



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Alleged Research Funding Irregularities at the Central Texas Veterans Health Care System Temple, Texas

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Contents

	Page
Executive Summary	i
Introduction	1
Purpose.....	1
Background	1
Scope and Methodology	5
Inspection Results	8
Issue 1: Alleged Mismanagement of VA Funds.....	8
Issue 2: Alleged Lack of Appropriate Administrative Response to Issues Raised by the Complainant.....	14
Issue 3: Alleged Improper Support for a Principal Investigator’s Research by CTVHCS Leadership in Exchange for Assumption of Certain Administrative Responsibilities.....	16
Issue 4: Other Findings.....	17
Recommendations.....	18
Comments	18
Appendixes	
A. Under Secretary for Health Comments.....	19
B. VISN Director Comments.....	24
C. Abbreviations and Acronyms.....	25
D. OIG Contact and Staff Acknowledgments	26
E. Report Distribution.....	27

Executive Summary

Introduction

VA's Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) received allegations of fiscal, scientific, and managerial wrongdoings in several facets of the operations of the Central Texas Veterans Health Care System's (CTVHCS's) Brain Imaging and Recovery Laboratory (BIRL). Allegations also included indifference on the part of CTVHCS's senior management when alerted to these irregularities, and improper support of a principal investigator in return for assuming an administrative position. It was alleged that the BIRL expended resources and funding without accountability on a non-traumatic brain injury (TBI) project of highly questionable scientific merit; that wasteful spending caused diversion of funds from TBI research; and that there was a misappropriation of funds, excessive billing practices by an outside consultant, and a project that lacked scientific productivity or validity. Overall, the complainant alleged "gross mismanagement, waste of taxpayer money, and abuse of authority by the leadership staff at Central Texas Veterans Health Care System."

Results

We partially substantiated the allegation of mismanagement of VA funds. BIRL funds had been misspent since approximately September 2006 because 8 hours per week of magnetic resonance imaging (MRI) scanner time at a rate of \$486.70 per hour was paid to the University of Texas at Austin without BIRL research to support expenditures of this magnitude. OHI concluded that CTVHCS entered into a faulty contract. We also found that CTVHCS did not comply with VA policy in contracting with a consultant at the BIRL and that the consultant was not employed with a valid contract. In the absence of a valid contract, it was difficult to assess whether fraud had occurred.

We concluded that the Research and Development (R&D) Committee did not appropriately review expenditures for a principal investigator's (PI's) project. We neither substantiated nor refuted an allegation of waste in the use of MRI time for research of questionable scientific merit. However, despite not assessing scientific merit, we did find evidence sufficient to raise concerns regarding one PI's studies.

We concluded that the CTVHCS took allegations that a PI's research was of questionable scientific merit seriously. Nevertheless, it may not have gone far enough. For example, after negative reviews were returned, the PI's work should have been further reviewed by the Institutional Review Board (IRB) and the R&D Committee. We concluded that the allegations related to mismanagement of funds at the BIRL should have been addressed formally and promptly. We did not find inappropriate reciprocity of research time for assumption of an administrative position.

We had several other findings. We reviewed disbursements from BIRL funds, almost all of which appeared to be expended in support of research activities from medical services funds when, in fact, some of these funds should have originated from the medical facilities appropriation rather than the medical services appropriation. We were concerned that funds intended by Veterans Integrated Service Network (VISN) 17 to support clinical and research activities were used to fund research exclusively, and we were concerned that the BIRL might constitute a research project in and of itself.

Recommendations

We recommended that the Under Secretary for Health ensure that all BIRL expenditures were paid out of the correct appropriation. We recommended that the VISN Director ensure that the CTVHCS Director: (a) ceases paying for 8 hours of MRI scanner time per week in the absence of a contractual obligation to do so if that scanner time is not being fully utilized; (b) properly executes contracts between consultants and the CTVHCS, in accordance with VA policies and procedures; (c) requests that the R&D Committee and the IRB review the PI's research and address issues identified in this report; and (d) directs the R&D Committee and the IRB to determine whether the BIRL itself constitutes a research project for purposes of obtaining IRB and R&D Committee approvals.

Comments

The Under Secretary for Health and the VISN Director agreed with our recommendations and provided acceptable action plans. We will follow up on the proposed actions until they are completed.

(original signed by:)

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Introduction

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) conducted an inspection to determine the validity of allegations regarding financial irregularities in the operations of the Central Texas Veterans Health Care System's (CTVHCS's) Brain Imaging and Recovery Laboratory (BIRL), indifference on the part of CTVHCS's senior management when alerted to these irregularities, and related issues.

Background

A. Central Texas Veterans Health Care System – Overview

CTVHCS is encompassed within Veterans Integrated Service Network (VISN) 17. It consists of two VA medical centers (VAMCs)—the Olin E. Teague Veterans' Center (OETVC), located in Temple, and the Waco VAMC. Additionally, CTVHCS provides health care and social services to veterans across a wide swath of central Texas at the Austin Outpatient Clinic and at the Brownwood, Bryan/College Station, Palestine, and Cedar Park community based outpatient clinics. CTVHCS serves 39 counties in Texas in five congressional districts. CTVHCS, along with the VA North Texas Health Care System and the South Texas Veterans Health Care System, combine to comprise the VISN 17 VA Heart of Texas Healthcare Network.

According to its fiscal year (FY) 2007 annual report, CTVHCS serves 238,349 veterans with 757 inpatient beds and the five outpatient facilities noted above. In FY 2007, CTVHCS had 829,011 outpatient visits, and 7,847 inpatients were treated. CTVHCS has 2,646 full-time employees complemented by a large cadre of volunteers.

CTVHCS's Temple facility is a tertiary care facility. It provides primary care, specialty care, and long-term care in key medical specialties, including internal medicine and its subspecialties, neurology, surgery, psychiatry, rehabilitative medicine, dentistry, geriatrics, and extended care. The Waco VAMC is a psychiatric hospital that provides both acute inpatient psychiatric care as well as long-term psychogeriatric care.

CTVHCS's primary academic affiliation is with Texas A&M University's College of Medicine. This affiliation is critical to both institutions in that after completing their basic sciences training at Texas A&M University's main campus in College Station, College of Medicine students then perform their clinical rotations off campus at institutions such as Scott & White Hospital in Temple and the OETVC. A second medical school affiliation also exists with the University of Texas Medical Branch in Galveston. Also, as is particularly prominent in this inspection, joint biomedical ventures are undertaken between CTVHCS and the University of Texas at Austin (UT/A).

B. Central Texas Veterans Health Care System – Research Program and Research Funding Overview

CTVHCS has an active biomedical research program. The FY 2007 report notes 69 active projects with 20 active VA investigators and 8 affiliated investigators. According to CTVHCS officials, as of May 12, 2008, CTVHCS had 56 active protocols of which 22 involved human subjects. Thirty-eight of the protocols were funded protocols, and there were 27 active investigators. Funding sources include VA's Office of Research and Development (ORD), the National Institutes of Health, and the Veterans Equitable Resource Allocation system. Research at CTVHCS is performed in numerous areas of biomedicine, with particularly strong areas being in hepatic diseases and mental health. The CTVHCS Director has a considerable background in promoting VA research activities.

In FY 2004, Congress divided the Veterans Health Administration's (VHA's) medical care funding into three separate appropriations: (1) medical services, (2) medical administration, and (3) medical facilities. All three medical care appropriations have been used to support research activities, and they are classified as either General Purpose funds or Specific Purpose funds. General Purpose fund allocations, in turn, are divided into nine elements, one of which is research support. Research is defined by VHA Handbook 1200.5¹ as "a systemic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." Accordingly, CTVHCS must comply with a set of standards protecting human subjects engaged in research and, again per VHA Handbook 1200.5, these standards apply to "all research that is conducted completely or partially in VA facilities, conducted in approved off-site locations, facilities, and/or conducted by VA researchers while on official VA duty time."

VISNs allocate research funding by station. Transfer disbursement authority codes track individual disbursements to the VISNs. These funds are further allocated into medical services (60), medical administration (52), or medical facility (62) categories. These funds are then arranged by cost center through budgetary processes at the level of the VAMC or the VA health care system (HCS) in the case of a multicenter institution such as CTVHCS. Numbers used for cost centers, and the specificity of those cost center categories, are also determined at the level of the VAMC or HCS.

One type of Specific Purpose fund includes congressionally appropriated Research and Development (R&D) funds. VHA Handbook 1200.2,² delegates to the facility's (in this case, to CTVHCS's) R&D Committee and Director the responsibility of determining the distribution and use of those funds. Prior to the beginning of each FY, VA Central Office (VACO) ORD assigns an Initial Target Allowance (ITA) for each facility's research

¹ VHA Handbook 1200.5, *Requirements for the Protection of Human Subjects in Research*, July 15, 2003.

² VHA Handbook 1200.2, *Research Business Operations*, May 23, 2002.

program. This ITA may be modified for a variety of reasons, including Congressional, Office of Management and Budget, or ORD actions. VAMCs and HCSs administer appropriated research funds, funds in the General Post Fund earmarked for research, and funds provided under an interagency agreement.

Appropriated research funds include those found in Program 821 of research funding. Program 821 funds are divided into cost centers based upon their purpose, such as administrative (101), common research support (102), merit reviewed medical research (103), and centrally directed priority areas (106). R&D programs may contract for consultative or other services under cost center 102-03 in accordance with the limitations of contracting authority found in 38 USC 4101(c). Such contracts include contracts for consultation and for other services. VA Manual M-3, Part I, Chapter 5³ specifies that contracts must include a statement of purpose, the need for the services, the reason for selecting a specific individual or organization, specific instructions for completion of vouchers for services, a timetable for the delivery of products, and a quarterly reporting mechanism. The duration of these contracts may not exceed 1 year.

Overall, VA Handbook 1200.5 indicates that “the medical center director is responsible for accomplishing the research mission at the facility and following all Federal and VA fiscal management policies and procedures.”

C. Central Texas Veterans Health Care System – Brain Imaging and Recovery Laboratory Overview and History

On February 14, 2002, VHA entered into a Cooperative Technology Administrative Agreement with UT/A. On February 28, 2003, CTVHCS corresponded with UT/A to explore opportunities for shared space at an imaging research center. UT/A formed a task force for the purposes of planning an imaging center, with members appointed by UT/A in consultation with the CTVHCS Director. According to the Imaging Task Force Report, the mission of this center was to “establish a world-class university-based brain imaging center for the investigation of brain mechanisms of cognition and motivated behavior that will provide knowledge critical to understanding the etiology, treatment, and prevention of neuropsychiatric disorders and substance abuse.”

On August 14, 2003, a research coalition composed of representatives from CTVHCS and UT/A sent VA’s VISN 17 Director a request for support of an imaging center, noting such advantages as clinical diagnostic services. On August 18, 2003, UT/A obtained \$4.5 million from the Office of National Drug Control Policy to purchase a functional magnetic resonance imaging (MRI) scanner for purposes of graduate education and research. Ten days later, on August 28, 2003, VA’s VISN 17 Director approved funding for approximately \$6.3 million from VISN Reserve Fund Origination Point 3412 for the “Austin Research/Clinical Imaging Center.”

³ VA Manual M-3, Part I, Chapter 5, *Research and Development Support*, March 5, 1985 (not rescinded).

In correspondence from the Vice President for Research at UT/A to VA's VISN 17 Director, reference is made to the decision to locate the BIRL where veterans would have easy access in recognition of the intent to serve both research and clinical needs.

A proposed budget for the BIRL, attached to an e-mail dated May 3, 2004, reinforces the concept that the BIRL was to have a clinical as well as research purpose. On April 26, 2004, funds were transferred into CTVHCS accounts from VISN 17. Funding documents supplied by CTVHCS reflect that by April 30, 2004, the funds in the BIRL account (0160X4) were approximately \$6.1 million. In December 2004, UT/A began construction of the BIRL, which was to be completed in November 2005.

In a February 9, 2004, e-mail, the acting VISN 17 Chief Financial Officer (CFO) stated that the original purpose of the funds was to permit VA to purchase the MRI machine and pay certain upfront costs associated with a lease. However, UT/A ultimately purchased the MRI scanner. Thus, the acting VISN CFO wrote, "CTVHCS now has a significant amount of medical care dollars that may languish until needed over the next several years." To avoid this outcome, the VISN proposed that the funding be moved to VISN control points at CTVHCS, requiring CTVHCS to send an annual request for the amount of funds needed with the understanding that these requests would be honored while funding remained in the account. The BIRL expended a significant amount of funds between April 30, 2004, and the end of FY 2007, resulting in an ending balance of approximately \$4.5 million.

On January 25, 2006, the University of Texas sponsored an opening ceremony for the Imaging Research Center, UT/A's name for the facility on the UT/A campus. The VA component of this imaging center has had several names, including the Austin Research/Clinical Imaging Center, the Austin Image Analysis Center, the Brain Imaging Center, and the BIRL. As the BIRL is the most recent name, that will be the name used in this report.

In July 2006, CTVHCS began recruitment for a clinical scientist to be the director of the VA component of the imaging center. An individual was selected for this position and began employment on July 8, 2007. This individual's title, according to CTVHCS personnel documents, was Physician-Medical Director of VA Austin Imaging Center.

D. Allegations

On February 5, 2008, VA's OIG received allegations of fiscal, scientific, and managerial wrongdoings in several facets of the BIRL's ongoing activities. Specifically, a complainant alleged:

"...BIRL expenditures of resources and funding without accountability on a non-TBI [traumatic brain injury] project of highly questionable scientific merit."

“...wasteful spending diverted from the traumatic brain injury program.”

“...misappropriation of funds was the result of an incentive to a physician with **no** [emphasis by complainant] research experience or nor [sic] **any** [emphasis by complainant] original publications to accept [an administrative position], a post which according to the Chief of Staff was ‘difficult to get anyone to take.’ Hence, the diversion of TBI funding and resources were made despite my concerns of excessive billing practices by the outside consultant and lack of any scientific productivity or validity.”

The complainant also alleged:

“In FY05, funding of approximately 5.4 million was secured for Central Texas Veterans Health Care System MRI brain imaging research at the University of Texas at Austin. Over the next 1½ years, over 1.2 million tax payer dollars were spent on salaries, supplies, MRI scanner time, etc. without the generation of a single research publication, grant, or grant proposal at the Austin facility....”

[A] “...recommendation for discontinued support was also reiterated by 5 external reviews from expert faculty...attempts to have excessive charges investigated and enact accountability for an outside consultant billing more than \$110,000 over 10 months (for one day per week at the facility) were ignored. Scanner time for the ‘pilot’ project drained funds from the TBI research fund at a rate of >\$6000 per week for many months.”

“When [it was] appealed to the Director of Central Texas Veterans Health Care System, his reply to [the] ongoing concerns about these mismanaged and wasteful expenditures that were diverting and impeding the Program’s progress was ‘there are often many agenda at play that don’t always fit the ordinary scheme of things.’”

Overall, the complainant alleged “gross mismanagement, waste of taxpayer money, and abuse of authority by the leadership staff at Central Texas Veterans Health Care System.”

Although not stated in the February 5 communication with the OIG, in subsequent communications and interviews, the complainant further indicated a belief that fraud was being perpetrated.

Scope and Methodology

A. Scope

We focused our review on the complainant’s February 5 communication. We reviewed the appropriateness of fund utilization for and by the BIRL, including lease agreements, contracts for services, and a fee basis contract for a VHA consultant. We examined only the research protocols mentioned by the complainant in reference to improper use of MRI

time and consultant fees. We also addressed the issue of whether BIRL expenditures were necessarily limited to TBI research. Also, we addressed the issue of whether there was wasteful spending in one of the BIRL's principal investigator's (PI's) work and whether this PI's research and MRI time was granted as an inappropriate incentive for a difficult-to-fill position. We examined CTVHCS senior management's response to the complainant's allegations.

We did not address the actual scientific merit of any BIRL project—proposed or ongoing. Additionally, prior to, during, and after being onsite at CTVHCS, OHI was apprised of numerous other allegations concerning BIRL operations. The complainant alleged reprisals for contacting the OIG, alleged scientific misconduct (falsification, fabrication, or plagiarism) in the conduct of a PI's research, and alleged violations of human subjects protections regulations. While onsite at CTVHCS, we were apprised that BIRL research activities were suspended pending this review and multiple other reviews and investigations. For example, VHA's Office of Research Oversight (ORO) is conducting a review of several aspects of BIRL operations. In addition, the complainant's allegations of reprisal are being addressed through another administrative process.

B. Methodology

During March 10–13, 2008, we met with the complainant as well as numerous staff at the CTVHCS. We interviewed the complainant, the CTVHCS Director, the Chief of Staff (COS), the Associate COS for R&D (ACOS/R), PIs, the Research Compliance Officer, and former research officials. We interviewed the chairpersons of CTVHCS's Institutional Review Board (IRB) and the R&D Committee. We also interviewed other CTVHCS staff who were knowledgeable about various facts pertaining to allegations made.

On April 2, we interviewed an MRI consultant who performed work at the BIRL. On April 15, we inspected the site of the BIRL in Austin and interviewed staff there.

We obtained funding documents from CTVHCS, VISN 17, and VACO. These were reviewed with officials at all three levels of VHA: CTVHCS, VISN, and VACO. We met with VHA's CFO and his staff to further understand the budgetary allocations and the flow of funds as they related to the BIRL and CTVHCS. We met with the Director of VHA's ORD to further understand critical research issues raised by this case. We discussed the case with the Director of VHA's ORO in Washington, DC, as well as with ORO's Regional Director for the area covering CTVHCS.

Contracting issues raised by this case were reviewed with OIG's Office of Contract Review.

Extensive documentation was reviewed, including purchase orders; contracts; requests for payments; vouchers; invoices; e-mail communications; and notes and minutes from various committees, such as the CTVHCS's IRB and the R&D Committee.

This inspection was performed in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Inspection Results

Issue 1: Alleged Mismanagement of VA Funds

The allegation of mismanagement of VA funds is partially substantiated.

A. Alleged Waste and Mismanagement in Brain Imaging and Recovery Laboratory Expenditures

The allegation of waste and mismanagement in BIRL expenditures is substantiated.

We found that BIRL expenditures included a number of contractual obligations. Beginning on January 1, 2005, CTVHCS leased office space for the BIRL. It also paid for MRI services under a contract with UT/A. This contract was signed on September 21, 2006, and covered the contract period of October 1, 2006, through September 30, 2007. Under the contract, CTVHCS purchased MRI scanner time at a cost of \$486.70 per hour. The CTVHCS paid for 8 hours per week, which totaled more than 400 hours and resulted in a charge of \$202,467.

CTVHCS leadership indicated that this was paid because the contract obligated the facility to pay for 8 hours of scanner time per week whether or not the facility used the scanner time. However, upon review of the contract, this obligation is not specified. Rather, payment was to be made on an hourly basis, which was estimated to be 8 hours per week. Nothing in the text of this contract obligated the BIRL or CTVHCS to pay for 8 hours of scanner time per week.

MRI scanner hours were utilized in part by a PI conducting MRI scans. On February 5, 2007, this physician was approved by CTVHCS's R&D Committee to begin a research protocol involving MRI scanning. This PI (PI 1) submitted a document to the R&D Committee indicating that there were no costs associated with the project other than the time on the MRI scanner. While documents submitted to the R&D Committee stated that MRI would be used, there is no reference to the need for a consultant to work on the proposal.

OHI was told by PI 1 that the MRI scanning time used for his protocol began at only 1–2 hours per week but increased when another PI at the BIRL no longer utilized the time. PI 1 indicated that because the BIRL was contractually obligated to pay for 8 hours per week regardless of whether the time was utilized, he believed he was preventing waste by utilizing the scanner time. Therefore, to the extent that the CTVHCS utilized scanner time inefficiently or paid for time that was not utilized, expenditures were wasteful and not supported by the written contract.

Conclusions

We concluded that BIRL funds had been misspent since approximately September 2006 because 8 hours per week of MRI scanner time at a rate of \$486.70 per hour was paid to UT/A without BIRL research to support expenditures of this magnitude. OHI concluded that these misspent funds were not because of PI 1's research work; rather, it was because of facility management's improper interpretation of the contract that existed between CTVHCS and UT/A. CTVHCS management believed that the contract obligated them to purchase 8 hours of scanner time every week whether or not it was needed. They further believed this was necessary in order to reserve future access to the MRI scanner for CTVHCS. And indeed, at least one individual indicated to OHI that on days other than Thursdays—when VA staff were using the scanner—the scanner was heavily utilized for UT/A projects. Nevertheless, this interpretation led to expenditures which were not required to complete approved research activities at the BIRL.

B. Alleged Waste in the Payment of a Brain Imaging and Recovery Laboratory Consultant

The allegation of waste in the payment of a BIRL consultant is neither substantiated nor refuted.

PI 1 indicated that his utilization of the MRI scanner greatly increased following approval of a second protocol. This protocol involved conducting MRI scans on 10 human subjects. On April 18, 2007, CTVHCS's IRB Chairperson performed an initial review. At this time, the review indicated concerns regarding the specificity of subject recruitment and the informed consent process. Nevertheless, on May 16, 2007, the IRB Chairperson recommended approval of the proposal to the full IRB, and on May 24, 2007, it was approved without changes to the proposal. We found no indication in the documents of the intent or need to utilize a consultant in this study. Furthermore, documents given to the IRB did not have a consultant listed as an investigator on the study.

However, on November 17, 2006, CTVHCS entered into what was described to OHI as a fee basis agreement with an outside consultant to perform technical services related to MRI research capabilities. The document, described as a contract, provided for a fee of \$75 per hour not to exceed 40 hours weekly without approval. This document stated that the agreement could be terminated by either party following a 14-day notice. We note that the document described as a contract did not specify the reason for selecting the specific consultant, instructions for completion of vouchers for services, a timetable for the delivery of products, nor a quarterly reporting mechanism.

On November 28, 2006, the document was signed by CTVHCS's Acting ACOS/R, the Chief of the Finance Office, the COS, and the CTVHCS Director. It was not signed by the consultant, who indicated in an interview that he never signed any contract with

CTVHCS. Therefore, we found that a written contract did not exist between the consultant and CTVHCS.

The consultant's curriculum vitae listed a number of publications in his field, the most recent in 1997. The consultant indicated that duties performed at the BIRL included teaching research techniques to the MRI operator and to medical doctors and developing the best methods to obtain the most accurate observations. He generally worked onsite at the BIRL on Thursdays.

Upon review of the consultant's timesheets, OHI found that the consultant billed numerous hours for general services related to setting the MRI scanner for research work being performed and for locating and distributing journal articles pertaining to MRI scanning techniques. Even if the agreement had been signed, it would still violate VA policy. In FY 2007, the consultant received payments totaling \$107,462. VA Handbooks 5007/16⁴ and 5007/17⁵ do not permit hourly payments under a fee basis contract. Rather, consultants must be paid on the basis of services rendered and not on the basis of time taken to complete the services.

The R&D Committee is responsible for reviewing the budgets of research proposals prior to approval. In this instance, neither of the two proposals submitted to the R&D Committee by PI 1 included the consultant as an investigator. In addition, documentation submitted to the R&D Committee in support of one of the protocols stated incorrectly that the only expenditures were related to MRI scanner time. Finally, R&D Committee minutes make no reference to a review of any budget for PI 1's research.

The complainant also alleged that a document submitted to the complainant by the consultant for his (the complainant's) own research protocol was substantially similar to other published work, suggesting improper billing because the consultant billed significant time for writing this document and did not produce it in a timely fashion. This allegation was referred to VHA's ORO. We evaluated the document only in the context of billing practices. This document was prepared in connection with a grant that had a due date of September 13, 2007. On the due date, the complainant alleged that the consultant stated that he had left the document at home. The consultant submitted the document by e-mail on September 29, 2007, (almost 2 weeks later) and billed for this product at \$75 per hour.

The consultant told OHI that he told the complainant that he had left the document at home. He stated, however, that he probably had not left it at home but just did not want to produce it. Therefore, we substantiated that the document was not produced in a timely fashion.

⁴ VA Handbook 5007/16, *Pay Administration*, November 26, 2004.

⁵ VA Handbook 5007/17, *Pay Administration*, June 13, 2005.

In our interviews with BIRL staff, we learned that the consultant was present and busy on the Thursdays he was at the BIRL. The billings in question, therefore, are primarily those for literature searches, construction of bibliographies, and background research work. As noted, there was an absence of a clear contract with deliverables, specifications, and performance measurements for this work.

Conclusions

We concluded that there was no valid contract between the consultant and CTVHCS because the consultant never signed the document purporting to be a contract. Further, consultant fees were not included in the budget submitted to the R&D Committee. Due in part to this omission, the R&D Committee did not appropriately review expenditures to be made from appropriated funds for PI 1's project. We concluded that this resulted in part from PI 1's failure to supply such information.

However, in the absence of a clear contract with deliverables, specifications, and performance measurements in completing the contract, coupled with the highly technical nature of the research billed for, OHI is unable to make an assessment as to whether there was overbilling by the consultant.

C. Alleged Fraud in the Payment of a Brain Imaging and Recovery Laboratory Consultant

The allegation of fraud is not substantiated.

As noted above, we learned that the consultant was present and busy on the days he was at the BIRL and paid by CTVHCS for his services. Moreover, contemporaneous notes by the consultant indicate that he was actively thinking about and working on the projects for which he was being paid. His contemporaneous notes suggest serious consideration of approaches to problems of both PI 1 and a second PI at the BIRL. He constructed bibliographies and performed grant proposal work, which appeared to OHI inspectors to represent a genuine attempt to address BIRL research issues with both R&D Committee approved proposals and the MRI scanner itself.

Conclusions

As previously noted, in the absence of a valid contract, we could not determine if the consultant's billings were excessive for the work product produced on days other than Thursdays when the consultant was not in the BIRL. Also, the consultant should not have withheld written work from the complainant. Overall, however, we concluded that the consultant's billing practices in the absence of a clear contract and the consultant's behavior in withholding a written document did not reach the level of fraud.

D. Alleged Waste in the Use of Magnetic Resonance Imaging Time for Research of Questionable Scientific Merit

We neither substantiated nor refuted this allegation. However, despite not assessing scientific merit, we did find evidence sufficient to raise concerns regarding PI 1's studies.

In a December 9, 2007, e-mail to the IRB Chairperson and the R&D Committee Chairperson, the complainant stated that PI 1's protocol involving human subjects could "lack validity to justify continued MRI scanner resources at the Brain Imaging and Recovery Laboratory (BIRL)." In support of this contention, the complainant supplied five reviews from research scientists not located at CTVHCS that impugned the scientific merit of the protocol.

In our interviews of PI 1, he admitted that he did not collect data or maintain PI files on the study participants. The only documents he had pertaining to the participants were the signed informed consent forms. These disclosed that the PI had recruited family members for participation in the study, including an adult child. On February 29, 2008, CTVHCS's Research Compliance Officer began an audit of this study. In a report dated March 11, 2008, the Research Compliance Officer also noted the absence of any documentation in the computerized medical record pertaining to study participants, including consent forms. The Research Compliance Officer further noted that a radiologic technician was not credentialed and had a license that expired on August 31, 2007.

PI 1's research was a minimal risk study, and PI 1 stated that this study was simply to determine appropriate settings with which to best perform imaging for his research. Further, he repeatedly referred to the study as a pilot study although it had full IRB and R&D Committee approval. The complainant supplied us with several e-mails from other institutions suggesting that a more appropriate MRI time allotment for a pilot study might be 8–10 hours total. However, ORD officials informed us that there is no time or budget limitation on a pilot study. While PI 1 did not know the exact hours used, he estimated them at about 6 hours a week over approximately a 3-month period.

Conclusions

We concluded that the multiple deficiencies in PI 1's protocols as found by both OHI and CTVHCS's Research Compliance Officer indicate problems that need to be addressed by CTVHCS's IRB and the R&D Committee, irrespective of actual scientific merit. To cite one example, failure to collect data or maintain individual case files could interfere with the ability of the study to contribute to generalizable knowledge, which is the definition of research.

E. Alleged Diversion of Funds Slated for Traumatic Brain Injury Research

We did not substantiate this allegation.

The complainant alleged that funds slated for TBI research associated with returning Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans were diverted to fund non-TBI research at the BIRL.

Funds may be specifically earmarked for TBI research and/or OEF/OIF research. For example, a TBI or OEF/OIF project as approved by ORD would require a researcher to stay within the parameters of that proposal. However, none of the ongoing research at the BIRL was funded by ORD. Likewise, Congress may mandate that funds be expended in specific clinical or research areas. For example, Public Law 110-28⁶ specifically mandates expenditures of funds for OEF/OIF veterans. It has specific mandates for expenditures for polytrauma care, the rubric under which TBI falls. However, BIRL projects were not performed under the auspices of that law. Ultimately, VHA Handbook 1200.5 indicates that “the medical center director is responsible for accomplishing the research mission at the facility.” The CTVHCS Director described to us a broad vision of imaging research which would not necessarily be limited to OEF/OIF or TBI projects.

Conclusions

We concluded that an area of confusion was clearly the multiple names the currently named BIRL has had—the Austin Research/Clinical Imaging Center, the Austin Image Analysis Center, the Brain Imaging Center, and the BIRL. The first two names are suggestive of imaging research and care, while the latter two suggest brain research exclusively. Further, the current mission of the BIRL is:

- “To discover and generate new knowledge about the mechanisms of brain injury and develop novel treatments to improve brain recovery.
- Exert an important influence on raising the standards of care for our wounded servicemen, veterans, and society at large.”

Finally, the complainant noted that he proposed a multi-year budget that utilized all existing BIRL monies and was approved by CTVHCS management. Thus, by inference, all BIRL projects would be the complainant’s projects, which were, as of the time of this review, TBI and OEF/OIF projects. By this line of reasoning, all BIRL projects had to be TBI and OEF/OIF projects. While we concluded that these arguments have some merit, in the final analysis, the CTVHCS Director had the authority to express his own vision of the BIRL and support multiple scanner uses. A budgetary commitment for one set of

⁶ Public Law 110-28; *U.S. Troop Readiness, Veterans’ Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007*; May 25, 2007.

projects does not preclude other projects. We also concluded that the BIRL's name may be overly limiting. Overall, we concluded that in a more collegial environment, these should have been manageable issues.

Issue 2: Alleged Lack of Appropriate Administrative Response to Issues Raised by the Complainant

This allegation is partially substantiated.

In several communications with OHI, the complainant indicated that he raised issues of mismanagement and waste related to PI 1's research during an August 24, 2007, meeting with the CTVHCS Director and COS. This meeting was apparently a routine update meeting, the complainant having been employed by CTVHCS for a short time. The complainant told OHI that it was "emphasized to [the CTVHCS Director] and [the COS] that over one million dollars had been wasted without any product over the last 1½ years." The complainant acknowledged that he did not raise issues of improper billing or scientific validity of the research at this meeting.

No minutes were made of this meeting. The recollection of the CTVHCS Director is that this meeting was "essentially a meet and greet after his arrival and [the complainant] and I had a very positive meeting. ...I don't recall any type of concern being raised, documents shared, comments made regarding concerns he may have had. This was just a fun exchange, high energy sharing of ideas."

The CTVHCS Director shared with us a follow-up e-mail (what appears below is the e-mail text in its entirety) in which the complainant wrote:

Thank you for taking the time to meet with me this past Friday [August 24, 2007]. I do believe that in short order the activities of the Brain Imaging and Recovery Lab (BIRL) will be a beacon of hope and inspiration reflecting proudly on CTVHCS. We will work hard to develop an integrative effort of clinicial [*sic*] research and discovery to rapidly improve the diagnosis and treatment of traumatic brain injury (and PTSD). This aim is in accord with the July Presidential Commission's charged to the [*sic*] help our returning "wounded warriors." I will follow-up with Ms. [Name] so that the delicate balance of collaboration without conflicts is achieved.

Further, I shall work with Drs. [Name], [Name], and [Name] on arriving at a solution for the manpower needs in Austin.

The complainant alleged that subsequently, on September 20 and again on October 11, he disclosed BIRL waste, mismanagement, and fraud to the ACOS/R. The complainant indicated that these allegations were made via telephone. We found no documentation of these calls. The ACOS/R indicated to OHI that he became aware of allegations of waste

in BIRL activities on or about October 10 (5 days before the complainant's letter of October 15 to the CTVHCS COS (see below)). Relevant CTVHCS senior management—the ACOS/R, the COS, and the CTVHCS Director—acknowledge being notified in October of alleged waste related to BIRL activities; however, none recollect at that time that the complainant alleged criminal behavior, such as fraud or fraudulent activities.

Later, in an October 15, 2007, letter to the COS, the complainant wrote:

I also reviewed ongoing expenses, some of which I felt were excessive and unjustified. In particular, over a \$100,000 were paid over 10 months for services by a single consultant. Work product I received from the consultant was also a concern in quality and in the hours charged for the service.

MRI scanner time presently \$486.70/hour and is scheduled to increase by 3% for FY08. One pilot study at the BIRL has been ongoing since March 2007 and in the last 7 months has accumulated **238** hours [complainant's emphasis] which represents \$115,834 of scanner time plus \$100,000 in consultant fees described above. I feel these types of expenditures, if left unchecked, will wastefully diminish the brain imaging research funds and threaten the success of the BIRL program.

In response, CTVHCS senior management agreed to have the complainant send PI 1's proposal to several experts knowledgeable in the field of this researcher's work. Accordingly, it was sent to five reviewers, and replies were obtained over the course of the next month. These reviews were of varying depth. However, all raised serious concerns. These external reviews were forwarded to CTVHCS's COS on November 12, 2007.

On December 3, 2007, the COS wrote to the complainant noting, "I discussed the external reviews with [the ACOS/R] on Friday. He and I agreed upon a plan." CTVHCS senior management concluded that, with the exception of one of the reviewer's comments, the external reviews were unduly harsh and possibly biased. Accordingly, their plan was to "contact that individual [the sole reviewer they felt was constructive] to ask if he would be willing to serve as a consultant to [PI 1] to assist in improving the study design." They further recollect that this reviewer was contacted and "he did agree to help." However, according to the COS, this plan of action was never implemented "because [PI 1] placed his research on hold."

Conclusions

We concluded that CTVHCS took allegations made by the complainant that PI 1's research was of questionable scientific merit seriously by virtue of agreeing to have the complainant submit PI 1's work for outside review and then developing a plan in light of

those reviews. However, we also concluded that after the negative reviews were returned, PI 1's work should have been further reviewed by the facility's IRB and the R&D Committee.

We also concluded that the allegations relating to mismanagement of funds at the BIRL were not addressed in a timely fashion. Following the letter of October 15, 2007, the complainant e-mailed the CTVHCS Director on December 5, 2007, alleging that "critical resources are being diverted and this is now impeding the Program's progress. The matter is unresolved despite the input of [the ACOS/R] and [the COS] and I ask for your help." We found no written evidence that CTVHCS leadership requested an accounting of BIRL expenditures following the October 15, 2007, letter or otherwise investigated the appropriateness of BIRL expenditures. If they had, contractual deficiencies, such as the absence of a valid contract between the consultant and the BIRL or a misinterpretation of the contract for MRI scanner time, may have been discovered prior to our review.

We concluded that the distance of the BIRL in Austin from CTVHCS's main campus at the OETVC, a multitude of new positions established in 2007 that affected the BIRL, and reports concerning personnel issues at the BIRL may have clouded the picture in relation to any one set of allegations.

Issue 3: Alleged Improper Support for a Principal Investigator's Research by CTVHCS Leadership in Exchange for Assumption of Certain Administrative Responsibilities

This allegation was not substantiated.

Despite being an inexperienced researcher, PI 1 has had a distinguished career and has a long-standing interest in biomedical research. When being recruited for an administrative position, multiple facets of his work responsibilities, schedule, and professional opportunities, including being able to pursue his research interest, were negotiated. In negotiating this position, CTVHCS management was agreeable to building in research time and resources. We found no evidence of inappropriate, unethical, or illegal reciprocity. Any research that this individual embarked upon would necessarily have to have been approved by CTVHCS's R&D Committee and the IRB. It was approved by both. While, as noted earlier in this report, we have reservations about aspects of the R&D Committee's and the IRB's approvals, we found no evidence of pressure or intervention by CTVHCS management in those processes.

Conclusions

We concluded that there was no inappropriate, unethical, or illegal reciprocity in employing PI 1 in the administrative position ultimately offered to him, and simultaneously being supportive of his research interests. However, overall, his projects

were extraordinarily complex, involving highly technical and uncharted areas in MRI scanning. The projects required either greater oversight by the CTVHCS research apparatus than was the case or to have been initially scaled down by the appropriate CTVHCS committees.

Issue 4: Other Findings

A. Inappropriate Funding Origination

We reviewed disbursements from BIRL funds, almost all of which appeared to be expended in support of research activities from medical services funds. However, an exception to this appeared to be FY 2004 expenditures, totaling \$106,998, which were expended for coordinating building construction, programming, feasibility studies, and a property appraisal. Additionally in FY 2004, fees related to a lease agreement were initially charged to medical services funds but subsequently redirected to the facilities funds. This should have originated from the medical facilities appropriation rather than the medical services appropriation.

B. Exclusive Research Funding at the Brain Imaging and Recovery Laboratory

A proposed budget for the BIRL that we reviewed reinforced the concept that the BIRL was to have a clinical as well as research purpose. For example, for FY 2005 projected through FY 2011, a proposed budget indicated that utilization of the MRI would include a range of 19–46 percent of time assigned for VA clinical functions and 18–31 percent of time allocated to VA research functions. The remainder of the time would be utilized by UT/A. However, the MRI scanner at the BIRL was 100 percent dedicated to research activities. OHI found no evidence that any clinical activities were performed at the BIRL. This was apparently due to legal and contractual difficulties in arranging for the appropriate care of veterans in and on this UT/A offsite facility. OHI found no documentation suggesting that VISN 17 was aware that activities at the BIRL were entirely dedicated to research and did not include patient care. Additionally, the VISN 17 CFO, whom we interviewed, was not aware of this. We therefore raise the issue that funds intended by VISN 17 to support clinical and research activities were used inappropriately to fund research exclusively.

C. Overall Brain Imaging and Recovery Laboratory Operations May Constitute a Research Project

As noted, based upon multiple interviews and documents, the BIRL never provided any clinical services. It was exclusively dedicated to research. The consultant hired for work on certain research protocols at the BIRL also indicated that he was experimenting to determine appropriate settings for optimal spectroscopic imaging. He indicated that these

techniques were being developed with the intent of publishing them in the medical literature and were not tied to any specific protocol or project at the BIRL. Almost half of the hours billed for these services were spent on the development of general MRI spectroscopic techniques and support and were not tied to specific research protocols. The director of the BIRL was a clinical scientist. As “research” includes activities conducted in preparation for research and because such activities occurred at the BIRL and were outside the confines of a given protocol, we raise the possibility that the BIRL itself constitutes a research project. In interviews, the IRB Chairperson and the R&D Committee Chairperson indicated that this idea had not been considered by either committee prior to our inspection.

Recommendations

Recommendation 1: We recommended that the Under Secretary for Health ensure that all BIRL expenditures were paid out of the correct appropriation.

Recommendation 2: We recommended that the VISN Director ensure that the CTVHCS Director ceases paying for 8 hours of MRI scanner time per week in the absence of a contractual obligation to do so if that scanner time is not being fully utilized.

Recommendation 3: We recommended that the VISN Director ensure that the CTVHCS Director properly executes contracts between consultants and CTVHCS, in accordance with VA policies and procedures.

Recommendation 4: We recommended that the VISN Director require that the CTVHCS Director requests that the R&D Committee and the IRB review PI 1’s research and address issues identified in this report.

Recommendation 5: We recommended that the VISN Director ensure that the CTVHCS Director directs the R&D Committee and the IRB to determine whether the BIRL itself constitutes a research project for purposes of obtaining IRB and R&D Committee approvals.

Comments

The Under Secretary for Health and the VISN Director agreed with our recommendations and provided acceptable action plans. The full text of their comments is in Appendix A (on pages 19–24). We will follow up on the proposed actions until they are completed.

Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: June 27, 2008

From: Under Secretary for Health (10)

Subject: OIG Draft Report, *Healthcare Inspection: Alleged Research Funding Irregularities at the Central Texas VA Health Care System, Temple, Texas*, Project No. 2008-01105-HI-0074 (WebCIMS 406045)

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and I concur with the recommendations. In reference to the report's investigation of allegations regarding the disregard of human subjects protections in the process of research at the Central Texas VA Health Care System, it is important to note that VHA's Office of Research Oversight (ORO) also conducted an on-site review of the health care system's human research protection programs during the week of May 19, 2008. As a result of its review, ORO developed and is currently overseeing the implementation of remedial actions related to program management and oversight on the part of facility leadership. These remedial actions, which are mainly of a general research oversight and accountability nature, are separate from and in addition to the OIG recommendations in this draft report. ORO will closely monitor implementation of these remedial actions, which are to be completed no later than December 31, 2008. ORO will detail its specific findings and actions in its report, which it plans to issue shortly.

2. As for the recommendation in the report related to Brain Imaging and Recovery Laboratory (BIRL) expenditures that is directed to me, VHA Office of Finance will conduct a complete review of BIRL expenditures to ensure that they were paid out of the correct appropriation. The Office of Finance will present the results of its review to me by September 15, 2008.

3. Thank you for the opportunity to review the report. Attached is VHA's plan of corrective action for the one recommendation in the report directed to me. Veterans Integrated Service Network (VISN) 17 will directly

respond to the other four recommendations in the report that are specifically provided to the VISN Director. If you have any questions, please contact Margaret Seleski, Director, Management Review Service (10B5), at (202) 461-8470.

(Original signed by:)

Michael J. Kussman, MD, MS, MACP
Attachment

**VETERANS HEALTH ADMINISTRATION
Action Plan**

**OIG Draft Report, Healthcare Inspection: Alleged Research Funding
Irregularities at the Central Texas Veterans Health Care System Temple, Texas
Project No. 2008-01105-HI-0074**

Recommendations/ Actions	Status	Completion Date
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Recommendation 1: We recommended that the Under Secretary for Health ensure that all BIRL expenditures were paid out of the correct appropriation.

Concur

VHA Office of Finance will conduct a complete review of all BIRL expenditures to ensure that they were paid out of the correct appropriation. Subsequently, VHA Office of Finance will present the results of this review to the Under Secretary for Health for final approval. If the review concludes that any expenditure was not paid from the correct appropriation, VHA Office of Finance will include the appropriate corrective action.

In Process

09/15/08

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: June 23, 2008

From: Director (10N17) Heart of Texas Veterans Health Care Network, Arlington, TX

Subject: **Draft Report – Healthcare Inspection – Alleged Research Funding Irregularities at the Central Texas Veterans Health Care System, Temple (CTVHCS), Texas**

To: Director, Office of the Inspector General (OIG), Medical Consultation and Review

1. In response to the **Draft Report – Healthcare Inspection – Alleged Research Funding Irregularities at CTVHCS, Temple, Texas**, attached are VISN comments in the template provided by the OIG.
2. If you have questions, please contact Bruce A. Gordon, CTVHCS Medical Center Director, at 254-743-2306.

(Original signed by:)

Timothy P. Shea, FACHE

VISN Director's Comments to Office of Inspector General's Report

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 2: We recommended that the VISN Director ensure that the CTVHCS Director ceases paying for 8 hours of MRI scanner time per week in the absence of a contractual obligation to do so if that scanner time is not being fully utilized.

Concur

Target Completion Date: June 30, 2008

Corrective Actions: Central Texas Veterans Health Care System (CTVHCS) has reviewed the contract language and agrees the language leads to the impression that CTVHCS is only liable for time used on the MRI. The intent was to guarantee exclusive use of the MRI 1 day per week by reserving and paying for 8 hours of MRI time. Therefore, CTVHCS paid for this usage weekly. Subsequent contracts will be written to meet appropriate standards and contracting guidance. I have directed the Medical Center Director to cease payment after May 2008. Contracting is providing further guidance regarding the ability to terminate the contract for the convenience of the Government. The contract is scheduled to end June 30, 2008, and will not be renewed with the current language.

Recommendation 3: We recommended that the VISN Director ensure that the CTVHCS Director properly executes contracts between consultants and CTVHCS, in accordance with VA policies and procedures.

Concur

Target Completion Date: July 7, 2008

Corrective Actions: I have directed the Medical Center Director to perform a full review of all fee basis contracts between consultants and CTVHCS to ensure conformity with VA policies and procedures. He has charged local HRMS with completing this review by the targeted completion date and will identify and correct those that require amendment.

Recommendation 4: We recommended that the VISN Director require that the CTVHCS Director requests that the R&D Committee and the IRB review PI 1's research and address issues identified in this report.

Concur

Target Completion Date: September 16, 2008

Corrective Actions: I have directed the Medical Center Director to review PI 1's research and address the issues identified. This review has already been initiated. The Medical Center Director is to confirm the necessary actions and will develop and issue a formal charge letter to the R&D and IRB committees.

Recommendation 5: We recommended that the VISN Director ensure that the CTVHCS Director directs the R&D Committee and the IRB to determine whether the BIRL itself constitutes a research project for purposes of obtaining IRB and R&D Committee approvals.

Concur

Target Completion Date: September 16, 2008

Corrective Actions: I have directed the Medical Center Director to direct the R&D committee and IRB to determine whether the BIRL constitutes a research project. The Medical Center Director will develop and issue a formal charge letter to the R&D and IRB committees.

Abbreviations and Acronyms

ACOS/R – Associate Chief of Staff for Research and Development

BIRL – Brain Imaging and Recovery Laboratory

CTVHCS – Central Texas Veterans Health Care System

IRB – Institutional Review Board

OEF – Operation Enduring Freedom

OETVC – Olin E. Teague Veterans' VA Medical Center

OHI – Office of Healthcare Inspections

OIF – Operation Iraqi Freedom

OIG – Office of Inspector General

ORD – Office of Research and Development

OSC – Office of Special Counsel

PI – principal investigator

R&D Committee – Research and Development Committee

TBI – traumatic brain injury

UT/A – University of Texas at Austin

VA – Department of Veterans Affairs

VAMC – VA medical center

VHA – Veterans Health Administration

VISN – Veterans Integrated Service Network

OIG Contact and Staff Acknowledgments

OIG Contact	George B. Wesley, M.D., Director, Medical Consultation and Review (202) 461-4665
Acknowledgments	Andrea C. Buck, M.D., J.D. Maureen T. Regan, J.D., Counselor to the IG Linda DeLong, R.N., M.S.N., Dallas Office of Healthcare Inspections Shirley Carlile, B.A., Dallas Office of Healthcare Inspections Debra L. Crawford, Office of Investigations Scott J. Eastman, Office of Investigations Ashley Ketchum, Office of Investigations

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