



**Department of Veterans Affairs
Office of Inspector General**

**Review of Contract No. VA549-P-0027
Between the
Department of Veterans Affairs and
The University of Texas Southwestern
Medical Center at Dallas (UTSWMC)
for Gulf War Illness Research**

To Report Suspected Wrongdoing in VA Programs and Operations

**Telephone: 1-800-488-8244 between 8:30AM and 4PM Eastern Time,
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Executive Summary

Introduction

At the request of the former Secretary of Veterans Affairs, the Office of Inspector General, Office of Contract Review (OCR) conducted a review of the pre- and post-award activities associated with Contract Number VA549-P-0027. This contract was awarded to the University of Texas Southwestern Medical Center at Dallas (UTSWMC) by the Department of Veterans Affairs (VA), Veterans Integrated Services Network (VISN) 17 to conduct Gulf War Illness research.

Public Law 109-114, dated November 30, 2005, included an earmark in the appropriation for Medical and Prosthetic Research. This earmark simply required not less than \$15 million be used for Gulf War Illness research. With respect to the earmarked funding, the Conference Report 109-305 directed VA to enter into a pilot study involving collaborative research with UTSWMC.

In April 2006, VA entered into a Memorandum of Understanding (MOU) with UTSWMC to conduct Gulf War Illness research. The stated purpose of the MOU was to “set forth an agreement between UTSWMC and VA to collaborate on Gulf War Illness research.” The MOU references both Public Law 109-114 and directly quotes the Conference Report in the purpose section. The MOU was to be followed by a contract with UTSWMC to perform the research.

In September 2006, a VISN 17 contracting official asked OCR to review a proposed Indefinite Delivery Indefinite Quantity (IDIQ) contract to be awarded to UTSWMC. OCR identified several issues with the proposed contract, including the type of contract, the use of 38 U.S.C. § 8153 authority, and the use of a contract in general to provide direct funding to UTSWMC, as it was unclear what direct benefit or use the Federal Government would be receiving from this research. These concerns were raised in a conference call between officials from OCR, Veterans Health Administration (VHA), the Office of Acquisition, and the Office of General Counsel (OGC) on October 16, 2006. During the conference call, OCR noted that the appropriate vehicle for providing funds for a public purpose is a grant. However, neither Public Law 109-114 nor Conference Report 109-305 provided grant authority to VA, and VA officials did not want to seek a technical amendment to receive grant authority as suggested by OCR. Based on the advice of OGC, the end result was a determination that the only way to satisfy the congressional mandate was a sole source contract award to UTSWMC citing § 8153.

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On November 14, 2006, VA entered into an IDIQ contract with UTSWMC for the purpose of procuring scientific studies (research) of various Gulf War Veterans' Illnesses. The contract, which consists of a base year and four 1-year option periods, was awarded under the authority of Title 38 U.S.C. § 8153, which gives VA the authority to enter into sole-source contracts with affiliated institutions for the purpose of procuring healthcare resources that might not be feasibly available. The contract stipulates that UTSWMC:

[S]hall have overall responsibility for submitting task order/research plans and for management of task orders awarded against this contract. Award of all task orders/research plans, and performance of all work under this contract are subject to VA review and approval...Within the limitations of this contract and federal appropriations for [Gulf War illness], VA will award task orders for all projects approved by UTSWMC's review process, after verifying that the Task Order Plans address the purpose for which the funds were appropriated (Gulf War Veterans' Illnesses research as described in Appendix I, Overall Research Plan).

Per the contract, UTSWMC, not VA, had the responsibility to identify, conduct and manage research projects supported by task orders that UTSWMC prepared and submitted to VA to be awarded against the contract. In fact, UTSWMC developed the Overall Research Plan included in the contract.

In February 2007, the President and the Congress agreed to remove the earmark for Gulf War Illness research from the FY 2007 appropriation. At that time, no task orders had been issued against the contract. The first task order was not issued until March 2, 2007. As of January 31, 2009, \$32.2 million has been obligated to fund task orders against the contract and the total amount paid was approximately \$8 million.

The terms and conditions of the contract and the contract vehicle itself have caused significant problems relating to contract administration. The most significant issue at this time is UTSWMC's refusal to comply with the terms and conditions of the contract relating to the ownership of data and information security. In October 2008, UTSWMC unilaterally changed the informed consent form that human subjects in the studies are required to sign. Contrary to the specific requirements in the contract, the revised form prohibits VA from access to certain information obtained by UTSWMC in conducting the research. The contract clearly states that this information is the "exclusive property of VA." UTSWMC also failed to notify VA of the change and it was not discovered by VA until January 2009 during the routine review of an invoice submission package. Since January, VA has made numerous, but unsuccessful attempts to have UTSWMC comply

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with the terms and conditions of the contract. Records show that UTSWMC's Principal Investigator requested the change in an expedited request to the Chair of UTSWMC's Institutional Review Board. The basis for the request was speculation that veterans may not participate in the studies if the information was released to VA. The Principal Investigator has not provided any evidence to support his concerns.

On June 8, 2009, after almost 6 months of attempts to obtain compliance from UTSWMC on this and issues relating to the UTSWMC's failure to comply with the information security requirements contained in the contract that are needed to ensure the protection of veteran data and privacy, VA issued a Cure Notice to UTSWMC. Failure to cure the deficiencies should result in termination of the contract for default.

On June 26, 2009, UTSWMC responded to the Cure Notice and agreed to comply with the information security requirements but refused to change the informed consent form back to the version agreed to by the parties when the contract was awarded.

Results

We found that there was no legal requirement for VA to enter into an MOU or contract with UTSWMC or any other third party to comply with the earmark in Public Law 109-114. The legislation only required VA to use \$15 million of the funds appropriated for medical and prosthetics research for Gulf War Illness research. It did not impose any requirements regarding how VA was to accomplish this. Specifically, the legislation did not require VA to enter into a long term contract with UTSWMC to conduct the research. The decision by VA management and OGC to use a sole-source IDIQ contract citing § 8153 authority placed VA contracting staff, including the Contracting Officer's Technical Representatives, in a position where they could not effectively administer this contract and funding.

VA appears to have entered into the MOU and the contract in response to the non-binding direction provided in the Conference Report that accompanied Public Law 109-114. However, neither agreement complied with the specific direction in the Conference Report that a VA Medical Center and UTSWMC conduct a collaborative pilot study. No pilot study was conducted and no collaborative research has been conducted under the contract.

We determined that the use of an IDIQ contract has caused numerous management and contract administration issues. These include invoicing and payment, UTSWMC contract management, training, information security and property rights. As a result, VA has

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expended significant time and resources across many levels of the organization in an attempt to make the contract work. The inappropriate use of an IDIQ contract has also led to significant involvement of OGC and VA managers in Central Office and in VISN 17, in the operation of the contract which impeded the ability of the contracting officers to effectively administer this contract. UTSWMC has also expended unnecessary resources which were paid for with VA funding, attempting to comply with contract terms and conditions.

The use of § 8153 contracting authority was inappropriate because VA had no defined need for the services and the contract included the purchase of more than \$1 million in supplies and equipment that are outside the scope of § 8153 authority. Because VA did not have a defined need, the scope of the contract and the work performed under the task orders issued against the contract was dictated by UTSWMC, including the review and approval of every research project to be conducted. The contract was merely a funding mechanism to support UTSWMC's research program.

Based upon our review of Public Law 109-114, the Conference Report, the MOU, the contract, the task orders, and other related documentation, and interviews with key VA personnel involved in the administration of the contract, we conclude that:

- The MOU and contract with UTSWMC were not mandated by the earmark in the FY 2006 appropriation or the direction provided in the accompanying Conference Report.
- Neither the provisions in the MOU nor the contract comply with the direction in the Conference Report for a VA Medical Center and UTSWMC to collaboratively conduct a pilot study.
- The MOU and contract were entered into without considering alternative means to comply with the earmark requiring VA to spend at least \$15 million of the amount appropriated for medical and prosthetics research for Gulf War Illness research.
- The use of § 8153 contacting authority was inappropriate and the use of an IDIQ contract resulted in multiple problems with contract administration.
- UTSWMC has been in default since October 2, 2008, because it failed to comply with terms of the contract relating to ownership of data and information security, which resulted in the issuance of the Cure Notice.

We offer no opinion regarding the merits of any research project being conducted by UTSWMC. The scope of our review was limited to the award and administration of the contract with UTSWMC. Many of the problems we identified could have been avoided

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if VA was able to treat and administer the earmark simply as a grant. Since VA management chose not to pursue grant authorization, they opted to misuse Federal procurement regulations and policy. We believe that a contract should not have been used to provide funds to UTSWMC or any other entity. If there was a Congressional mandate for UTSWMC to conduct this research, the funds should have been given directly to UTSWMC or VA should have been given, or sought, grant authority.

Suggestions

Given UTSWMC's continued refusal to comply with the terms and conditions of the contract, UTSWMC has given VA no option other than to terminate the contract for default. Although such action is extreme, allowing UTSWMC to violate a critical requirement in the contract sets a precedent that the terms and conditions of VA contracts are discretionary, not mandatory.

In the event the contract is not terminated for default, we suggest that VA re-evaluate whether the MOU and contract with UTSWMC are necessary or in the best interest of the Government. Factors that should be taken into consideration in making this decision should include the issues identified in this report. If it is decided that the contract is not necessary or in the best interest of the Government, VA should consider terminating the contract or letting it expire by not exercising the next option year. In the meantime, VA should consider not awarding any additional task orders against the contract.

If a decision is made that an agreement with UTSWMC or other third party for Gulf War Illness research is necessary and will provide value to VA, VA should consider asking Congress for grant authority. If this is not possible, VA should consider renegotiating the terms and conditions of the existing contract to address the issues raised in this report. In the alternative, VA could let the existing contract expire and negotiate a new contract with UTSWMC or other research entity.

(original signed by:)
MARK A. MYERS
Director, Division A
Office of Contract Review

Introduction

Purpose

At the request of the former Secretary of Veterans Affairs, we conducted a review of the pre- and post- award activities associated with contract number VA549-P-0027, awarded by Veterans Integrated Services Network (VISN) 17 to the University of Texas Southwestern Medical Center at Dallas (UTSWMC). The contract, which was awarded on a sole-source basis under the provisions of 38 U.S.C. § 8153, was for the conduct of research relating to Gulf War Illness. The former Secretary requested the review because of concerns brought to his attention by the former Under Secretary of Health. Our review objectives included an assessment of:

- The development, award, and administration of the contract, including compliance with the contract's terms and conditions.
- The requirements of Public Law 109-114, Military Quality of Life and Veterans Affairs Appropriations Act, 2006, November 30, 2005, and the related Conference Report, 109-305.
- The use of contracting authority under 38 U.S.C. § 8153, "Sharing of health-care resources."
- The memorandum of understanding between UTSWMC and VA that preceded the award of the contract.

Background

Public Law 109-114 appropriated \$412,000,000 for the programs of medical and prosthetic research of which not less than \$15 million was earmarked for Gulf War Illness research. These funds were available through September 30, 2007. Other than earmarking \$15 million for Fiscal Year 2007 for Gulf War Illness research, the Public Law did not provide any specific direction to VA on how the money should be spent, including where the research would be conducted, by whom, or for what period of time.

In response to Public Law 109-114, in April 2006, VA entered into a Memorandum of Understanding (MOU) with UTSWMC to conduct Gulf War Illness research. The basis for entering into the agreement with UTSWMC was the non-binding language in Conference Report 109-305, which stated:

In complying with the RAC recommendations, the Department is directed to devote at least \$15 million to Gulf War Illness research in this fiscal year, and in each of the next four fiscal years. In addition, this initiative

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shall, at a minimum, begin with a pilot study involving collaborative research between a VA Medical Center and the University of Texas, Southwestern Medical Center, which is presently conducting extensive research on Gulf War Illness.

The stated purpose of the MOU was to “set forth an agreement between UTSWMC and VA to collaborate on Gulf War Illness research.” The purpose statement also provided that, “the terms and conditions of this MOU shall be consistent with and are authorized by 38 U.S.C. § 8153.” The MOU outlines general agreement terms, for collaboration, review process, research contracts, the purchase of Magnetic Resonance Imaging (MRI) equipment, authority, good faith discussion, intellectual property, and database information. It also includes terms for amendments, effective period and termination. In November 2006, VA entered into an Indefinite Delivery Indefinite Quantity (IDIQ) contract with UTSWMC to conduct the research. The contract type appears to be Research and Development as defined under FAR Part 35, Research and Development Contracting. It is not clear whether the MOU had any enforceability or impact once the contract was signed.

In September 2006, the OIG Office of Contract Review (OCR) was asked by the Contracting Officer to review the proposed IDIQ contract. This was associated with a request to expedite pre-award reviews of proposed task orders against the contract. Pre-award reviews of proposals for healthcare resources are required under VA Directive 1663. OCR identified several problematic issues, to include type of vehicle, the use of 38 USC § 8153 authority, as well as inconsistencies between the MOU and the proposed contract. OCR discussed these concerns with the Contracting Officer, other VA officials, and the Office of General Counsel (OGC) in a conference call on October 16, 2006. OCR raised concerns regarding the use of a contract to direct funding to UTSWMC because it was unclear what direct benefit or use the Federal Government¹ would be receiving from this research. When questioned, the contracting officer could not identify a need by VA for the contract. The sole basis for the contract with UTSWMC was the language in the Conference Report. OCR noted that the appropriate vehicle for providing funds for research such as that identified in the contract is a grant. However, VA does not have statutory authority to award grants and did not want to seek a technical amendment to receive grant authority as suggested by OCR during the conference call. Based on advice from OGC, VA made a determination that the only way to satisfy the congressional mandate was a sole source contract to UTSWMC using 38 U.S.C. § 8153

¹ In accordance with FAR 35.003 a contract may only be used when the principal purpose is the acquisition of supplies or services for the direct benefit or use of the Federal Government.

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contracting authority. Notwithstanding the issues raised by OCR during the conference call, the Chief Logistics Officer for VISN 17 subsequently sent an email announcing that the “Deputy Assistant Secretary for Acquisition and Material Management has endorsed and has our complete support to move on with the ID/IQ Request for Proposal (RFP). The RFP will be forwarded to UTSWMC for their review and acceptance today.”

On November 14, 2006, VA entered into an IDIQ contract with UTSWMC for the purpose of procuring scientific studies (research) of various Gulf War Illnesses. The IDIQ contract was issued with an estimated contract value of \$75 million dollars and was for a base period of one year plus 4 one-year option periods. Prior to award, VHA obtained several waivers including a waiver from the requirement in VA Directive 1663 for a pre-award review of proposed pricing.

The contract was awarded under the authority of 38 U.S.C. § 8153. Unlike other contracts awarded by VA under § 8153, the contract does not identify or define specific requirements or deliverables. Rather, UTSWMC was responsible for requesting task orders and for developing a task order plan to support each request. UTSWMC was also responsible for identifying, conducting, and managing research projects identified and supported by the task orders.

The contract contains an Overall Research Plan which included research objectives considered to be of high priority by the Research Advisory Committee (RAC) for Gulf War Illness. The RAC was chartered by VA at the direction of Congress to advise VA on its Gulf War Illness research priorities. The Overall Research Plan has been modified to add additional topics that the RAC has added to its recommended focus areas.

The contract stipulates that UTSWMC:

[S]hall have overall responsibility for submitting task order/research plans and for management of task orders awarded against this contract. Award of all task orders/research plans, and performance of all work under this contract are subject to VA review and approval.

However, the following language in the contract strictly limits VA’s review and approval process to whether the research project is related to Gulf War Illness research:

Within the limitations of this contract and federal appropriations for GWVI, VA will award task orders for all projects approved by UTSWMC’s review process, after verifying that the Task Order Plans address the purpose for which the funds were appropriated (Gulf War

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Veterans' Illnesses research as described in Appendix I, Overall Research Plan)...Award will take place within a period of thirty (30) days after [VA] is in receipt of all required documentation.

The contract did not contain firm-fixed labor hour rates. Instead, it contained a table of possible labor categories and minimum, medium, and maximum annual and hourly rates for each. These rates were not based on, and bore no relationship to, actual labor hour rates for personnel at UTSWMC. The contract also contained additional pricing provisions for post-doctoral trainees and individuals with UTSWMC faculty appointments. Although the contract discussed the role for a Principal Investigator, the contract did not include a labor category or an established labor rate for Principal Investigator. Actual prices were to be negotiated at the time each task order was issued.

Section C of the contract contains the statement of objectives. Section C.2 requires UTSWMC to establish an "internal Merit Review Process to review for scientific merit all research projects to be funded with federal appropriations for [Gulf War illness] research under this contract." The first step of the Merit Review process was the development of an Overall Research Plan. The contract states that the head of the Merit Review process is the Dean of the UTSWMC Medical School or his designees and that he will be the "sole determiner of the content of the Overall Research Plan, subject to government review and approval."

Section C.3.4 requires the establishment of a UTSWMC Merit Review Group (MRG) whose members shall be appointed by the Dean of the medical school. The MRG may include scientists on the faculty of UTSWMC or the VA North Texas Health Care System. It also must include one scientist who is not an employee of UTSWMC or the Dallas VA Medical Center. According to the contract, the purpose of the MRG is to decide whether proposed task orders fit the Overall Research Plan in the contract and have enough potential merit and benefit to be worthy of contract funding. The MRG had no VANTHCS representation.

In addition, the Dean of UTSWMC Medical School has sole authority to determine how opportunities for research support under the contract will be communicated to the research community. UTSWMC was allowed to solicit research proposals from third parties for the task orders. If a VA facility wished to submit a proposal, it had to be submitted to the UTSWMC MRG, but only after it had been reviewed by the appropriate VA Research and Development (R&D) Committee and Institutional Review Board (IRB).

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Sections C.6.4 and C.6.5 address the role of IRBs for animal and human subjects research, respectively. These sections require that at least one VA employee, who is also a faculty member at UTSWMC sit on the respective IRBs. We understand that the requirement that the individual(s) also be UTSWMC faculty members was added at the request of UTSWMC. The VA employee who participates on UTSWMC's IRB for research involving human subjects not only has a faculty appointment at UTSWMC, but is also a part-time UTSWMC employee. His participation is limited to weighing benefits against risks for participants in each proposed study, not whether the individual research proposals are sound.

Section H of the contract includes provisions for using and safeguarding information protected by the Privacy Act, VA confidentiality laws, and the Healthcare Insurance Portability and Accountability Act (HIPAA). The requirements included training of all contractor and subcontractor personnel who had access to protected data.

Section H.7.2 specifically states that "Information, including, but not limited to, veteran individually identifiable information and personal healthcare information, gathered or created by UTSWMC in the performance of this contract is the exclusive property of VA." This is reinforced by the inclusion of FAR clauses 52.227-17, Special Works, and 52.227-16, Additional Data Requirements, in the contract.

Records indicate that on February 15, 2007, Congress and the President passed a joint resolution for FY 2007, removing the \$15 million earmark for Gulf War Illness research. On February 22, 2007, the contracting officer requested additional guidance on spending of FY 2006 earmarked funds, and funding for FY 2007 and future years. VACO/OGC and the Deputy Under Secretary for Health provided guidance that VA is authorized to spend the \$15 million in FY 2006 earmarked funds and that VA intends to continue funding the contract at the rate of \$15 million per year through 2010, subject to Congressional funding of the research budget for each of those fiscal years—even though, at that time, there was no longer any statutory requirement to spend \$15 million Gulf War Illness research. As of the date the earmark was removed, no task orders had been issued against the contract.

The first task order issued against the contract was issued on March 2, 2007, in the amount of \$1.2 million for program management, not human or animal research studies, for a two year period beginning on March 1, 2007. This amount was subsequently increased to \$2.5 million through two modifications to the task order. As of January 31, 2009, \$32.2 million has been obligated against task orders issued against the contract and the total amount actually paid by VA was approximately \$8 million. Of the \$32.2 million, \$10.8 million was obligated from the FY 2006 appropriation; \$14.1

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million from the FY 2007 appropriation; and, \$7.3 million from the FY 2008 appropriation. No funds had been obligated from the FY 2009 appropriation. Funds from each appropriation were available for 2 years. Therefore, funding from the FY 2006 and FY 2007 appropriations have expired.

There have been significant issues between the parties regarding invoicing and payment, UTSWMC contract management, training, information security and property rights. The VHA Issue Brief dated November 13, 2008, includes discussion regarding termination for default due to UTSWMC being delinquent on deliverables and invoices. The brief further stated that UTSWMC's hardware and management practices need to be corrected to ensure protection of veteran data and privacy (Office of IT Oversight and Compliance report dated October 20, 2008), background investigations are in arrears, and required training has not been completed. Since January 2009, VA has been in discussions with UTSWMC to bring them into compliance with the terms and conditions of the contract. On June 8, 2009, the Contracting Officer issued a Cure Notice to UTSWMC. A cure notice puts the contractor on notice that they are in default and provides the contractor the opportunity to become compliant prior to VA terminating the contract for default. In a response dated June 26, 2009, UTSWMC agreed to take action to comply with deficiencies related to information security but did not agree to comply with contract terms and conditions relating to property rights. As such, UTSWMC is in default of the contract.

To date no approved research projects have been completed. We understand that only 46 veterans have undergone Magnetic Resonance Imaging (MRI) to be analyzed under the research protocols related to various approved task orders.

Scope and Methodology

To address the objectives of this review, we reviewed the earmark legislation, the MOU, the contract and all documentation provided by VISN 17 in response to our request for all contractual documents. We also reviewed all task orders issued against the contract and all invoices and payments through January 2009. We reviewed all VHA Issue Briefs from September 29, 2006 through January 8, 2009. We followed contract status from the time the formal demand for UTSWMC to take affirmative action to resolve the issues on April 10, 2009 to the issuance of a formal cure notice on June 8, 2009. We also interviewed the Contracting Officer, Contracting Officer Technical Representatives (COTRs), the VISN 17 Network Contract Manager, and the VA physician who participates in UTSWMC's IRB.

Results

We found that the use of a contract to conduct medical research in order to comply with the requirement of the earmark in Public Law 109-114 as well as the direction provided in the Conference Report has caused numerous management and administration issues. As a result, VA has expended significant resources across many levels of the organization attempting to make the contract work. UTSWMC has also expended unnecessary resources (at VA's expense) attempting to comply with contract terms and conditions. These resources include a task order valued at over \$2.5 million dedicated solely to management of the project and complying with the contract's deliverable requirements, invoicing, performance monitoring, managing contract funds, conducting scientific reviews of proposed projects, and submitting research proposals. Although the MOU and the subsequent contract with UTSWMC appear to have been entered into primarily to satisfy the direction given in the Conference Report, we found that they did not meet the minimal direction which was to conduct a pilot study involving collaborative research between a VA Medical Center and UTSWMC.

Because VA had no defined need for the services and the contract included the purchase of equipment, we concluded that the use of 38 U.S.C. § 8153 as the contracting authority was improper. The contracting authority appears to have been used to justify awarding a sole-source contract to UTSWMC.

The scope of the contract and the task orders issued against it are dictated by UTSWMC and are accepted by VA as long as they meet the broad objectives of the Overall Research Plan. In essence, UTSWMC tells VA what they are going to do, how much it will cost, how long it will take, and who will do the work. None of the research proposals were reviewed by technical experts in VA who were familiar with projects of this magnitude. We also believe that the involvement of VA managers in Central Office and VISN 17, and OGC, impeded the ability of the contracting officers and the Contracting Officer's Technical Representatives (COTRs) to effectively administer this contract.

Poor performance and noncompliance with contract terms and conditions have been prevalent during the contract period. Documented performance issues include delinquent deliverables, noncompliance with contract terms and conditions related to timely billing, required billing, UTSWMC's unilateral changes to the agreed upon informed consent form, and failure to comply with required security training.

Issue 1: The Contract with UTSWMC was Not Required by Public Law 109-114 and did Not Meet the Direction Provided to VA in the Conference Report.

Our review of Public Law 109-114 found that the only requirement associated with the earmark in the Public Law, was that VA devote a minimum \$15 million of the Fiscal Year 2006 medical and prosthetics research appropriation to Gulf War Illness research. The funding was available through September 30, 2007 and the legislation did not mandate how this was to be done or by whom. Accordingly, the decision to enter into an MOU and potential 5 year contract with UTSWMC was not necessary to comply with the earmark in the Public Law.

The decision to enter into these agreements with UTSWMC appears to have been based on the directions to VA contained in the non-binding Conference Report, dated November 18, 2005. The Conference Report stated:

Gulf War Illness.—The conferees recognize the unique nature of Gulf War Illness and direct the Department to implement the recommendations of the Research Advisory Committee (RAC) on Gulf War Veterans' Illness in the context of the overall Department research program. One aspect of this effort is the establishment of a research center of excellence devoted to Gulf War Illness research. The conferees are supportive of this effort and direct the Department to report to the committees on Appropriations of both Houses of congress regarding establishment of such a center by March 15, 2006. In complying with the RAC recommendations, *the Department is directed to devote at least \$15,000,000 to Gulf War Illness research in this fiscal year, and in each of the next four fiscal years. In addition, this initiative shall, at a minimum, begin with a pilot study involving collaborative research between a VA Medical Center and the University of Texas, Southwestern Medical Center, which is presently conducting extensive research on Gulf War Illness.* (Emphasis added)

The only specific direction to VA in the Conference Report relating to UTSWMC was that the research begins with a pilot study involving collaborative research between VA and UTSWMC. A collaborative pilot study was never conducted and was not included in the MOU or subsequent contract between VA and UTSWMC.

On February 15, 2007, just 6 months after the contract was awarded and before the first substantive task order was issued,² Congress and the President passed a joint resolution that removed the earmark for Gulf War Illness Research from the Fiscal Year 2007 budget in Section 20810 of Public Law 110-5, Revised continuing Appropriations Resolution, 2007. Although this would have been an opportune time to reassess the need for the potential 5 year contract with UTSWMC valued at \$75 million, a decision was made to continue funding for the contract through 2010. Records indicate that this guidance was provided by the former Deputy Under Secretary for Health and OGC. The underlying reasons for the decision are not documented in the records that have been provided to us.

For FY 2008 and 2009, the Congress and the President did not add back the earmark in the Medical and Prosthetic Research section in either appropriations act. However, the administrative provisions section in both appropriations acts state: “The Department shall continue research into **Gulf War** Illness at levels not less than those made available in fiscal year 2007, within available funds contained in this Act.” Although the intent is to ensure that a portion of the funds appropriated for research is used for research related to Gulf War Illness, there is no mandate to fund research conducted by UTSWMC or any other external entity.

Issue 2: The Contract with UTSWMC Does Not Allow for VA Collaboration on the Research Funded by VA.

The MOU entered into between VA and UTSWMC in April, 2006, laid the groundwork to satisfy the research requirement specified in Public Law 109-114 and the directions contained in the Conference Report. The term “collaborative” is used throughout the MOU suggesting that the research efforts are collaborative between VA and UTSWMC. For example:

- The title of the MOU states that it is, “for sharing of resources for collaborative research.”
- The purpose statement of the MOU states: “This Memorandum of Understanding (MOU) sets forth an agreement between the University of Texas Southwestern Medical Center (UT Southwestern) and the Dallas VA Medical Center (VAMC) to collaborate on Gulf War Illness research.”

² Task Order 2 was issued via a letter contract on April 27, 2007, and definitized on July 23, 2007. This was the first task order issued that related directly to research.

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- Paragraph 1 under General Agreements reads: “Collaboration. VAMC will work with the office of the Dean, Southwestern Medical School, and/or his designee, on all matters concerning this MOU.”
- Paragraph 3.b. states UT Southwestern and VAMC will collaborate and work closely to develop an expedited contract award process for the research projects which are the subject of this MOU, within 30 days of execution of this MOU.

Notwithstanding the use of terms indicating “collaboration” throughout the MOU, the research being conducted is not collaborative in nature and the terms and conditions of the contract are not consistent with collaborative research. The references to collaboration in Paragraphs 1 and 3.b. of the MOU indicate that “collaboration” is limited to administrative functions, not the actual research being conducted.

Although the contract specifically allows for the MRG at UTSWMC to include VA participation, we found that no VA employees are on the MRG. As required under the contract, a VA employee with an academic appointment at UTSWMC participates on the Institutional Review Board. However, his role is limited to weighing the risks versus benefits to veterans. The contract requirement that the individual also have an academic appointment at UTSWMC was stipulated by UTSWMC. The individual who performs this task not only has an academic appointment, he also is a paid employee of UTSWMC, which creates the appearance of a conflict of interest. This also diminishes any appearance of collaboration that having this minimal level of participation may convey.

We concluded that the MOU and the resulting contract are merely a funding source for UTSWMC to conduct research of its choosing relating to Gulf War Illness. VA has no involvement in the research, including key decisions regarding the merits of research proposals reviewed and approved by UTSWMC’s MRG. Had the earmark for Gulf War research been treated as a grant, VA would have been involved in the approval of research proposals before authorizing funding. Although VA does not have grant authority, we believe that the terms and conditions of the contract could have required more involvement by VA in the process for approving research proposals and developing the statements of work.

Further evidence of the lack of collaboration between the parties is the current dispute relating to unilateral changes that UTSWMC made to the informed consent form that precluded sharing veteran data with VA. As will be discussed in greater detail later in this report, the decision was made by UTSWMC’s principal investigator and approved by UTSWMC’s IRB without any discussion with the VA Contracting Officer or COTRs. In fact, VA was not even notified of the change to the informed consent form as it was discovered during a routine review of an invoice submission packet.

The lack of VA presence and participation in the MRB to determine what research projects are to be funded, supports the absence of the principle purpose required to award contracts (i.e. for the direct benefit or use of the Federal Government).

Issue 3: Title 38 U.S.C. § 8153 was Not the Proper Contracting Authority.

VA awarded the sole-source contract to UTSWMC under the authority of 38 USC § 8153, Sharing of health-care resources. Section 8153 authorizes VA to “secure health-care resources which otherwise might not be feasibly available, or to effectively utilize certain other health-care resources.” The statute allows VA to award contracts on a sole-source basis to institutions affiliated with VA. Although the statute does allow VA to purchase research, to our knowledge VA has never awarded a similar contract for research using § 8153 authority and has not implemented any regulations, policy, or guidance specific to contracts for research.

We question whether § 8153 authority was appropriate given that VISN 17 did not have a requirement for the research to be conducted by UTSWMC. In the October 2006 conference call, the contracting officer stated that she did not develop a clear statement of work delineating VA’s requirements because they had no requirements.

The Public Law only mandated that VA spend \$15 million to conduct Gulf War Illness research. The Public Law did not state that the research had to be conducted by a third party nor did it direct VA to enter into a contract with UTSWMC to conduct research for a period of 5 years. There is no documentation in the records provided to OCR that indicated that the only way, or that the most efficient and effective way, to comply with the Public Law was to enter into an MOU or contract with UTSWMC or anyone else.

We concluded that the sole basis for contracting with UTSWMC was the direction provided in the Conference Report. If this was a legislative mandate, which it was not, VA should have used general contracting authority and justified the sole-source award under the provisions of Federal Acquisition Regulation (FAR) 6.302-5 - Authorized or Required by Statute. Absent a legislative mandate, § 8153 was the only possible contracting authority available to VA through which VA could award a sole-source contract to UTSWMC, because UTSWMC is an affiliate of VA, without the need for a written justification that met the requirements of FAR Subpart 6.3.

More importantly, the only direction to VA in the Conference Report was to enter into a pilot study involving collaborative research between a VA Medical Center and the

UTSWMC. The Conference Report did not direct VA to enter into a 5-year IDIQ contract with UTSWMC, particularly one that did not include a pilot study involving collaborative research.

We also found that the contract included provisions that allowed for payment for the purchase of more than \$1,000,000 worth of supplies and equipment, of which approximately \$235,000 was for computers and related equipment valued under \$5,000 that became the property of UTSWMC. The purchase of equipment is outside the scope of § 8153 contract authority. The authority is to purchase health care resources, which are defined in Title 38 U.S.C. § 8152 as hospital care and medical services, and other health-care services, support, or an administrative resource. VA regulations and policy implementing § 8153 limit the authority to the purchase or sale of services. While we understand there may be a need to purchase supplies to perform the research, there was minimal effort by VA to determine whether the prices were fair and reasonable or whether VA could purchase the items off existing VA contracts at a lower price.

Issue 4: The Use of an IDIQ Contract with No Specific Deliverables Caused Problems with Contract Administration.

An IDIQ contract is used when the Government knows what supplies or services it requires but is uncertain, beyond the stated minimum, the quantity of supplies or services it requires. In this case, the Government had no idea what would be required beyond the broad framework of the Overall Research Plan, the possible types of personnel that could be required to perform the research, and a funding limit of \$15 million. The manner in which the contract was formed left it up to UTSWMC to determine the type and necessary funding for the research to be conducted and paid for through the contract.

The contract itself did not require any specific work or obligate funds to a specific research project. Rather, it laid the foundation to issue task orders on a cost, or firm-fixed price basis. In general, the labor portions of the task orders were to be firm-fixed-price, while other resources necessary to achieve the individual task order objectives were to be on a cost basis. These items include, but are not limited to, supplies, travel, consulting costs, and equipment.

The contract with UTSWMC specified the terms and conditions under which individual task orders were to be developed and awarded. Most contracts for healthcare services specify specific labor categories and associated fixed rates to be used in accomplishing the work. However, the contract with UTSWMC included only broad ranges of salaries (or hourly rates) for a long list of possible labor categories, and included an Overall Research Plan that was developed and provided by UTSWMC. The fact that UTSWMC

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developed the Overall Research Plan, as opposed to VA, further supports that VA did not have a need for the services to be provided under the contract. Although the contract identified the need for a principal investigator, it did not include a labor category or labor rate for principal investigator.

As of November 25, 2008, the contract was modified eight times. Three of the modifications were unilateral by VA because they were administrative in nature. Five modifications were bilateral requiring UTSWMC's signature. These modifications included changes to clauses in the contract, changes to positions covered, and changes to fringe benefit rates to be applied to salaries. UTSWMC signed these five modifications signifying that they agreed to the changes in terms and conditions to the IDIQ contract.

We identified numerous deficiencies with the award and administration of task orders issued against the contract. The following are a sample of the issues that were identified:

Prices were negotiated before VA received the proposed task orders. In addition to the fact that the task orders, including the statements of work, were developed by UTSWMC, not VA, documentation provided by the contracting officer, indicates that prices for the task orders were negotiated prior to VA receiving the proposed task orders from UTSWMC. The normal contracting process is for the contractor to submit a proposal to the contracting officer for review and evaluation before negotiation occurs.

Prices were based on national salary surveys. Prices were to be based on actual salaries. However, instead of using the actual salaries and benefits paid to the individuals involved in the research, contract pricing was based on national published salary surveys, such as the survey published by the Association of American Medical Colleges. These salary surveys are unreliable and cannot be used to determine whether prices are fair and reasonable. In fact, these salary surveys should not be used to determine fair and reasonable pricing in sole-source contracts awarded under § 8153. Per VA policy, pricing is based on the actual salary and benefits of the individuals providing the services. We also identified instances where the proposed prices were compared to incorrect salaries such as individuals who were PhD's but their salary was compared to the Medical Doctor survey. Because there was a great disparity between the survey amount and the amount proposed, the proposed costs were determined to be fair and reasonable. The contract also disallows profit and without knowing actual salary and fringe benefits, VA does not know if it is paying profit to UTSWMC. If VA is paying in excess of actual salary amounts, then UTSWMC is realizing a profit which is disallowed by the contract and as such, a determination that the proposed costs are fair and reasonable would be difficult to support. Discussions with the contracting officer indicate that in some cases they were

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provided with salary agreements that they used to establish actual salary amounts. However, these salary agreements were not in the documentation provided to us.

Pre-award audit requirement was waived. VA Directive 1663 requires pre-award reviews by OCR for all sole source contracts valued at \$500,000 or more awarded under § 8153 authority. This requirement was waived for the contract with UTSWMC. As a result, there is no assurance that the prices paid were fair and reasonable.

Level of effort of researchers was not verified. Task Orders were issued based on a percentage of effort for an annual salary for the personnel proposed. For each individual, UTSWMC estimated the percentage of the person's time that may be spent providing services under the task order and this was used as the basis for funding and payment. No process is in place to verify the accuracy of the estimates or the actual work performed by the individuals. As a result VA is at risk of overpaying for services. As discussed above, this format conflicts with the schedule in the contract.

Task orders exceeded the contract performance period. Task Orders were issued based on a two-year period of performance which conflicts with the IDIQ contract formation as a base plus 4 one-year option periods of performance. While this may have been consistent with the two year appropriation funding, task order period of performance should correspond with the time periods in the contract. A better option would have been a series of 1- or 2-year contracts to correspond to the availability of the various appropriations that may be used to fund the contract.

The contract provided for the inappropriate purchase and treatment of equipment. The Price Negotiation Memorandum for Task Order 1 includes a discussion regarding ownership of equipment under \$5,000. UTSWMC questioned VA's position that all equipment would be owned by VA. VA personnel were unaware that the terms of the contract stated that equipment purchased by VA for under \$5,000 would vest with UTSWMC. Task orders issued to UTSWMC included the purchase of laptops or desktops for nearly every person assigned to the task order regardless of whether the equipment was to be used primarily for performance under the task order or not. As noted above, § 8153 is limited to the purchase of services; the purchase of equipment is outside the statutory authority.

UTSWMC invoiced VA for work outside of the scope of the task orders. Task Orders 4.0 through 4.15 were issued in advance of the task order 4.16, which was the first task order to include human subject testing. Although the work to be performed under these task orders was related to the actual testing of human subjects, UTSWMC hired staff and started charging VA for services reportedly performed under the task orders.

Invoices received by VA were rejected because the statement of work required results from the human subjects testing. UTSWMC explained to VA that they were performing functions in preparation for receiving results from the human subjects testing from which to do the research required by the individual task orders. Notwithstanding that the charges were outside the scope of the task orders, based on advice from OGC, VISN management instructed the VA COTR to deem the billings from UTSWMC as adequate as long as the work performed fit within the broad framework of the intent of the research, even if the work was outside the scope of the requirements of the task orders.

Issue 5: UTSWMC has Failed to Comply with the Terms and Conditions of the Contract.

Poor performance and noncompliance with contract terms and conditions have been prevalent during the contract period. Documented performance issues include delinquent deliverables, noncompliance with contract terms and conditions related to timely billing, required billing, UTSWMC's unilateral changes to the agreed upon informed consent form, and failure to comply with required security training. For example:

Task Order 1, valued at \$2.5 million, was awarded as the Administrative Management core to include all administrative tasks required under the project, including:

- Set up of the Administrative Management Core I Workgroup;
- Conduct Scientific Review;
- Submit task order/research plans;
- Monitor performance of task orders awarded for research projects;
- Monitor budget of task orders awarded for research projects;
- Ensure timely submission of deliverables and invoices;
- Prepare annual progress report;
- Ensure compliance with VA Requirements for information and IT systems security.

We found that UTSWMC's program manager did not prepare and submit deliverables, nor were billings prepared as scheduled—even though VA was funding all administrative functions through Task Order 1. Although UTSWMC replaced the program manager, invoices continued to be rejected by VA because they contained errors such as unauthorized travel, labor rate errors, and other similar issues.

In an attempt to resolve these issues, UTSWMC proposed several solutions. UTSWMC first requested a change in vehicle type from a contract to a grant because this would relieve them of complying with the more stringent requirements included in the FAR.

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This request was denied by VA's OGC. UTSWMC then proposed that VA provide additional staffing to expedite the technical reviews. OGC concurred with UTSWMC's request and entered into an agreement with UTSWMC. As the result of this agreement, in August 2008, the VA Contracting Officer and two other VA contracting staff were placed on-site at UTSWMC to assist UTSWMC with managing the contract, and providing technical guidance in the preparation of invoices. In essence, VA employees were tasked to perform some of the work for UTSWMC that was included in Task Order 1 (submission of adequate invoices). There was no off-set to the funding to UTSWMC to perform these functions.

We learned that when these VA employees were temporarily relocated to UTSWMC, they were provided with VA issued laptops that were not equipped with VA Virtual Private Network software which would have enabled a remote connection back to VA servers. As a result, the time spent at UTSWMC was unproductive because they had no access to their VA email, or files, which precluded them from performing their other duties and responsibilities.

In addition to the documented performance issues relating to Task Order 1, in October 2008, UTSWMC unilaterally modified information contained in the consent form executed by veterans participating in the human testing performed under Task Order 4.16. The initial informed consent allowed VA access to all of the information collected on individual veterans in accordance with the terms of the contract. This was consistent with Section H.7.2 of the contract, which specifically states that "Information, including, but not limited to, veteran individually identifiable information and personal healthcare information, gathered or created by UTSWMC in the performance of this contract is the exclusive property of VA." This requirement is reinforced by the inclusion of FAR clauses 52.227-17, Special Works, and 52.227-16, Additional Data Requirements, in the contract. The circumstances involving the modification to the agreed upon consent form was not known by VA until January 27, 2009 at which time the VA took immediate action in an attempt to correct the problem and have UTSWMC comply with the terms and conditions of the contact.

Numerous discussions with UTSWMC failed because UTSWMC refused to change its position. UTSWMC maintained that they would not be able to get veterans to participate in the study if VA were given access to the data as required by the contract. However, UTSWMC provided no evidence to support this assertion and documentation shows that it is based on mere speculation. Records show that some veterans who agreed to participate in the study, and signed the original consent form, complained about problems they had with VA that were unrelated to the study. While none of the veterans refused to participate in the study, their statements were used by UTSWMC's Principal Investigator

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as the basis for his request for an administrative change to the agreed upon consent form. His request was expedited and approved by the Chair of UTSWMC's IRB on October 8, 2008. VA discovered the change in January 2009 and began discussions with UTSWMC to resolve the issues. After the fact, UTSWMC convened the IRB in March 2009 for a formal vote on the matter. While the IRB does include VA representation, it should be noted that the member is also a paid UTSWMC faculty member. The VA member voted with the IRB to refuse to change the consent form to allow VA access to the data collected. Until this dispute concerning informed consent is resolved, no human subjects are being tested which has placed a hold on research related to human subjects.

In addition, UTSWMC was significantly behind in performing the training required by the contract and has asked VA to waive some of the requirements. VA considered the request but denied it on March 17, 2009.

On June 8, 2009, the Contracting Officer issued a Cure Notice in accordance with Contract Clause I. 19, 52-249-9 DEFAULT (FIXED-PRICE RESEARCH AND DEVELOPMENT). The notice identified performance failures in the area of Data Rights & Informed Consent, as well as failure to perform required training. The Notice required UTSWMC to respond, within ten calendar days of issuance, with a written plan of corrective actions. The formal notification was executed after several failed attempts by VA to informally resolve the UTSWMC contract violations.

Once UTSWMC became aware that a cure notice was imminent, they took action to involve UTSWMC management, VA management, and congressional contacts in an attempt to delay formalizing the process. These efforts continued even after the Cure Notice was issued. On the day before UTSWMC's response to the notice was due, they asked for an extension to June 30, 2009, because they claimed that several members of the IRB, were unavailable or out of the country. On June 18, 2009, the Contracting Officer rejected UTSWMC's request for an extension but was later directed by OGC and the VHA's Chief Logistics Officer to retract the denial, and grant the extension.

The following time line shows the significant efforts by VA to resolve the issues relating to UTSWMC's non-compliance with the contract prior to issuing a formal Cure Notice:

- July 25, 2007: UTSWMC's IRB approves the original consent form.
- October 2, 2008: Principal Investigator receives approval via an expedited review from the IRB Chair to modify the informed consent document to specifically bar VA from receiving identifiable data. The request was based on a purported change in VA IT policies, which has no basis in fact.

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- January 27, 2009: Modification to the informed consent form discovered by VA during a review of routine invoice submission package.
- February 23, 2009: Teleconference with VA OGC and UTSWMC legal staff. UTSWMC legal staff agree that VA has contractual rights to the data but question VA's need to receive it.
- March 5, 2009: VA provides its privacy policy to UTSWMC as requested. UTSWMC also notified VA that: "No research subjects are being enrolled at the current time, pending completion of the investigation concerning use of the consent forms. UT Southwestern will provide a plan to address the continuation of enrollment and the re-consent of previously enrolled subjects upon completion of the investigation."
- March 10, 2009: After numerous discussions with OGC, the VA Contracting Officer notified UTSWMC that VA cannot pay for any work on human subjects conducted since October 2, 2008, when the consent form was changed.
- March 12, 2009: VA notifies UTSWMC in writing that it must revert to using the approved VA informed consent document immediately as required under the contract. This is followed by numerous discussions with UTSWMC, without resolution.
- March 19, 2009: Full IRB meeting voted to keep the informed consent as modified by UTSWMC in October, 2008. This was based on the Principal Researcher's assertion that an unspecified number of veterans are concerned about VA knowing about their participation in contract studies.
- March 27, 2009: Contracting Officer informs OCR of Senate level inquires to VHA and OGC expressing concern with VA's "requests for data from UT."
- March 31, 2009: Conference call including various local and Central Office representatives from OGC, VHA, and VISN 17 to discuss options.
- April 10, 2009: Letter outlining issues is sent to UTSWMC's Vice President for Legal Affairs from VA's Acting General Counsel. UTSWMC was provided 10 business days for response.
- April 28, 2009: UTSWMC requested meeting to discuss the issues (8 days after deadline).
- May 11, 2009: At UTSWMC's request, a meeting held in Washington, D.C. attended by senior VA officials and UTSWMC administrators (30 days after deadline).
- June 8, 2009: Cure Notice issued with a June 18, 2009, due date for response.
- June 16, 2009: UTSWMC requests extension to June 30, 2009.
- June 18, 2009: VA CO denies extension at 12:21 PM, requires response no later than 1 PM 6/30/09.

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- June 18, 2009: VA CO retracts the denial extension based on verbal direction from OGC at 5:46 PM.
- June 26, 2009: UTSWMC submitted response to the Cure Notice.

The cornerstone of UTSWMC's refusal to change to the original consent form remains their assertion that they would not be able to get veterans to participate in the study if the veterans think that their personally identifiable information will be shared with VA. To date, UTSWMC has offered no empirical evidence to support their assertion, just speculation.

UTSWMC's actions support a conclusion that it believes the contract is merely a vehicle to fund its research projects, much like a research grant, and not a contract that requires compliance with agreed upon terms and conditions.

Conclusions and Suggestions

Based upon our review of Public Law 109-114, the Conference Report, the MOU, the contract, the task orders, and other related documentation, and interviews with key VA personnel involved in the administration of the contract, we conclude that:

- The MOU and contract with UTSWMC were not mandated by the earmark in the FY 2006 appropriation or the direction provided in the accompanying Conference Report.
- Neither the provisions in the MOU nor the contract comply with the direction in the Conference Report for a VA Medical Center and UTSWMC to collaboratively conduct a pilot study.
- The MOU and contract were entered into without considering alternative means to comply with the earmark requiring VA to spend at least \$15 million of the amount appropriated for medical and prosthetics research.
- The use of § 8153 contracting authority was inappropriate and the use of an IDIQ contract resulted in multiple problems with contract administration.
- Significant involvement of VA management was an impediment to VA contracting staff to adequately perform their duties.
- UTSWMC has been in default since October 2, 2008, because it failed to comply with terms of the contract relating to ownership of data and information security, which resulted in the issuance of a cure notice.

We offer no opinion regarding the merits of any research project being conducted by UTSWMC. The scope of our review was limited to the award and administration of the contract with UTSWMC. Many of the problems we identified could have been avoided if VA was able to treat and administer the earmark simply as a grant. Since VA management chose not to pursue grant authorization, they opted to misuse Federal procurement regulations and policy. We believe that a contract should not have been used to provide funds to UTSWMC or any other entity. If there was a Congressional mandate for UTSWMC to conduct this research, the funds should have been given directly to UTSWMC or VA should have been given, or sought, grant authority.

Given UTSWMC's continued refusal to comply with the terms and conditions of the contract, it appears that UTSWMC has given VA has no option other than to terminate the contract for default. Although such action is extreme, allowing UTSWMC to violate a critical requirement in the contract sets a precedent that the terms and conditions of the contract are discretionary, not mandatory.

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In the event the contract is not terminated for default, we suggest that VA re-evaluate whether the MOU and contract with UTSWMC are necessary or in the best interest of the Government. Factors that should be taken into consideration in making this decision should include the issues identified in this report, including the fact that the basis for the action, the earmarked funding, no longer exists. If it is decided that the contract is not necessary or in the best interest of the Government, VA should consider terminating the contract or letting it expire by not exercising the next option year. In the meantime, VA should consider not awarding any additional task orders against the contract.

If a decision is made that an agreement with UTSWMC or other third party for Gulf War Illness Research is necessary and will provide value to VA, VA should consider asking Congress for grant authority. If this is not possible, VA should consider renegotiating the terms and conditions of the existing contract to address the issues raised in this report. In the alternative, VA could let the existing contract expire and negotiate a new contract(s) with UTSWMC or other research entities.

Appendix A

OIG Contact and Staff Acknowledgments

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Acknowledgments	Karen Summers
	Marci Anderson

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