health Registries. Who is Most Likely to Seek Evaluation? *Am J Epidemiol* 148: 343-349, 1998.
 - vii) Hallman WK, et al., Symptom Patterns Among Gulf War Registry Veterans. *Am J Public Health* 93: 624-630, 2003.

- viii) Hopper T, et al., Leveraging Existing Databases to Study Vehicle Crashes in a Combat Occupational Cohort: Epidemiologic Methods. *Am J Indust Med*48: 118-127, 2005.
- ix) Hopper T, et al., Understanding the effect of deployment on the risk of fatal motor vehicle crashed: A nested case-control study of fatalities in Gulf war era veterans, 1991-1995. *Accident Analysis and Prevention* 38: 518-525, 2006.
- x) Kang HK, et al., Pregnancy Outcomes Among U.S. Gulf War Veterans: A Population Based Survey of 30,000 Veterans. *Ann Epidemiol* 11: 504-511, 2001.
- xi) Kang HK, et al., Mortality among US and UK Veterans of the Persian Gulf War: a review. *Occup Environ Med* 59: 794-799, 2002.
- xii) Kang HK, et al., Post-Traumatic Stress Disorder and Chronic Fatigue Syndrome-like Illness Among Gulf War Veterans: A Population - based Survey of 30,000 Veterans. *Am J Epidemiol* 157: 141-148, 2003.
- xiii) Kang HK, et al., The Role of Sexual Assault on the Risk of PTSD among Gulf War Veterans. *An Epidemiol* 15: 191-195, 2005.
- xiv) Kang HK, et al., Health of US Veterans of 1991 Gulf War: A Follow-Up Survey in 10 Years. *J Occup Environ Med* 51: 401-410, 2009.
- xv) Kang HK and Bullman TA. Mortality Among U.S. Veterans of the Persian Gulf War. *N Engl J Med* 20: 1498-1504, 1996.
- xvi) Kang HK and Bullman TA. Counterpoint: “Negligible “Healthy-Warrior Effect” on Gulf War Veterans’ Mortality. *Am J Epidemiol* 148: 324-325, 1998.

11) E-mail Correspondence, subject “Fw: ORO Review: Miscellaneous related to professional relationships,” dated March 22, 2013, with 11 attachments

- i) E-mail, subject “New improved version of draft manuscript,” dated November 18, 2009
- ii) E-mail, with attachment, subject “New improved version of draft manuscript” dated October 20, 2009 and Word document attachment, Coughlin et.al., “Seeking Causal Explanations in Epidemiology Sub-disciplines,” undated 23 pages
- iii) E-mail, subject “Book Citations,” dated August 2, 2009
- iv) E-mail, with attachment, subject “Article for OPH Website?” dated October 17, 2012 and PDF attachment, NIH PA Author Manuscript, titled “Anxiety and Depression: Linkages with Viral Diseases,” by Coughlin, S., undated
- v) E-mail, subject “Article for OPH Website?,” dated October 17, 2012
- vi) E-mail, subject “Poster Criteria for VA National Research Week 2012,” dated March 29, 2012
- vii) E-mail, subject “New Gen - Non-response Bias Analysis for OMB,” dated March 15, 2012
- viii) E-mail, subject “New Gen – Non-response Bias Analysis for OMB,” dated March 19, 2012
- ix) E-mail, subject “Fw: 2900-0722 HSNGV,” dated March 1, 2012 with OMB forms and supporting statements

- x) E-mail, subject "Gulf War Follow-up Assessment of Non-response Bias," dated March 5, 2012 and attachment, titled "Gulf War Follow-up Study: Response to OMB Regarding Assessment of Non-response Bias" undated
 - xi) E-mail, subject "Workplace Safety" dated December 21, 2012
- 12) E-mail Correspondence, subject "ORO REVIEW: NEW GEN EMAILS," dated March 22, 2013 with 12 attachments
- i) E-mail, subject "Article in OPH Clearance – Draft dated August 8, 2012," with attachment, titled "Suicidal Ideation and Neurological Illness"
 - ii) E-mail, subject "New Gen Investigator Issue," dated March 21, 2013
 - iii) E-mail Correspondence, subject "New Gen Alcohol Paper – Timetable," dated March 21, 2013
 - iv) E-mail, subject "New Request for Approval," dated March 21, 2013
 - v) E-mail, subject "New Gen Review Letter," dated February 4, 2013, with attachment, titled "Decision on Your Manuscript #HSOR-D-12-00019," dated January 15, 2012
 - a. Review of "Adjustments for temporal misclassification of exposure status in surveys of health outcomes," by Yoon, et al. undated
 - b. Review of Article "Adjustments for Temporal Misclassification of Exposure Status in Surveys of Health Outcomes." Manuscript number HSOR-D-12-00019, undated
 - c. Health Services and Outcomes Research Methodology: Adjustments for Temporal Misclassification of Exposure Status in Surveys of Health Outcomes (Manuscript Draft) undated
 - vi) E-mail, subject "RE: Final Draft Manuscript," dated August 27, 2012
 - vii) E-mail, subject "RE: Alcohol Questions, New Gen," dated July 25, 2012
 - viii) E-mail, subject "New Gen: Review of Weighting Plan and Proposed Post-Stratification Plan," dated May 16, 2012, and attachment, titled "National Health Study for a New Generation of U.S. Veterans: Review of Weighting Plan and Proposed Post-Stratification Plan," draft report by Sukasih A, Yoon F, Lazicky C, and Jang D, dated May 16, 2012
 - ix) E-mail, subject "RE: Study Team Meeting Minutes for Comment," dated May 1, 2012
 - x) E-mail, subject "new Gen Respiratory Analyses," dated April 9, 2012, and attached article titled "Newly Reported Respiratory Symptoms and Conditions Among Military Personnel Deployed to Iraq and Afghanistan: A Prospective Population-based Study," by Smith B, et al., Am J Epidemiol 170, 2009
 - xi) Excel Document, titled "Table 1: Demographic characteristics of respondents by deployment status, National Health Study for a New Generation of U.S. Veterans, 2009-2011, undated
 - xii) E-mail, subject "New Gen Study Alcohol Paper," dated March 8, 2012

13) E-mail Correspondence, subject "Fw: ORO Review - Obstructing Manuscripts Mortality Paper," dated March 20, 2013, with 2-attachments:

- i) E-mail, subject "Manuscripts for Comment," dated October 16, 2012
- ii) E-mail, subject "RE: Note From Meeting - Schneiderman/Coughlin," date September 24, 2012

14) E-mail Correspondence, subject "Fw: ORO Review - Publications From the National Health Study for a New Generation of U.S. Veterans," dated March 22, 2013, with 6 attachments:

- i) Survey Practice Article, titled "The Effectiveness of a Monetary Incentive on Response Rates in a Survey of Recent U.S. Veterans," by Coughlin S, et al., April 2012
- ii) Manuscript Draft, titled "Prevalence of Respiratory Disease among Veterans of Operation Enduring Freedom and Operation Iraqi Freedom: Results from the National Health Study for a New Health Study for a New Generation of U.S. Veterans," undated
- iii) Manuscript Draft, titled "Health Services and Outcomes Research Methodology Adjustments for Temporal Misclassification of Exposure Status in Surveys of Health Outcomes," by Yoon F, et al., undated
- iv) Letter From Health Services & Outcomes Research Methodology (HSOR), subject, "Decision on Your Manuscript #HSOR-D-12-00019," dated January 15, 2013
- v) Review of Article "Adjustments for temporal misclassification of exposure status in surveys of health concerns" by Yoon et al., undated
- vi) Review of Article "Adjustments for Temporal Misclassification of Exposure Status in Surveys of Health Outcomes," Manuscript No. HSOR-D-12-00019, undated

15) E-mail Correspondence, subject "Fw: ORO Review - Respiratory Paper (New Gen,)" dated March 20, 2013, with 3 attachments:

- i) E-mail, subject "RE: Asthma Results - New Gen Respiratory Paper Analysis," dated November 28, 2012, and e-mail, subject "Final File New Gen," dated November 28, 2012
- ii) E-mail, subject "RE: Asthma Results - New Gen Respiratory Paper Analysis," dated November 28, 2012
- iii) E-mail, subject "FW: Memo for Record," dated December 3, 2012

16) E-mail Correspondence, subject "Fw: ORO Review Response to RAC-OMB Public Comment," dated March 21, 2013, with 2 attachments

- i) Response to Public Comments From RAC on Gulf War Illnesses (Draft), dated November 26, 2012

- ii) Excel Document, VA Gulf War OMB Request, undated
- 17) E-mail Correspondence, subject "Fw: Submission of Collaborative Manuscript for OPH Clearance," dated March 22, 2013
- 18) E-mail Correspondence, subject "Fw: ORO Review - STAT Weights Project," dated March 22, 2013 with 7 attachments:
- i) E-mail, subject "Statistical Analysis - PR 2237 101-11-4-1697-0069," dated September 9, 2011, and "Review of Ambit Group Proposal," dated September 29, 2011
 - ii) E-mail, subject "New Acquisition Package: Statistical Analysis," with 6-attachments:
 - a. Statistical Analysis - Streamline Acquisitions Plan, dated May 21, 2009
 - b. Statistical Analysis - Statement of Work, (7-pages) undated
 - c. Statistical Analysis - Market Research Report, undated
 - d. Statistical Analysis - IGCE, dated October 21, 2011
 - e. Statistical Analysis - VA Handbook 6500.6, Appendix A - Checklist For Information Security In The Initiation Phase of Acquisitions, undated
 - f. Request, Turn-In, and Receipt for Property or Services, dated October 21, 2011
 - iii) E-mail, subject "RE: VA 730-12-Q-0026," dated February 21, 2012
 - iv) E-mail, subject "New Gen Article," dated October 3, 2012
 - v) E-mail, subject "RE: New Gen Article," dated January 31, 2013
 - vi) E-mail, subject "RE: Attn: Don Jang," dated July 14, 2011
 - vii) Standard Form 1449, Solicitation, Contract, Order For Commercial Items Offeror Awarded to Mathematica Policy Research, Incorporated, March 6, 2012
- 19) E-mail Correspondence, subject "Fw: ORO Review Surveys," dated March 20, 2013, with 4 attachments:
- i) 1995 National Health Survey of Persian Gulf War Era Veterans Questionnaire
 - ii) 2005 Longitudinal Health Study of Persian Gulf War Era Veterans Questionnaire
 - iii) 2012 Follow Up Study a National Cohort of Gulf War and Gulf Era Veterans Questionnaire
 - iv) 2012 National Health Study of a New Generation of US Veterans Questionnaire
- 20) E-mail Correspondence, subject "Fw: ORO Review," dated March 19, 2013, with 3 attachments:
- i) Email from Burke_RE Independent Reviewer.txt dated April 5, 2011
 - ii) Email from Ricci_RE FW RESEND documents for review.txt dated May 19, 2011
 - iii) Veterans_Study_Ricci_Final.pdf

21) E-mail Correspondence, subject "Fw: ORO Review1," dated March 19, 2013, with 3 attachments:

- i) Witness to conversation_request.htm dated July 24, 2012
- ii) Witness.htm dated July 24, 2012
- iii) SC_201220618 Coughlin events of June 12 2012.tif

22) E-mail Correspondence, subject "Fw: ORO Review10," dated March 22, 2013, with 4 attachments:

- i) Email Forward: consultation request dated July 27, 2012
- ii) Email Forward: telephone Survey and Safety dated July 31, 2012
- iii) Email Forward: notes from our meeting this afternoon dated July 27, 2012
- iv) Gulf Ward Followup Safety Plan 07 18 2012.docx

23) E-mail Correspondence, subject "Fw: ORO Review11," dated March 22, 2013, with 2 attachments:

- i) GW poster 2012 3 29.pdf
- ii) Issts_2012 v6Final.pptx

24) E-mail Correspondence, subject "Fw: ORO Review3," dated March 20, 2013, with 1 attachment, i.e., Spouses of Persian Gulf War 1 Veterans.tif

25) E-mail Correspondence, subject "Fw: ORO Review4," dated March 21, 2013, with 1 attachment, i.e., 20130321073422082.pdf- Abstract-Pregnancy Outcomes Among U.S. Gulf War Veterans

26) E-mail Correspondence, subject "Fw: ORO Review6," dated March 21, 2013, contains email string with Contract Officer dated April 11, 2012

27) E-mail Correspondence, subject "Fw: ORO Review7," dated March 21, 2013, with 9 attachments of Gulf War Publications:

- i) 200611-a study.pdf (A Study of Gulf War Veterans...)
- ii) 19991-the health.pdf (The Health Status of Gulf War Veterans...)
- iii) 19992-prevalence.pdf (The Prevalence of Chronic Fatigue...)
- iv) 20002-illness.pdf (Illnesses Among U.S. Veterans of the Gulf War...)
- v) 20021-evidence.pdf (Evidence for a Deployment-Related Gulf War Syndrome...)
- vi) 20044-clinical.pdf (Clinical & Lab Assessment of Distal Peripheral Nerves...)
- vii) 20051-is test.pdf (Is Testicular Cancer Related to Gulf War Deployment?...)
- viii) 200057-health1.pdf (Health Effects in Army Gulf War Veterans-Part 1...)

ix) 20058-health2.pdf (Health Effects in Army Gulf War Veterans-Part II...)

28) E-mail Correspondence, subject "Fw: ORO Review9," dated March 22, 2013, contains email: VA-245-08-RP-0073 Clarification Request dated July 30, 2008.

29) E-mail Correspondence, subject "Fw: ORO Review - Misc General," dated March 22, 2013 with 15 attachments:

- i) Re: Aaron's poster presentation on shared drive, dated October 19, 2012
- ii) Re: Poster criteria for VA National Research Week 2012, dated March 29, 2012
- iii) Re: Dr. Coughlin...information regarding your poster presentation for National Research Week, dated April 14, 2012
- iv) Re: Comment on your article, dated January 13, 2012
- v) Re: tour dates Re: question about misclassification of deployment, dated May 20, 2011
- vi) Re: points not clear Re: Reviewers Comments, The Effectiveness of a Monetary Incentive on Response Rates in a Survey of Recent U.S. Veterans, dated December 7, 2010
- vii) Draft book title for submission to R&D, dated December 30, 2011
- viii) FW: final version of book manuscript, dated August 3, 2011
- ix) Final version of article on PTSD and cardiovascular disease, dated May 19, 2011
- x) Book Manuscript, dated February 16, 2010
- xi) Brief manuscript with PTSD example, dated January 12, 2010
- xii) New improved version of draft manuscript, dated October 20, 2009
- xiii) Draft Commentary, dated October 20, 2009
- xiv) Draft Commentary, dated August 5, 2009
- xv) RE: Publications – for our EES website, dated April 3, 2009

30) E-mail Correspondence, subject "Fw: ORO Review - New Gen Misc," dated March 22, 2013, with 24 attachments:

- i) RE: Aaron's poster presentation materials on Shared Drive, dated October 25, 2012
- ii) RE: final file new gen, dated November 28, 2012
- iii) Steves SAS code for number of deployments - New Gen, dated March 16, 2012
- iv) RE: study team meeting minutes for comment, dated May 1, 2012
- v) RE: New Gen – Non response bias analysis for OMB, dated March 19, 2012
- vi) RE: Timeline templates for New Gen topics, dated April 30, 2012
- vii) RE: Study team meeting April 25 f/up, dated May 4, 2012
- viii) FW: new request for approval, dated May 22, 2012
- ix) RE: corrected Powerpoint slides, dated January 11, 2012
- x) RE: 1 or 2 pager (regarding ETOH article), dated October 21, 2011

- xi) RE: New Gen weekly study team meeting –Tuesdays 10am?, dated February 7, 2011
- xii) RE: PTSD/TBI Paper, dated October 24, 2012
- xiii) RE: PTSD/TBI Paper, dated October 22, 2012
- xiv) RE: Draft Abstract – New Gen study article on depression, dated September 25, 2012
- xv) Study team meeting April 25 f/up, dated May, 2, 2012
- xvi) New Gen manuscript tracking spreadsheet, dated January 12, 2012
- xvii) FW: Spreadsheet for New Gen study Papers, dated October 20, 2011
- xviii) RE: Call for abstracts – deadline November 15, dated August 2, 2011
- xix) ETOH paper, dated March 14, 2012
- xx) “FW: draft manuscript dated 10-21-2011”, dated January 12, 2012
- xxi) RE: deferential RE: current status of deployment status adjudication, dated May 18, 2011
- xxii) RE: VA New Generation Study: Draft Agenda + CATI Overview, dated April 8, 2010
- xxiii) RE: Statistical Weights RE: Longitudinal Study weekly report, dated January 10, 2009
- xxiv) RE: New Gen one pager proposals, dated May 14, 2012

31) E-mail Correspondence, subject “Fw: ORO Review - Respiratory Paper,” dated March 22, 2013, with 25 attachments:

- i) RE: updated respiratory tables, dated October 18, 2012
- ii) RE: New Gen respiratory paper analysis, dated October 22, 2012
- iii) RE: New Gen respiratory analyses, dated April 11, 2012
- iv) RE: respiratory paper, dated February 24, 2012
- v) RE: bronchitis results – New Gen respiratory paper analysis, dated December 6, 2012
- vi) RE: Asthma results – New Gen respiratory paper analysis, dated November 28, 2012
- vii) RE: Asthma results-New Gen respiratory paper analysis, dated November 27, 2012
- viii) RE: New Gen respiratory paper analysis, dated November 23, 2012
- ix) FW: draft paper on respiratory exposures and conditions, dated November 20, 2012
- x) RE: New Gen respiratory paper analysis, dated October 22, 2012
- xi) RE: respiratory paper, dated December 8, 2011
- xii) RE: JOEM letter, dated November 30, 2011
- xiii) RE: respiratory paper, dated November 22, 2011
- xiv) RE: draft manuscript-respiratory diseases OIF/OEF, dated November 17, 2011
- xv) FW: draft manuscript-respiratory diseases OIF/OEF, dated November 17, 2011
- xvi) RE: draft manuscript-respiratory diseases OIF/OEF, dated November 17, 2011

- xvii) RE: more about mast New Gen file, dated November 4, 2011
 - xviii) "RE: draft paper on respiratory exposures and conditions", dated October 19, 2011
 - xix) "Minutes form weekly team mtg Friday 9-16-11", dated September 19, 2011
 - xx) Draft paper on respiratory exposures and conditions, dated September 16, 2011
 - xxi) RE: respiratory exposures and diseases, dated August 30, 2011
 - xxii) RE: respiratory exposures and diseases, dated August 9, 2011
 - xxiii) Article on work related validation/exposure study, for your interest, dated August 8, 2011
 - xxiv) RE: respiratory exposures and diseases, dated August 8, 2011
 - xxv) FW: respiratory exposures and diseases, dated August 8, 2011
- 32) E-mail Correspondence, subject "Fw: gw_newsletter-Mar 00," contains copy of Gulf War Review, Vol 8, No. 2, Information for Veterans who Served in Desert Shield /Storm, dated March 2000
- 33) OIG Issue 1366 – "Follow-up Study of a national Cohort of Gulf War and Gulf Era Veterans CLARIFICATION," dated June 14, 2012
- 34) OIG Issue, RE ID 01366 - Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans CLARIFICATION," dated June 13, 2012
- 35) E-mail Correspondence, subject "ORO Review - E-mails About New Gen Study Resp Disease Analysis," dated November 28, 2012
- 36) E-mail Correspondence, subject "ORO Review - Recommendation About SC," dated September 27, 2012
- 37) E-mail Correspondence, subject "ORO Review - Research Assistant Gulf War Follow-up Study," dated September 27, 2012
- 38) E-mail Correspondence, subject "ORO Review - Resignation Situation," dated December 21, 2012
- 39) E-mail Correspondence, subject "ORO Review - Suicide and Neurological Illness," dated September 13, 2012
- 40) E-mail Correspondence, subject "ORO Review - Depression Viral Infection Article," dated September 7, 2012
- 41) E-mail Correspondence, subject "ORO Review - Depression Viral Illness," dated March 20, 2013

- 42) E-mail Correspondence, subject "ORO Review - Hospitalizations for Suicide Attempts New Gen Study," dated November 20, 201
- 43) E-mail Correspondence, subject "ORO Review - HVAC Questions on Gulf War Follow Up Study and Suicidal Ideation," dated October 26, 2012
- 44) E-mail Correspondence, subject "ORO Review - Letter of Counseling," dated October 3, 2012, with 2-attachments:
 - i) DVA Memorandum, subject "Written Counseling," dated October 3, 2012
 - ii) DVA Memorandum, subject "Formal Grievance Mutual Resolution," dated October 2, 2012
- 45) E-mail Correspondence, subject "ORO Review - SC Memo to Record," dated June 12, 2012
- 46) E-mail Correspondence, subject "ORO Review5," dated March 21, 2013
- 47) E-mail Correspondence, subject "ORO Review8," dated December 20, 2012, with an attachment, titled "Meeting between Drs. Schneiderman, Coughlin and Waters Concerning Performance Plan Regarding Dr. Coughlin," dated December 20, 2012
- 48) E-mail Correspondence, subject "ORO Review of HVAC Hearing Issues," dated March 22, 2013
- 49) E-mail correspondence, subject "Requested Articles" dated April 23, 2013 with 10 attachments:
 - i) See H.10.x above
 - ii) See H.10.ii above
 - iii) Bullman TA, et al., Mortality in US Army Gulf War Veterans exposed to Khamisiyah chemical munitions destruction. Am J Public Health 95: 1382-1988, 2004.
 - iv) Barth SK et al., Neurological mortality among US veterans of the Persian Gulf War: 13-year follow up. Am J In Med 52- 663-670, 2009
 - v) Coughlin SS et al., Alcohol use and selected health conditions of 1991 Gulf War veterans: survey results 2003-2005. Prev Chronic Dis 2011; 8(3).
 - vi) Young HA, et al., Factor analysis of fatiguing syndrome in Gulf War era veterans: Implications for etiology and pathogenesis. J Occup Environ Med 45: 1268-1273, 2003.
 - vii) See H.9.iv
 - viii) See H.10.xiv
 - ix) See H.8.iv

- x) Kang HA, et al., Evidence for a deployment-related Gulf War syndrome by factor analysis. Arch Environ Health 57: 61-68, 2002.
- 50) E-mail Correspondence, subject "Clarification Clinical Followup" dated May 2, 2013
- 51) Factual corrections/comment on Draft ORO Special Report Findings, OPH, dated May 16, 2013

Date: October 29, 2013

Subject: Response to “Special Review of Allegations Related to Research Conducted by the VHA Office of Public Health”

From: Office of Public Health, Veterans Health Administration, Department of Veterans Affairs

The Veterans Health Administration's Office of Public Health (OPH) has reviewed the Office of Research Oversight (ORO) report, “Special Review of Allegations Related to Research Conducted by the VHA Office of Public Health” (dated July 13, 2013 and received September 25, 2013 by OPH). OPH concurs with most of ORO's findings. However, OPH disagrees with or further expands on several ORO findings. Specifically, OPH:

- Expands on and clarifies OPH practices with regard to epidemiologic research,
- Expands on and clarifies OPH's data release and selection processes,
- Disagrees that the Gulf War family registry data were “research” data,
- Explains how OPH actions protected human subjects,
- Provides details and clarification to the response to the allegation that actions were taken against the Complainant.

Specific OPH concerns are addressed in the narrative below.

Allegation 1: Policy Bias

Although ORO correctly found that *there is no bias by OPH against epidemiologic associations* of Gulf War exposures with Veterans' health status (particularly neurologic outcomes), the findings imply that OPH did not have an orderly approach for undertaking epidemiologic research.

OPH undertakes epidemiologic research in a manner that is comparable to that of other epidemiologic research organizations. The team designs and implements research and carries out collection and management of data. Scientific and human subjects' use reviews are done according to regulations and ethical research practices. Team investigators routinely discuss and debate merits of analyses and priorities but ultimately determine an order of analyses. The team initially reviews data for anticipated or likely associations. These first reviews are based on expert knowledge gleaned from relevant scientific literature, anecdotal reports by clinicians or patients, and known gaps in knowledge that are needed to inform policy. These 'big picture' analyses are done and reports are prepared for dissemination within VA and to the clinical and scientific communities through presentations at conferences and in peer-reviewed articles along with other scientific communications. Other stakeholders, including Veterans, are informed through briefings and meetings of service organizations, newsletters, and social media. Secondary analyses proceed concurrently, to the extent possible, with the first order analyses and stem from investigators' observations in their review of data or from the team's interactions. Collaborations with other researchers are sometimes arranged to capitalize on scientific interests or special expertise. Analyses of results from any such investigative work may result in new or unanticipated findings and associations. A research team's collective understanding of and agreement on study design, execution and interpretation are fundamental to progress on research projects, dissemination of findings, and translation of findings into clinical practice or policies.

Allegation 2: Data Availability

OPH fully *agrees with the principle of sharing research data* with the qualified¹ scientific community in a manner that is consistent across the Department. In accordance with other research organizations, we agree that the original research team should have a fair initial period of time and opportunity to analyze and report on findings. The VA Gulf War Veterans Illnesses Research Advisory Committee (several of whom are members of research teams engaged in research on consequences of Gulf War deployment) has also requested that OPH share data with non-VA scientists and we concur with them.

Allegation 3: Selective Data Release

OPH agrees with ORO *that OPH leadership has both the authority and the responsibility to set program priorities*. The program of research undertaken for the New Generation Study was initiated with the objective of developing population prevalence estimates of measures of health for OEF/OIF Veterans. This could be achieved only with data that have been cleaned, prepared for analysis, and augmented by appropriate statistical weights and correction factors. OPH does not selectively release data to influence data interpretation.

Data from the New Generation study was not immediately ready for analysis upon completion of data collection. The response rate for the New Generation survey was 34%, and although this is similar to other large cohort studies of Veterans, in the arena of epidemiological surveys, it is low. There was concern by the investigators that Veterans who responded to the survey were different than those Veterans who chose not to participate with respect to health outcomes. This could result in bias, or a systematic deviation from the truth, which can lead to invalid results. A major goal of the New Generation Study was to derive population estimates of health conditions, and the sample was very carefully selected to represent the entire population of OEF/OIF Veterans; when only about one third of the sample responds, investigators cannot be confident that the results truly reflect the population without further careful consideration.

Additionally, about 20% of the sample was misclassified with respect to the main exposure of interest (deployment). Due to the length of time between when the sample was drawn from the Defense Manpower Data Center (DMDC), the tempo of DoD operations, and survey mail-out to the sample, a number of Veterans originally identified as non-deployed by DMDC's records had deployed (in part a function of the length of the OEF/OIF conflicts and the deployment of a large majority of the available personnel). Deployment status was one of the main stratification factors in the complex sampling scheme designed to ensure representativeness. The senior statistician who developed the plan advised the research team that without addressing these issues the results would be biased.

Non-response can be addressed by weighting the data, and is a very straightforward statistical technique. However, the misclassification issue was much more complex; there are very sophisticated analytic techniques to address misclassification and non-response simultaneously, and this was beyond the expertise of the statisticians in OPH. A contract was awarded to survey statisticians at Mathematica Policy Research to develop these weights. Once the weights were developed and provided to OPH in October 2012, analysis and manuscript preparation began.

¹ The definition of 'qualified' should include experience conducting epidemiologic research according to sound and principled research practices, publishing in high quality peer reviewed journals and without conflicts of interest.

The New Generation Study analytical plan was divided into short-term and intermediate-term goals, based on natural chronology and topic importance. For example, the epidemiological and statistical methods papers were developed first, as they explain in detail the complex methods used for data collection and analytical weighting, and are used as a reference in all health outcome papers. Next, analyses related to the most pressing health concerns of OEF/OIF Veterans (respiratory conditions, traumatic brain injury and post-traumatic stress disorder, reproductive outcomes, and overall health) were performed. All of these have been completed and either accepted for publication or are under review. Currently, OPH staff is working on analyses that fall under the intermediate goals, including complementary and alternative treatments, military sexual trauma, and a comparative analysis of VA users and non-users in the OEF/OIF population.

Allegation 4: Selective Data Exclusion

The ORO reviewers correctly found *there are no selective data exclusions* on the part of OPH researchers. This accusation is one of the most egregious and destructive made by the Complainant as it addresses a most fundamental principle of research, which is to present findings accurately, honestly, and completely. OPH researchers follow the highest standards of research.

With regard to the specific decision by OPH to exclude doctors' visits and hospitalizations from the respiratory analysis², there is a methodological reason why this question was not considered. The question on the survey that was used to ascertain the respiratory outcomes was question 11: "Has a doctor ever told you that you have any of the following conditions?" Participants who endorsed asthma, bronchitis, or sinusitis, were considered to have the outcome. This was agreed upon by the Complainant, who was the Principal Investigator of the New Generation Study prior to his resignation, and the other investigators on the study before the analysis was performed.

The specific questions that the Complainant refers to in his testimony about doctors' visits and hospitalizations were questions 14a-14b and 15a-15b which read: "During the past twelve months, how many clinic or doctor visits have you made because you had a health problem? Please explain the reason for visit(s) or diagnosis" and "During the past 12 months, how many times have you been hospitalized overnight or longer? Please explain reason for visit or diagnosis." These are fundamentally different questions than the one that was used to ascertain the respiratory outcome and it would have been inappropriate to combine them. Questions 14a-14b and 15a-15b elicit information about clinic visits and hospitalizations, respectively. These questions ask for the reasons or diagnoses for clinic visit or hospitalization. Why an individual seeks medical attention and the ultimate diagnosis are not the same thing (e.g. an individual goes to the doctor for stomach pain, the diagnosis is appendicitis). The participants are asked to write in their response; the investigators had no way to determine if the participant meant their response to be a reason for a visit or a diagnosis. Misinterpretation of the meaning of participants' written responses by the investigators could introduce a bias of unknown magnitude and direction, potentially corrupting the findings. Omitting these questions did not "obscure important associations" because the information solicited by these questions cannot support investigation of the associations under analysis.

² Statement of the Complainant to the House Veterans Affairs Oversight and Investigations subcommittee, March 13, 2013: "I coauthored a paper for publication on important research findings from the New Generation study on the relationship between exposures to burn pits and other inhalational hazards and asthma and bronchitis in OIF/OEF veterans. My supervisor, Dr. Aaron Schneiderman, told me not to look at data regarding hospitalizations and doctors' visits. The tabulated findings obscure rather than highlight important associations."

The Complainant alleged that he was included as an author on a scientific meeting presentation without his permission. However, the primary author of this presentation had received written comments from the Complainant about the presentation. The Complainant was positive about the work being presented at the meeting, but was upset that his comments and critiques were not fully incorporated in the final version of the presentation. The usual interpretation of a named co-author's commenting on a scientific meeting presentation is that the co-authorship is tacitly approved. Thus the presentation was submitted to the meeting organizers with the Complainant listed as a co-author. The Complainant later rescinded his agreement to be a co-author, and his name was removed prior to the presentation.

Allegation 5: Gulf and Family Registry Data

Medical records that were part of the Persian Gulf Spouse and Children Examination Program have not been lost. ORO correctly notes that these "medical records specific to individual family members would have been kept at the VA medical centers or fee basis locations where the family registry exams were conducted."

ORO mistakenly calls the data that were "lost" at Austin "research data" (pg. 30) and says that OPH should follow disposition instructions that are published in VHA's Record Control Schedule (RCS 10-1) as required by VHA Handbook 1200.05 section 26.h. (Handbook 1200.05 is titled "Requirements for the Protection of Human Subjects Research.") However, the Persian Gulf Spouse and Children Examination Program was not a research study, and VA's record storage regulations for research data would therefore not apply.

There were summary data related to the Persian Gulf Spouse and Children Examination Program that existed on a server at the VA Austin Data Center. According to our information, in 2005 the Austin Data Center upgraded their systems. The upgrade occurred after this examination program had terminated, after the data from the program had been analyzed, and with the examination records secured at individual VA medical center sites. At that time, previous Environmental Agents Service leadership in OPH determined that the data at Austin related to this program no longer needed to be maintained by the Austin server.

There was also a VA research study, Phase III of the National Health Survey of Persian Gulf Veterans and Their Families (1998 – 2001) (Section II, Study #1), which was a separate effort. This study included physical examinations of 2,000 selected Gulf War Veterans and their family members (Eisen, S.A., et al., *Spouses of Persian Gulf War I Veterans: Medical Examination of a US Cohort*, *Military Medicine*, 171: 613, 2006). These data are intact at the Hines VA Medical Center and provide a similar cross-sectional view of Gulf War family members' health.

ORO is aware of this distinction since their report states that the registry data are "distinguished from Phase III of the National Health Survey of Persian Gulf Veterans and Their Families (1998 - 2001) Section II, Study #1), which was a research study that included physical examinations of 2,000 selected Gulf War Veterans and their family members..." (pg. 9).

Allegation #6: Gulf War Illness Research Advisory Committee (RAC) Recommendations

OPH agrees with ORO that *OPH had 'the authority and responsibility' to be discerning* in the use of comments and recommendations of the VA Gulf War Illness Research Advisory Committee. In usual

practice, advisory committees serve to provide suggestions and opinions to research teams and do not solely determine the ultimate direction of research³.

Allegation #7: Scientific Review of RAC Recommendations

OPH agrees with ORO that *OPH obtained an expert and impartial review* from an experienced survey researcher when requested to do so by the VA Chief of Staff on the Follow-up Study of a National Cohort of Gulf War and Gulf War Era Veterans.

Allegation #8: Institute of Medicine (IOM) study

OPH agrees with ORO that *OPH in no way attempted to influence selection of members of the committee that wrote the IOM report* on Gulf War and Health: Treatment for Chronic Multisymptom Illness. OPH, VA, Veterans, other Departments of the U.S. government, and the American public rely on IOM to fairly and expertly evaluate the most difficult questions in clinical science. In our opinion, for the Complainant to frivolously impugn the independence of the IOM in a statement to Congress displays a profound ignorance of, or disdain for IOM history, reputation, and process.

Allegation #9: Follow-up of Suicidal Ideation

OPH leadership *agreed with the desire of the Complainant to follow-up with Veterans* who indicated they had thoughts of intent to harm themselves or indicated risk for suicide, such as depression, in their survey responses. Even though following up with survey respondents who attest to depression or intent to self harm is not a standard practice in large scale epidemiologic studies, OPH had previously studied making call backs to telephone respondents of the New Generation Study. Analysis of the data from those calls demonstrated that almost 15% of Veteran respondents would meet mental health criteria for a call back. That study did not determine the clinical outcomes for those called, including whether they received mental health care from VA or another source, attempted suicide, or even completed suicide. Accordingly, we did not know that the follow-up calls resulted in these beneficial outcomes for Veterans, only that calls were able to be accomplished, were acceptable to Veterans, and that, in a percentage of calls, Veterans were referred to the Veterans Crisis Line or other sources of mental health care. However the results of the call backs on the New Generation Study were meaningful enough that OPH sought to amend the already-approved Gulf War Follow-up Study to call back not only telephone respondents who met criteria for distress, but web and paper respondents as well.

OPH leadership, however, requested that the 500 Veteran pilot phase of the Gulf War Follow-Up Study not be halted by the Principal Investigator (the Complainant) or the Institutional Review Board (IRB) on June 12, 2012. The study had IRB approval, was deemed to be a “minimal risk” study by the IRB, and as a standard practice to aid distressed Veterans included the protective measure of placing the Veterans Crisis Line toll free number in prominent places in the survey and accompanying materials. Thus, continuing this survey study did not place Veterans at risk while an appropriate protocol

³ The charter of the advisory committee in effect at the time of this allegation stated: “the Department of Veterans Affairs (VA) Research Advisory Committee on Gulf War Veterans’ Illnesses provides advice and makes recommendations to the Secretary of Veterans Affairs on proposed research studies, plans, and strategies related to understanding and treating the health consequences of military service in the Southwest Asia theater of operations during the 1990-1991 Gulf War (Operations Desert Shield and Desert Storm).”

amendment that defined call back criteria and that identified appropriate mental health clinicians to make calls was established for telephone, paper, and web respondents.

The Complainant's June 11, 2012 amendment to the protocol, which OPH leadership found unsatisfactory, stated that three epidemiologists would do the call backs and lacked criteria for which Veterans should be called back and which should be referred to the Veterans Crisis Line or other sources of mental health care. Therefore, the Complainant's amendment did not adequately protect human subjects because unqualified VA staff would be assessing and advising Veterans. The Complainant's amendment also did not demonstrate appropriate use of human subjects as it did not lay out a plan for the appropriate collection of information from Veterans who received call backs.. OPH leadership also recognized that continuation of the Gulf War Follow-up Study while we put this appropriate protocol amendment in place allowed us ongoing contact with Veterans (and provided Veterans with the Veterans Crisis Line '800' number), whereas halting the study would result in possible missed opportunities for individual contacts with at-risk Veterans. OPH's intent was that all Veterans meeting criteria for concern about depression or intent to self-harm would be called back whether they responded to the survey before or after an amendment was put in place.

The Complainant was told to ensure that an appropriate plan was implemented that defined which Veterans would be called back (e.g. Veterans with any evidence of depression or only those who indicated intent to self-harm?) and that licensed mental health clinicians, not non-clinically trained epidemiologists, would make the follow-up telephone calls. In addition, OPH leadership required that the Complainant develop a plan for data collection and analysis so that we would have the necessary components in place to evaluate the call back protocol for telephone, paper, and web survey respondents for its ability to provide opportunities to aid at-risk Veterans.

The Complainant failed to carry out these assignments, for reasons that are not made clear in the ORO report. It was not because he did not agree.. OPH leadership knew that the Complainant preferred that mental health professionals perform call backs to Veterans and given his background in research, he knew the need for orderly data collection. OPH leadership is not certain why the organizational work of identifying mental health clinicians and drafting the improved protocol amendment or asking assistance from his supervisor or colleagues to do so were not accomplished by the Complainant. Instead, the Complainant's reactions to the events of the day were to send an email to the IRB chair and the VA Office of the Inspector General (OIG) indicating that he was a victim of workplace hostility. As it was, other investigators on the research team developed the improved protocol amendment while the Complainant was on a scheduled vacation that began on June 13, 2012. Two licensed clinicians were identified to make call backs and a safety plan was devised by the Complainant's supervisor, the Chief Consultant, and Deputy Chief Consultant. Calls began 8/1/12 and were continued until data collection on the study was complete. Six Veterans who met criteria for call backs between June 12 and August 1, 2012, the dates the study would have been halted, were called by the licensed mental health professionals.

In summary, the actions of OPH leadership on June 12, 2012 were designed to protect and respect the Veterans who responded to the Gulf War Follow-up Study survey. OPH leadership accomplished this by developing well-reasoned telephone call back criteria for distressed Veterans, by enlisting mental health clinicians to make these telephone calls, and by collecting information about the calls to help inform OPH how to conduct future surveys. And, if OPH had halted the study as the Complainant

requested, six Veterans who were referred to VA mental health resources would not have been contacted.

Allegation #10: Threats against the Complainant

OPH agrees with the ORO's findings that *the complainant was not threatened*. OPH provided ORO with much evidence to show that our goal was to always treat the Complainant with understanding and respect. The evidence also shows that the Complainant disliked the OPH environment of directed research by a team as opposed to one of investigator-initiated research. OPH allowed the Complainant a great deal of research freedom (as evidenced by his numerous publications that did not directly relate to the work of his group), but still required him to work with research study teams in accordance with an overall strategic plan.

The ORO recommendations include that OPH leadership staff be 'retrained' in aspects of personnel management, including dispute resolution, management of medical information in the workplace, and supervision and that we work with VHA Workforce Management and Consultation and the VA Office of General Counsel with regard to taking of personnel actions. The implication is that we failed to do so with regard to the Complainant. OPH did and does, very appropriately, work with VHA Workforce Management and Consultation and the VA Office of the General Counsel with regard to personnel actions; we point out that there were no findings to the contrary by ORO in this case.