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United States Government Accountability Office  
Washington, DC 20548

May 5, 2010

The Honorable Bob Filner  
Chairman  
Committee on Veterans' Affairs  
House of Representatives

Subject: *VA Health Care: Status of VA's Approach in Conducting the National Vietnam Veterans Longitudinal Study*

Dear Mr. Chairman:

In addition to providing health care to over 5 million veterans each year, the Veterans Health Administration, part of the Department of Veterans Affairs (VA), funds research on specific health conditions that veterans may experience. One condition that is examined in VA-funded research is post-traumatic stress disorder (PTSD), an anxiety disorder that can occur after a person is exposed to a life-threatening event.<sup>1</sup> According to VA, experts estimate that up to 30 percent of Vietnam veterans and up to 20 percent of Operation Enduring Freedom veterans and Operation Iraqi Freedom veterans have experienced PTSD.<sup>2</sup> Veterans suffering from PTSD may experience problems sleeping, maintaining relationships, and returning to their previous civilian lives.<sup>3</sup> Additionally, studies have shown that many veterans suffering from PTSD are more likely to be diagnosed with cardiovascular disease and other diseases.

After the Vietnam War, Congress wanted information about the psychological effects of the war on Vietnam veterans to inform the need for PTSD services at VA. Consequently, in 1983, Congress mandated that VA provide for the conduct of a study on PTSD and related postwar

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<sup>1</sup>American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (Washington, D.C., 2000).

<sup>2</sup>Unless otherwise noted, Vietnam veterans refers to those who served in Vietnam during the Vietnam era, from February 28, 1961, through May 7, 1975. See 38 U.S.C. § 101(29). Estimates for Vietnam veterans who have experienced PTSD vary. For example, according to the Centers for Disease Control and Prevention's 1989 *Vietnam Experience Study*, about 15 percent of Vietnam veterans have experienced PTSD. According to RAND's 2008 report *Invisible Wounds of War: Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery*, from 5 to 15 percent of Operation Enduring Freedom veterans and Operation Iraqi Freedom veterans have experienced PTSD. Operation Enduring Freedom, which began in October 2001, supports combat operations in Afghanistan and other locations, and Operation Iraqi Freedom, which began in March 2003, supports combat operations in Iraq and other locations.

<sup>3</sup>Those diagnosed with PTSD may also suffer from other ailments, such as depression and substance abuse.

psychological problems among Vietnam veterans.<sup>4</sup> VA contracted with an external entity, the Research Triangle Institute, to conduct the National Vietnam Veterans Readjustment Study (NVVRS).<sup>5</sup> This cross-sectional study<sup>6</sup> determined the incidence and prevalence of PTSD<sup>7</sup> among Vietnam veterans and Vietnam-era veterans.<sup>8</sup> Under contract with VA, Research Triangle Institute researchers designed the study and analyzed the information collected for the study, which was initiated in 1984 and completed in 1988. Participants' identities were not provided to VA because of the Research Triangle Institute's concerns about Vietnam veterans' distrust of government agencies. According to VA, the NVVRS was a landmark study and is the only nationally representative study that focuses on PTSD in Vietnam veterans. The NVVRS data have since been used in other studies of PTSD.<sup>9</sup>

PTSD is an ongoing concern for Vietnam veterans, and today, Vietnam-era veterans still constitute the largest group of veterans receiving VA care for PTSD. Congress and others have been concerned about the continued prevalence of PTSD and VA's capacity to meet the needs of Vietnam veterans. In section 212 of the Veterans Benefits and Health Care Improvement Act of 2000, Congress required that VA contract with an appropriate entity to conduct a follow-up study to the NVVRS.<sup>10</sup> The law specified certain requirements that the follow-up study must meet, including that the study must use the database and sample of the NVVRS and be designed to yield information on the long-term effects of PTSD and whether particular subgroups were at greater risk of chronic or more severe problems with PTSD.

In 2001, VA awarded another contract to the Research Triangle Institute to plan and conduct a follow-up study, the National Vietnam Veterans Longitudinal Study (NVVLS).<sup>11</sup> However, in 2003, before data collection for the study began, VA terminated the contract and the study

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<sup>4</sup>Veterans' Health Care Amendments of 1983, Pub. L. No. 98-160, § 102, 97 Stat. 993, 994-95. This law defined Vietnam veterans as those who served in Vietnam or elsewhere in the Vietnam theater of operations from August 5, 1964, through May 7, 1975, the Vietnam era. See 38 U.S.C. § 101(29) (1982).

<sup>5</sup>Other collaborators, such as Louis Harris and Associates, Inc., and The Graduate Center of the City University of New York, were also involved in conducting the NVVRS.

<sup>6</sup>A cross-sectional study assesses study participants at one point in time rather than at multiple points in time.

<sup>7</sup>Incidence refers to the rate of new cases for a condition in a given population. Prevalence refers to the proportion of a given population that has the condition during a period of time.

<sup>8</sup>In the NVVRS, Vietnam veterans are defined as those who served in or around Vietnam, Laos, or Cambodia from August 5, 1964, through May 7, 1975; Vietnam-era veterans are defined as those who served in the U.S. military in any location except in or around Vietnam, Laos, or Cambodia from August 5, 1964, through May 7, 1975. When we use "Vietnam-era veteran" in this report outside the context of the NVVRS, we are using the current governing definition: from February 28, 1961, through May 7, 1975, for veterans who served in Vietnam, and from August 5, 1964, through May 7, 1975, for veterans who served in any other location. See 38 U.S.C. § 101(29).

<sup>9</sup>The publicly available NVVRS data that have been used in other studies of PTSD do not include participants' identifying information.

<sup>10</sup>Pub. L. No. 106-419, § 212, 114 Stat. 1822, 1843-44. Throughout this report, we refer to section 212 as the law. See enc. I for the full text of section 212.

<sup>11</sup>A longitudinal study approach involves the repeated examination of a set of study participants over time.

was not completed.<sup>12</sup> (In this report, we will use “2001 NVVLS attempt” to refer to the efforts that began in 2001 to complete the NVVLS.) In January 2009, VA corresponded with the Chairman of the House Committee on Veterans’ Affairs regarding whether the committee would accept ongoing studies examining PTSD in male twin Vietnam-era veterans<sup>13</sup> and female Vietnam-era veterans<sup>14</sup> as an alternative to restarting the NVVLS. The Chairman concluded in June 2009 that these two studies did not adequately address the law. In September 2009, the Secretary of Veterans Affairs announced that the agency planned to award a contract to an external entity to conduct the NVVLS.

You asked us to report on VA’s current efforts to address the law. As agreed with your office, in this report, we specifically discuss (1) the recent progress VA has made in conducting the NVVLS and (2) the challenges VA faces in its plans to conduct the NVVLS.

To obtain information about VA’s progress in conducting the NVVLS and its challenges, we interviewed VA officials responsible for managing VA’s PTSD research, including officials on the project team responsible for restarting the NVVLS.<sup>15</sup> To obtain further information about VA’s efforts to address the law, we also interviewed VA officials who are conducting VA’s studies of PTSD in male twin Vietnam-era veterans and female Vietnam-era veterans. In addition, we obtained and reviewed relevant documents regarding VA’s PTSD research studies, including a draft performance work statement<sup>16</sup> and progress report for the NVVLS, study protocols for the studies on male twin Vietnam-era veterans and female Vietnam-era veterans,<sup>17</sup> and other documents related to the study methodologies. In order to understand how the NVVLS will be conducted, we also obtained and reviewed information about the NVVRS and the 2001 NVVLS attempt.

To provide context for the information we obtained from VA, particularly about VA’s reported challenges in conducting the NVVLS, we interviewed 10 researchers who are currently involved in or have previously been involved in managing or conducting PTSD research.<sup>18</sup> The criteria we used to select the researchers we interviewed included expertise in PTSD, as indicated, for example, by service on national committees focused on veterans and PTSD, and knowledge of or involvement with the NVVRS, the 2001 NVVLS attempt, or the NVVLS. We chose these researchers to represent a range of perspectives on the studies we examined: for example, we interviewed both researchers who are currently employed by VA

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<sup>12</sup>After the contract was terminated, VA’s Office of Inspector General investigated the 2001 NVVLS attempt. The resulting 2005 report found that VA did not properly plan or administer the study contract. It recommended that VA use appropriate contracting processes to complete the mandated follow-up study. See Department of Veterans Affairs, Office of Inspector General, *Audit of VA Acquisition Practices for the National Vietnam Veterans Longitudinal Study* (2005).

<sup>13</sup>This study defines the Vietnam era as 1965 through 1975.

<sup>14</sup>This study defines the Vietnam era as July 4, 1965, through March 28, 1973.

<sup>15</sup>The NVVLS project team is composed of 14 individuals, including 7 VA officials who are handling various aspects of the study, 3 VA representatives who are subject matter experts, 2 non-VA representatives who are subject matter experts, and 2 facilitators.

<sup>16</sup>A performance work statement, also known as a statement of work, is a description of the work the government expects the contractor to perform.

<sup>17</sup>A study protocol is a document that describes the formal design of a research study.

<sup>18</sup>We contacted a total of 13 researchers, but 3 researchers declined to speak with us. Two of them felt unable to provide specific comments on our issues, and the third stated that he did not have time to speak with us.

and researchers who are not employed by VA. See enclosure II for more information on the individuals we interviewed. To obtain additional perspectives on study design techniques and feasibility issues, we also interviewed three Department of Health and Human Services methodologists: two from its Agency for Healthcare Research and Quality and one from its Centers for Disease Control and Prevention.<sup>19</sup>

We conducted this performance audit from October 2009 through April 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

### **Results in Brief**

Since September 2009, VA has taken a number of steps toward conducting the NVVLS. VA convened a project team for the NVVLS consisting of VA officials and PTSD experts both within VA and outside of VA. According to VA officials, the NVVLS project team developed a performance work statement, which outlines VA's requirements for the contractor selected to conduct the NVVLS. VA expects to select a contractor for the NVVLS in the summer of 2010 and for the NVVLS to be completed in 2013. VA officials stated that they plan for the NVVLS to meet all of the requirements of the law where scientifically feasible. In addition, VA is continuing its studies of PTSD in male twin Vietnam-era veterans and female Vietnam-era veterans, and VA officials maintain that these studies will also provide useful information in response to the law.

VA reported that it faces several challenges in restarting the NVVLS. However, in several instances, the researchers and methodologists we interviewed offered suggestions for how these challenges could be addressed. For example, VA officials stated that they did not know how many of the NVVRS participants would agree to participate in the NVVLS, which could impact the feasibility of the study. All 10 researchers and 3 methodologists stated that it was important for NVVLS participants to receive assurances of confidentiality—that is, assurances regarding use of their identifying information, as was done with the NVVRS participants—to encourage participation.<sup>20</sup> The 3 methodologists we interviewed agreed that providing assurances of confidentiality is particularly important for government-funded studies because many people distrust government agencies. According to VA's draft performance work statement, the agency plans to take possession of all the study data, including participants' identifying information, at the conclusion of the NVVLS. While 9 of the researchers and 1 methodologist commented that this requirement could impact whether veterans would agree to participate in the NVVLS, VA stated that it conducts many internal research studies and has no material issues recruiting study participants due to mistrust of VA. Overall, VA officials do not know whether, given the challenges they face, the NVVLS can be completed. VA's draft NVVLS performance work statement includes an initial phase during which VA expects the contractor to assess the feasibility of the study. All 10 researchers we

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<sup>19</sup>In addition, we interviewed representatives of two veteran service organizations, the Vietnam Veterans of America and Disabled American Veterans, in order to obtain their perspectives on the concerns and needs of veterans with PTSD. We also contacted representatives from the American Legion.

<sup>20</sup>The NVVRS provided participants with assurances of confidentiality via the NVVRS consent form, which stated that their identifying information would not be disclosed in any government proceedings.

interviewed said that restarting the study soon is important because as the study participants continue to age, an increasing number will be lost for follow-up because of illness or death. Nine of the researchers told us that they believe it is important for VA to complete the NVVLS because it will potentially provide important, nationally representative information on PTSD and related issues in Vietnam-era veterans.

In responding to a draft of our report, VA affirmed its ownership of the NVVRS and NVVLS study data and confirmed that the agency intends to receive all the NVVLS study data, including participants' identifying information, upon completion of the study. VA also stated that the NVVLS consent form will explain to participants that VA does not intend to use the data to determine eligibility for VA benefits.

## **Background**

The NVVRS included 2,348 veterans—1,632 Vietnam veterans and 716 Vietnam-era veterans.<sup>21</sup> According to the NVVRS report, the study participants were chosen so that generalizable findings could be made about the entire veteran population of the Vietnam era. The NVVRS was required by law to provide information on certain subgroups, specifically veterans with service-connected disabilities, female veterans, and minorities.

The objectives of the NVVRS were

- to provide information about the incidence, prevalence, and effects of PTSD and related postwar psychological problems among Vietnam veterans;
- to describe comprehensively the total life adjustment of Vietnam veterans and to compare their adjustment with the adjustment of Vietnam-era veterans who did not serve in Vietnam and nonveterans; and
- to provide detailed scientific information about PTSD in particular.

To address these study objectives, all NVVRS participants were administered an in-person survey that lasted 3 to 5 hours and was conducted by trained interviewers. The NVVRS survey collected information on stressful and traumatic life events, physical health status, and the use of physical and mental health services.<sup>22</sup>

To provide the most accurate possible determination of the prevalence of PTSD—that is, the proportion of veterans who had ever experienced PTSD—a subset of the study participants received further in-depth clinical interviews conducted by doctoral-level mental health professionals with experience in diagnosing and treating stress disorders.<sup>23</sup> According to the NVVRS report, because there was no widely accepted PTSD screening method at the time the study was conducted, a multimeasure approach involving the use of multiple PTSD

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<sup>21</sup>Potential study participants were identified through three data sources: the National Archives' National Personnel Records Center, the Department of Defense's Defense Manpower Data Center, and Department of Defense data on female Vietnam veterans specially prepared for VA.

<sup>22</sup>The specific instrument used in the NVVRS survey to assess the prevalence of specific mental disorders was the National Institute of Mental Health Diagnostic Interview Schedule.

<sup>23</sup>This subset included more than 300 Vietnam veterans and 100 Vietnam-era veterans and was chosen to be representative of the NVVRS study participants.

assessment instruments was employed to identify PTSD in this subset.<sup>24</sup> A PTSD diagnosis was made for each participant in the subset based on a composite analysis of this detailed clinical information and the results of the NVVRS survey for the participant. The overall PTSD prevalence estimates presented in the NVVRS were based on these diagnoses.

The NVVRS estimated that about 31 percent of male Vietnam veterans (over 960,000 men) and 27 percent of female Vietnam veterans (over 1,900 women) had PTSD at some time during their lives.<sup>25</sup> The NVVRS also found that 15 percent of male Vietnam veterans had PTSD during the 6-month period preceding their participation in the NVVRS. In addition, the prevalence of PTSD among Vietnam veterans who experienced high levels of combat exposure and other war-related stressors was consistently higher than that of others. Since the NVVRS was completed, other researchers have reexamined PTSD prevalence rates for the Vietnam-era veteran population by, for example, applying updated PTSD diagnosis criteria to the NVVRS data.<sup>26</sup>

### **VA Has Taken Steps toward Conducting the NVVLS and Plans to Award a Contract to an External Entity in 2010 to Conduct the Study**

Since September 2009, when the Secretary of Veterans Affairs announced that the agency planned to award a contract to an external entity to conduct the NVVLS, VA has taken a number of steps toward conducting the NVVLS. VA convened a project team for the NVVLS consisting of VA officials and subject matter experts both within VA and outside of VA.<sup>27</sup> The NVVLS project team has developed a performance work statement, which outlines VA's requirements for the contractor selected to conduct the NVVLS.<sup>28</sup> VA officials also reported in April 2010 that they prepared a cost estimate for the NVVLS and an acquisition plan that contains additional contract specifics. VA expects to select a contractor for the NVVLS in the summer of 2010 and for the NVVLS to be completed in 2013. (See table 1 for VA's planned NVVLS timeline.)

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<sup>24</sup>Specifically, the participants in the subset were administered 10 instruments measuring PTSD by a mental health professional, in addition to the National Institute of Mental Health Diagnostic Interview Schedule. The instruments were the Mississippi Combat-Related PTSD scale, the Minnesota Multiphasic Personality Inventory PTSD Scale, the Structured Clinical Interview for DSM-III-R (*Diagnostic and Statistical Manual of Mental Disorders*) Disorders, a self-report scale of PTSD symptoms in the past 6 months, the Intrusion subscale of the Stress Response Rating Scale, the Avoidance subscale of the Stress Response Rating Scale, the Reactivity subscale of the Stress Response Rating Scale, the Intrusion subscale of the Impact of Event Scale, the Avoidance subscale of the Impact of Event Scale, and the Global Assessment Scale.

<sup>25</sup>These estimates are for individuals who were identified in the NVVRS as having "full-blown" PTSD, which was defined in the study as those who met the diagnostic criteria for PTSD in the *Diagnostic and Statistical Manual for Mental Disorders III-R*.

<sup>26</sup>See, for example, Bruce Dohrenwend et al., "The Psychological Risks of Vietnam for U.S. Veterans: A Revisit with New Data and Methods," *Science*, vol. 313, no. 5789 (2006).

<sup>27</sup>According to a VA document, the NVVLS project team, composed of 14 individuals, includes 5 subject matter experts. Included in the 10 PTSD researchers we interviewed are 3 out of the 5 subject matter experts on the NVVLS project team. Specifically, we interviewed both of the non-VA experts and 1 VA expert on the NVVLS project team.

<sup>28</sup>We reviewed a draft version of the performance work statement for this report.

**Table 1: VA’s Planned NVVLS Timeline**

Milestone	Estimated date
Finalize NVVLS performance work statement, cost estimate, and contract details	February 2010
Release NVVLS request for proposals	Spring 2010
Award NVVLS contract	Summer 2010
Begin NVVLS participant recruitment	2011
Complete NVVLS report	2013

Source: GAO analysis of VA information and GAO interviews with VA officials.

VA officials stated that they plan for the NVVLS to address all the requirements of the law where scientifically feasible. In addition to conducting the NVVLS, VA is continuing its national studies of PTSD in male twin Vietnam-era veterans and female Vietnam-era veterans. VA officials maintain that these studies will also provide useful information in response to the law (see enc. III for more information on these two VA studies).

### **VA Officials Report Facing Various Challenges in Conducting the NVVLS, Raising Uncertainty about Whether the Study Can Be Completed**

VA reported that it faces several challenges in conducting the NVVLS, including locating the original participants and obtaining their agreement to participate in the study, dealing with potential bias, and determining how to identify PTSD in the follow-up study. Given these challenges, VA officials are uncertain whether the NVVLS can be completed. In several instances, however, the researchers and methodologists we interviewed offered suggestions for addressing these challenges.

#### Although VA Officials Report Facing Various Challenges in Conducting the NVVLS, Researchers and Methodologists Had Ideas for Addressing Them

##### Locating NVVLS Participants

VA officials stated that they did not know how many of the original NVVRS participants could be located to participate in the NVVLS. Six of the 10 researchers we interviewed agreed that it could be challenging to locate the original participants. Similarly, the 3 methodologists we interviewed commented that locating study participants after 20 years could be a significant challenge. However, 9 of the researchers we interviewed believed that this challenge could be addressed.<sup>29</sup> Seven of the researchers we interviewed suggested that the NVVLS contractor could use the same data sources that were used at the time of the NVVRS—which included military records and Internal Revenue Service data—to locate participants. According to the NVVRS report, over 95 percent of possible participants were located using these data sources.<sup>30</sup> One researcher stated that when he was involved in the 2001 NVVLS attempt, a large number of the original participants were located and he was optimistic that a large number could be found today.<sup>31</sup> In addition, half of the researchers we interviewed noted that

<sup>29</sup>The one researcher who did not offer a suggestion stated that VA may not be able to overcome the challenge.

<sup>30</sup>In some cases, the addresses contained in the military records were up to 20 years old when they were used in the NVVRS.

<sup>31</sup>According to the Department of Health and Human Services’ Office of Inspector General, in 2005, the Research Triangle Institute provided VA with updated location information on the NVVRS participants.

new technologies, such as the Internet, could make locating study participants easier than it has been in the past. Three of the researchers and 1 methodologist had other suggestions for finding participants, such as using Social Security numbers and accessing VA or Medicare records.

#### Gaining Consent from NVVLS Participants

VA officials stated that they did not know how many of the original NVVRS participants would agree to participate in the NVVLS. VA officials expressed concern about being able to complete the NVVLS if not enough NVVRS participants agreed to participate. Four of the researchers and all the methodologists we interviewed agreed that the participation rate would have a direct impact on whether VA can conduct or complete the NVVLS. All 10 researchers and 3 methodologists stated that it was also important for NVVLS participants to receive assurances of confidentiality—that is, assurances regarding use of their identifying information, as was done with the NVVRS participants—to encourage participation.<sup>32</sup> The 3 methodologists we interviewed agreed that providing assurances of confidentiality is particularly important for government-funded studies because many people distrust government agencies. According to the draft performance work statement, the NVVLS consent form will not contain these assurances of confidentiality but it will state that study participation will not affect participants' VA benefits or VA health care. Two of the methodologists also recommended that VA work with veteran service organizations to help increase the participation rate of Vietnam veterans.

#### Having Access to Participants' Identifying Information

VA officials reported in September 2009 that there were legal and logistical issues that needed to be resolved related to transferring the study data, including NVVRS participants' identifying information, from the Research Triangle Institute to the new contractor after it is selected. After the 2001 NVVLS attempt concluded in 2003, VA attempted to take possession of the NVVRS participants' identifying information. Because of concerns about the confidentiality assurances provided to NVVRS participants, Research Triangle Institute declined to provide the data to VA. In October 2009, VA officials stated that a provisional agreement had been made whereby Research Triangle Institute will transfer NVVRS participants' identifying information to the new contractor for the NVVLS, once one has been chosen. According to the draft NVVLS performance work statement, after the NVVLS concludes, VA will require the contractor to provide all NVVLS data, including participants' identifying information, to VA. Nine of the researchers and one of the methodologists we interviewed warned that the requirement that VA take possession of this information at the conclusion of the NVVLS could impact whether the veterans would agree to participate in the NVVLS.<sup>33</sup> One researcher did not agree that this would impact the participation rate because he believes Vietnam veterans no longer mistrust VA. VA stated that it conducts many internal research studies and has no material issues recruiting study participants due to mistrust of VA.

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<sup>32</sup>The NVVRS provided participants with assurances of confidentiality via the NVVRS consent form, which stated that their identifying information would not be disclosed in any government proceedings.

<sup>33</sup>Representatives of veterans' service organizations also felt that the release of participants' identifying information to VA would significantly impact the participation rate for the NVVLS.

## Mitigating Possible Bias in a Follow-up Study

VA officials said that there could be bias in the NVVLS because the NVVRS was not designed to accommodate a follow-up study. Three researchers we interviewed disputed VA's statement about the design of the NVVRS.<sup>34</sup> They noted that on the NVVRS consent form participants were notified that they could be contacted again in the future. In addition, according to a VA document, shortly after the NVVRS, there were discussions about planning a follow-up study. However, ultimately, VA did not fund efforts for the Research Triangle Institute to maintain contact with the NVVRS participants. According to two of the methodologists we interviewed, bias is a legitimate concern with any follow-up study. The three methodologists stated that this challenge was closely related to the challenges of locating the original participants and obtaining their agreement to participate in the study—that is, bias would be present in the NVVLS if representative participation across all of the subgroups defined in the NVVRS is not achieved. Furthermore, the three methodologists stated that if bias in the NVVLS is a concern, VA could survey additional individuals from the general Vietnam-era population to supplement the original NVVRS cohort or develop a new sample of participants from the general Vietnam-era population for the NVVLS. VA's NVVLS draft performance work statement states that the contractor can choose to examine all or some of the NVVRS participants, but does not address the question of whether the contractor could propose to survey other Vietnam-era veterans.

## Assessing PTSD in the NVVLS

VA officials were concerned about appropriately assessing PTSD in the NVVLS given that the NVVRS used a complex approach that has not been used in other PTSD studies and would not be desirable to replicate. Nine of the 10 researchers we interviewed stated that the multimeasure method used to identify PTSD in the original study was not of concern.<sup>35</sup> Eight researchers commented that the approach, which identified PTSD through multiple PTSD assessment instruments, was used because there was no one widely accepted PTSD assessment instrument at the time the study was conducted. In addition, 8 of the 10 researchers we interviewed stated that several of the instruments used in the NVVRS, such as the Mississippi Combat-Related PTSD scale and the Structured Clinical Interview for DSM Disorders, are still used today and that the method used to identify PTSD in the NVVRS was rigorous.<sup>36</sup> Two of the 3 methodologists we interviewed commented that using multiple instruments is generally preferred, specifically when assessing mental health disorders like PTSD. In order to provide comparable longitudinal data, 9 of the researchers and 2 of the methodologists we interviewed recommended that the NVVLS contractor use PTSD assessment instruments similar or identical to those used in the NVVRS in addition to more current approaches.<sup>37</sup> According to the NVVLS draft performance work statement, the PTSD instruments used in the NVVRS should be used in the NVVLS, when appropriate, to enhance

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<sup>34</sup>These researchers were involved in conducting the NVVRS.

<sup>35</sup>One researcher thought the method used to identify PTSD in the NVVRS was of concern because the PTSD assessment instruments used in the method lacked validity. However, this researcher acknowledged that these instruments may have been the best available at the time.

<sup>36</sup>One researcher did not know if the instruments were used today and one researcher did not think the approach was rigorous.

<sup>37</sup>One researcher said that this approach would not necessarily be recommended because it may burden the participants and reduce participation rates.

consistency and facilitate long-term analyses. It also recommended that newer measures, such as the Clinician-Administered PTSD Scale, should be included when possible.<sup>38</sup>

### VA Reports That Further Study Is Needed to Determine the Feasibility of Completing the NVVLS

Overall, VA officials do not know whether, given the challenges they face, the NVVLS can be completed in response to the law. VA's NVVLS draft performance work statement includes an initial phase during which VA expects the contractor to assess the feasibility of the study. For example, the contractor will determine which NVVRS participants are alive and where they are located; based on this information, the contractor will estimate an expected participation rate for the NVVLS. Once feasibility is assessed by the contractor, VA officials will determine whether the study will move forward to data collection.

All 10 researchers we interviewed said that restarting the study soon is important because as the study participants continue to age, an increasing number will be lost for follow-up because of illness or death.<sup>39</sup> Nine of the researchers told us that they believe it is important for VA to complete the NVVLS because it will potentially provide important, nationally representative information on PTSD and related issues in Vietnam-era veterans.<sup>40</sup> Furthermore, because the NVVRS was explicitly designed to collect information about certain subgroups, such as ethnic and racial minorities, the NVVLS also has the potential to provide generalizable information about these groups. In addition, these researchers said that having as much information as possible on the experiences of Vietnam veterans will help VA and the Department of Defense plan for and meet the needs of veterans of Operation Enduring Freedom and Operation Iraqi Freedom.<sup>41</sup>

### **Agency Comments**

VA provided written comments on a draft of this report, which we have reprinted in enclosure IV. VA did not comment specifically on our findings but rather explained its position on the ownership of the NVVRS and NVVLS study data. VA stated that the NVVRS contract provided that the study data was the property of the agency and did not provide that the identifying information be kept from VA. The agency also stated that the NVVRS consent documents did not restrict VA from possessing the identifying information of participants. VA affirmed that the agency intends to receive all the NVVLS study data, including participants' identifying information, upon completion of the study, and stated that the NVVLS consent

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<sup>38</sup>According to VA's National Center for PTSD, the Clinician-Administered PTSD Scale is the gold standard in PTSD assessment.

<sup>39</sup>The youngest Vietnam-era veterans still living today would be approximately in their early 50s. During the 2001 NVVLS attempt, the researchers estimated that 8.5 percent of the Vietnam-era veterans who originally participated had died.

<sup>40</sup>One researcher did not think the NVVLS would provide important information and thought it should not be completed.

<sup>41</sup>One researcher stated that information about Vietnam-era veterans is not relevant to veterans in other conflicts. In 2010, the Institute of Medicine described differences in the experiences of Operation Enduring Freedom and Operation Iraqi Freedom veterans as compared to veterans of previous conflicts, but it also noted that there are relevant data on previous conflicts that are useful in addressing issues in Operation Enduring Freedom and Operation Iraqi Freedom populations. See Institute of Medicine, *Returning Home from Iraq and Afghanistan: Preliminary Assessment of Readjustment Needs of Veterans, Service Members, and Their Families* (2010).

form will explain to participants that VA does not intend to use the data to determine eligibility for VA benefits. We revised our report based on VA's comments as appropriate.

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We are sending a copy of this report to the Secretary of Veterans Affairs. The report also is available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [williamsonr@gao.gov](mailto:williamsonr@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in enclosure V.



Randall B. Williamson  
Director, Health Care

Enclosures – 5

**Veterans Benefits and Health Care Improvement Act of 2000, Section 212**

PUBLIC LAW 106-419—NOV. 1, 2000

VETERANS BENEFITS AND HEALTH CARE IMPROVEMENT ACT OF 2000

SEC. 212. STUDY OF POST-TRAUMATIC STRESS DISORDER IN VIETNAM VETERANS.

(a) STUDY ON POST-TRAUMATIC STRESS DISORDER.—Not later than 10 months after the date of the enactment of this Act, the Secretary of Veterans Affairs shall enter into a contract with an appropriate entity to carry out a study on post-traumatic stress disorder.

(b) FOLLOW-UP STUDY.—The contract under subsection (a) shall provide for a follow-up study to the study conducted in accordance with section 102 of the Veterans Health Care Amendments of 1983 (Public Law 98-160). Such follow-up study shall use the data base and sample of the previous study.

(c) INFORMATION TO BE INCLUDED.—The study conducted pursuant to this section shall be designed to yield information on—

- (1) the long-term course of post-traumatic stress disorder;
- (2) any long-term medical consequences of post-traumatic stress disorder;
- (3) whether particular subgroups of veterans are at greater risk of chronic or more severe problems with such disorder; and
- (4) the services used by veterans who have post-traumatic stress disorder and the effect of those services on the course of the disorder.

(d) REPORT.—The Secretary shall submit to the Committees on Veterans' Affairs of the Senate and House of Representatives a report on the results of the study under this section. The report shall be submitted no later than October 1, 2004.

Enclosure II

**Place(s) of Employment and Relevant Positions Held by the Researchers  
We Interviewed**

<b>Place(s) of employment</b>	<b>Relevant positions held</b>
Department of Veterans Affairs (VA); Dartmouth University	Executive director, National Center for Post-Traumatic Stress Disorder (PTSD) Member, Executive Committee, 2001 National Vietnam Veterans Longitudinal Study (NVVLS) attempt Professor, Psychiatry
VA; Duke University	Co-chair, VA Under Secretary for Health's Special Committee on PTSD Co-principal investigator, National Vietnam Veterans Readjustment Study (NVVRS) Subject matter expert, NVVLS project team Member, Institute of Medicine (IOM) Committee on Veterans' Compensation for PTSD Associate professor, Medical Psychology
Columbia University	Member, Scientific Advisory Committee, NVVRS Member, Scientific Advisory Board, 2001 NVVLS attempt Subject matter expert, NVVLS project team Professor, Social Science
National Institute of Mental Health	PTSD portfolio manager, National Institute of Mental Health Subject matter expert, NVVLS project team
Abt Associates	Co-principal investigator, NVVRS Principal investigator, 2001 NVVLS attempt
Abt Associates	Co-principal investigator, NVVRS Corporate officer in charge, 2001 NVVLS attempt Member, IOM Committee on Veterans' Compensation for PTSD
Yale University	Chair, Scientific Advisory Committee, NVVRS Chair, Scientific Advisory Board, 2001 NVVLS attempt Professor, Epidemiology
Connecticut Department of Veterans Affairs; Yale University	Interviewer, NVVRS Member, Scientific Advisory Board, 2001 NVVLS attempt Professor, Nursing
University of Hawaii	Professor, Psychology Associate editor, Journal of Traumatic Stress
Medical University of South Carolina	Director, National Crime Victims Research and Treatment Center, Medical University of South Carolina Member, IOM Committee on Veterans' Compensation for PTSD Professor, Psychiatry

Sources: GAO interviews and e-mail communication; curriculum vitae; July 25, 2007, congressional press release; Institute of Medicine; 2001 NVVLS Attempt Office of Management and Budget supporting statement; Richard A. Kulka, et al., *Access Denied: Trauma and the Vietnam War Generation: Report of Findings from the NVVRS* (New York: Brunner/Mazel Inc., 1990); William E. Schlenger, et al., "The Psychological Risks of Vietnam: The NVVRS Perspective," *Journal of Traumatic Stress*, vol. 20, no. 4 (2007); and September 2009 VA Update to Congress.

**Information on VA’s Studies of Post-Traumatic Stress Disorder  
in Twins and Women**

Department of Veterans Affairs (VA) officials reported that in addition to taking a number of steps toward conducting the National Vietnam Veterans Longitudinal Study (NVVLS), they currently have two national studies under way—one on male twin Vietnam-era veterans<sup>42</sup> and one on female Vietnam-era veterans<sup>43</sup>—that will also provide useful information in response to the law. (See enc. I for the full text of the law.) This enclosure provides information on these two VA studies.

- **Twin study.** The twin study, officially titled “A Twin Study of the Course and Consequences of PTSD in Vietnam Era Veterans,” began in 2006 and is projected to finish in 2013.<sup>44</sup> The objectives of the twin study are (1) to estimate the longitudinal<sup>45</sup> course and current prevalence of post-traumatic stress disorder (PTSD); (2) to identify the relationships between the longitudinal course of PTSD and veterans’ current mental and physical health conditions, such as cardiovascular disease, diabetes, depression, and substance use disorders; and (3) to identify the relationships between PTSD and veterans’ current functional status and disability. The twin study uses part of the Vietnam Era Twin Registry, a VA data source consisting of information collected over time on 14,738 Vietnam-era veteran male twins.<sup>46</sup> The twin study estimates that 5,306 men will participate in the study.<sup>47</sup> Data relevant to the study objectives will be collected through mailed questionnaires and structured phone interviews. The study will collect information on the health care services used by these veterans in the last 6 months. These data will be compared, when possible, to information from the study participants’ medical records and to data on PTSD in Vietnam Era Twin Registry twins collected in 1987 and 1992. The study will include analysis of the relationship between PTSD and each participant’s location of service, race, and educational level. The study protocol for the twin study was approved by VA’s Institutional Review Board<sup>48</sup> in January 2010, and according to study researchers, data collection was expected to begin after this approval. VA estimates that the twin study will cost \$6.1 million.

**Women’s study.** The women’s study, officially titled “Long Term Health Outcomes of Women’s Service During the Vietnam Era,” began in 2008 and is projected to conclude in 2014.<sup>49</sup> The women’s study will examine the following issues in Vietnam-era female veterans: (1) the prevalence of lifetime and current psychiatric conditions, including PTSD; (2) physical

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<sup>42</sup>This study defines the Vietnam era as 1965 through 1975.

<sup>43</sup>This study defines the Vietnam era as July 4, 1965, through March 28, 1973.

<sup>44</sup>This study is also known as VA cooperative studies program number 569.

<sup>45</sup>A longitudinal study approach involves the repeated examination of a set of study participants over time.

<sup>46</sup>In the Vietnam Era Twin Registry, there are 7,369 male-male twin pairs.

<sup>47</sup>According to VA, almost 94 percent of the men available to participate in the twin study are white.

<sup>48</sup>The Institutional Review Board is an independent committee that reviews research based on ethical considerations.

<sup>49</sup>The women’s study was previously known as “Determining the Physical and Mental Health Status of Women Vietnam Veterans.” It is also known as VA cooperative studies program number 579.

### Enclosure III

health; and (3) the level of current disability. A cross-sectional study,<sup>50</sup> the women's study plans to contact 10,000 Vietnam-era female veterans from VA's Vietnam Era Cohort data, which were compiled using military records and data from the Department of Defense's Defense Manpower Data Center.<sup>51</sup> According to VA, approximately 7,000 women will participate in the study. Data relevant to the study objectives will be collected through mailed questionnaires and structured phone interviews. The researchers will also collect information on the health care services used by female veterans in the last 6 to 12 months. The study plans to assess participants' history of medical conditions, such as cardiovascular disease and diabetes. According to VA, the study protocol for the women's study received Institutional Review Board approval in March 2010. According to the study researchers, data collection is expected to begin in 2010. VA estimates that the women's study will cost about \$5.6 million.

According to VA officials, VA's twin and women's studies, if completed as planned, will provide useful information in response to the law. For example, both studies will provide information on the long-term medical consequences of PTSD, describe whether particular subgroups of veterans are at greater risk of chronic or more severe problems with PTSD, and provide information on the services used by veterans who have PTSD and the effect of those services on PTSD. For some aspects of the study methodologies, the twin and women's studies were designed so that their results could be compared with each other, according to VA documents. For example, the twin and women's studies will use some of the same questionnaires to assess conditions such as PTSD, disability, and functional status.<sup>52</sup> While neither the twin study nor the women's study will include all of the National Vietnam Veterans Readjustment Study (NVVRS) participants, VA considers it highly likely that some participants in the women's study would have participated in the NVVRS. However, the extent of overlap is unknown because the women's study researchers do not have access to the NVVRS data that would identify the study participants. Finally, because the women's study is cross-sectional and does not plan any longitudinal assessments of PTSD, only the twin study will provide information on the long-term course of PTSD.

See table 2 for a comparison of the twin and women's studies to the NVVRS and NVVLS.

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<sup>50</sup>A cross-sectional study assesses participants at one point in time rather than at multiple points in time.

<sup>51</sup>According to VA, the majority of female Vietnam veterans were nurses. Three of the researchers we interviewed also stated that the majority of female Vietnam veterans were white.

<sup>52</sup>Specifically, the twin and women's studies both plan to use the Composite International Diagnostic Interview to assess PTSD and other mental health conditions, the World Health Organization Disability Assessment Schedule II to assess disability, and the Short Form 36 to assess functional status.

**Table 2: Overview of Selected VA-Funded PTSD Research Studies**

	<b>National Vietnam Veterans Readjustment Study (NVVRS)</b>	<b>A Twin Study of the Course and Consequences of PTSD in Vietnam Era Veterans (twin study)</b>	<b>Long Term Health Outcomes of Women’s Service During the Vietnam Era (women’s study)</b>	<b>National Vietnam Veterans Longitudinal Study (NVVLS)</b>
Status	Completed in 1988	Under way; projected completion in 2013	Under way; projected completion in 2014	Currently being planned; target completion in 2013
Study type	Contracted to external entity	Internal VA study	Internal VA study	To be contracted to an external entity (planned)
Study participants	2,348 Vietnam and Vietnam-era veterans <sup>a</sup> and 668 civilians	5,306 male twin Vietnam-era veterans <sup>b</sup> (planned)	Approximately 7,000 female Vietnam-era veterans <sup>c</sup> (planned)	NVVRS participants (planned; number to be determined)
Location of study participants’ identifying information upon completion	Research Triangle Institute	VA	VA	VA (planned)
Data collection methods	Structured in-person survey; semistructured in-person clinical interviews <sup>d</sup>	Structured phone interviews and mailed surveys	Structured phone interviews and mailed surveys	To be determined
Key study objectives	<p>(1) Provide information about the incidence, prevalence, and effects of PTSD and related postwar psychological problems among Vietnam veterans</p> <p>(2) Describe the total life adjustment of Vietnam theater veterans and compare their adjustment with the adjustment of Vietnam-era veterans who did not serve in the Vietnam theater and nonveterans</p> <p>(3) Provide detailed scientific information about PTSD in particular</p>	<p>(1) Estimate the longitudinal course and current prevalence of PTSD</p> <p>(2) Identify the relationships between the longitudinal course of PTSD and veterans’ health conditions</p> <p>(3) Identify the relationships between PTSD and veterans’ current functional status and disability</p>	<p>(1) Examine the prevalence of lifetime and current psychiatric conditions, including PTSD</p> <p>(2) Examine physical health status</p> <p>(3) Examine the level of current disability</p>	<p>(1) What is the long-term course of PTSD in Vietnam veterans?</p> <p>(2) What is the relationship between PTSD and other psychiatric disorders and physical health in Vietnam veterans?</p> <p>(3) Are particular subgroups of Vietnam veterans at greater risk of chronic, more severe problems with such psychiatric disorders, including later life onset of PTSD?</p> <p>(4) What services are used by Vietnam veterans who have or have had PTSD, and what is the relationship between those services (VA and other) on the course of PTSD? (planned)</p>

Enclosure III

	<b>National Vietnam Veterans Readjustment Study (NVVRS)</b>	<b>A Twin Study of the Course and Consequences of PTSD in Vietnam Era Veterans (twin study)</b>	<b>Long Term Health Outcomes of Women’s Service During the Vietnam Era (women’s study)</b>	<b>National Vietnam Veterans Longitudinal Study (NVVLS)</b>
Does study include or plan longitudinal analysis of PTSD?	No; however, comparison of NVVRS data to NVVLS data will be possible if the NVVLS is completed as planned	Yes; comparison to Vietnam Era Twin Registry data on PTSD collected in 1987 and 1992	No	Yes; comparison to NVVRS data collected from 1986 through 1988

Sources: GAO analysis of GAO interviews; twin study protocol; women’s study protocol; NVVLS Draft Performance Work Statement; 2001 NVVLS Attempt Office of Management and Budget supporting statement; Richard A. Kulka, et al., *Access Denied: Trauma and the Vietnam War Generation: Report of Findings from the NVVRS* (New York: Brunner/Mazel Inc., 1990); and September 2009 VA Update to Congress.

<sup>a</sup>In the NVVRS, Vietnam veterans are defined as those who served in or around Vietnam, Laos, or Cambodia from August 5, 1964, through May 7, 1975; Vietnam-era veterans are defined as those who served in the U.S. military in any location except in or around Vietnam, Laos, or Cambodia from August 5, 1964, through May 7, 1975.

<sup>b</sup>This study defines the Vietnam era as 1965 through 1975.

<sup>c</sup>This study defines the Vietnam era as July 4, 1965, through March 28, 1973.

<sup>d</sup>In addition to a completing an in-person survey, a subset of 440 NVVRS participants also received clinical interviews.

**Comments from the Department of Veterans Affairs**



Department of Veterans Affairs  
Office of the Secretary

April 23, 2010

Mr. Randall Williamson  
Director  
Health Care  
U.S. Government Accountability Office  
441 G Street, NW  
Washington, DC 20548

Dear Mr. Williamson:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, ***VA HEALTH CARE: Status of VA's Approach in Conducting the National Vietnam Veterans Longitudinal Study (GAO-10-578R)***.

The enclosure provides comments to the draft report. VA appreciates the opportunity to comment on your draft report.

Sincerely,

  
John R. Gingrich  
Chief of Staff

Enclosure

Department of Veterans Affairs (VA) Comments to  
Government Accountability Office (GAO) Draft Report  
**"VA HEALTH CARE: Status of VA's Approach in  
Conducting the National Vietnam Veterans  
Longitudinal Study  
(GAO-10-578R)**

**Comments:**

**Page 2, Paragraph 1, Line 10:** Participants' identities were not provided to VA because of concerns about Vietnam veterans' distrust of government agencies.

**VA Comment:** VA's original NVVRS contract with Research Triangle Institute (RTI) provided that all the data developed in that study was the property of VA. Therefore, VA owns that data. The NVVRS contract did not provide that identifying data should be kept confidential from VA, nor did the consent documents that were provided to Veteran subjects include such a restriction. To the extent that individuals made this representation, it was without a basis in law or contract and not the position of VA on this matter.

**Page 8, beginning at Paragraph 2 to Page 9:**

**VA Comment:** We would like to acknowledge that the information provided in this paragraph correctly reflects the status of the performance work statement, cost estimate, and acquisition plan. GAO's Statement of Facts, which was provided to VA prior to the draft report, did not contain the correct information.

**Page 11, Paragraph 2, Line 4:** After the 2001 NVVLS attempt concluded in 2003, VA attempted to take possession of the NVVRS participants' identifying information. Due to concerns about the confidentiality assurances provided to NVVRS participants, Research Triangle Institute, as custodian of the identifying information, declined to provide the data to VA.

**VA Comment:** RTI is not the custodian of the data. RTI has no legal basis upon which to withhold the data from VA. However, in lieu of litigating this matter further, VA has secured an agreement memorialized in correspondence with RTI to transmit these data to VA's NVVLS contractor upon its selection. The terms of the NVVLS contract will require new informed consents from Veteran subjects in accordance with HIPAA and VA will receive all these data, including identifiable data, as a result of the research conducted. VA is required by federal law, including the Federal Records Act, to be the ultimate custodian of such data, to ensure that it is secured and, if determined by law, appropriately destroyed. If RTI declines to act in accordance with these conditions, VA shall take appropriate legal steps to recover these data. Thereafter, VA shall insist that RTI relinquish control of or certify the destruction of these data, if any, that remains in its possession.

**Page 11, Paragraph 2, Line 13:** Nine of the researchers and one of the methodologists we interviewed warned that the requirement that VA take possession of this information at the conclusion of the NVVLS could impact whether the veterans would agree to participate in the NVVLS.

Enclosure

Department of Veterans Affairs (VA) Comments to  
Government Accountability Office (GAO) Draft Report  
**"VA HEALTH CARE: Status of VA's Approach in  
Conducting the National Vietnam Veterans  
Longitudinal Study  
(GAO-10-578R)**

**VA Comment:** Notwithstanding whether individual researchers believe that VA should not receive identifiable data, there is no further legal question on this point, and, VA shall own, receive and retain such data created and used in the performance of the NVVLS contract. The informed consent that VA's NVVLS contractor will create shall include a statement that VA does not intend to use such data for eligibility (or continued eligibility) for Veterans' benefits. VA conducts many research projects in-house and has no material issues with securing research subjects due to any mistrust of VA.

Enclosure V

**GAO Contact and Staff Acknowledgments**

**GAO Contact**

Randall B. Williamson, (202) 512-7114 or williamsonr@gao.gov

**Acknowledgments**

In addition to the contact named above, Mary Ann Curran, Assistant Director; Susannah Bloch; Stella Chiang; Martha R. W. Kelly; Melanie Krause; Lisa Motley; Michelle Paluga; Rebecca Rust; and Suzanne Worth made key contributions to this report.

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