CLOSURE FOR 2009-00717-HL-0494

BS 10-1426 Approved 4/13/10

Healthcare Inspection
Alleged Research Program Improprieties
VA Central Iowa Health Care System
Des Moines, Iowa
2009-00717-HI-0109
Administrative Closure

Purpose – The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) conducted an inspection to determine the validity of allegations that a physician (Dr. A) conducted unauthorized human subjects research at the VA Central Iowa Health Care System (the facility). It was further alleged that Dr. A presented the research results at an international conference. The purpose of the inspection was to determine the extent of the research and if the facility followed proper procedures.

Background – VA OIG criminal investigators informed OHI that during the course of a Department of Health and Human Services (DHHS) fraud investigation, it was revealed that Dr. A, (b)(6) , had conducted unauthorized research on facility patients. The investigator reported that the facility does not have an Institutional Review Board (IRB) or a shared IRB with another facility. In addition, the investigator shared a Power Point (poster) presentation of the research findings Dr. A allegedly presented at a (b)(6) . Dr. A initially worked as a (b)(6) at the facility during early 2005, and again from May 29, 2007, through February 13, 2008.

VA OIG criminal investigators determined that no criminal behavior occurred and referred the case to OHI to determine if there were possible health care infractions.

Scope and Methodology – We conducted an onsite inspection on October 27–28, 2009. We interviewed senior facility managers and employees with knowledge of the alleged research activities, employees from other VA facilities where Dr. A worked or attempted to seek employment, a senior manager from Veterans Health Administration (VHA) Office of Research Oversight (ORO), a special agent from DHHS, and criminal investigators from the VA OIG Office of Investigations. We reviewed VHA policies, facility fact-finding documents, (b)(6) , credentialing and privileging files, facility correspondence with ORO, and a facility Administrative Investigation Board (AIB) report. In addition, we reviewed reports of interviews conducted by DHHS and VA OIG criminal investigators.

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

Inspection Objectives

Issue 1: Unauthorized Human Subjects Research

We substantiated that Dr. A was conducting research and that the activities had not been approved by an IRB.

Based on VHA definition of research as, "the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question,"[1] we determined that Dr. A conducted unauthorized human subjects research. This act constituted a research impropriety. The term research impropriety refers to noncompliance with the laws, regulations, and policies regarding human subject protections. The VA is one of 17 Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (Common Rule), effective June 18, 1991 (56 Federal Register 28001).[2]

At the request of the facility to voluntarily discontinue their research program, the VA deactivated the research program on July 3, 2007, and DHHS Office for Human Research Protections (OHRP), deactivated it on August 3, 2007. VHA policy requires that once deactivated, no human subject research of any kind can be conducted at the facility or by individuals acting as the facility's employees or agents, unless the facility applies for and receives a new Federal-wide Assurance (FWA) approved by OHRP with an effective FWA addendum approved by ORO.[3] Interviewees confirmed that when the facility did have an active IRB, Dr. A never sought approval for a research study. VHA policy specifies that all proposed research involving human subjects must be reviewed and approved by the IRB and the Research and Development Committee prior to the initiation of the research project.[4] These procedures apply to all VA employees, including [b;6;].

Documents and interviews from Dr. A and nuclear medicine staff support that he requested an extra film image of patients at the first 5-minute period [b;6;] [b;6;]. Typically, an image is only collected at 60 minutes. Dr. A stated he was analyzing the data he collected over a period of approximately 3 months and planned to publish his findings. He believed taking the additional image at 5 minutes led to an improved diagnosis of [b;6;] [b;6;]. A nuclear medicine technologist reported no patient harm occurred because there was no additional radiation exposure, and that there was no extra cost to the facility. A [b;6;] confirmed that assessment. According to facility patient logs, there were 41 patients who were subjects of the additional 5-minute radiology image. While all the patients had informed consent for the [b;6;] testing, none of the consents included information on the additional image. Medical record documentation and consents for the testing only noted the standard 60-minute film.

Dr. A told the nuclear medicine technologists that he was writing a paper and would recognize their assistance. When workload started to increase and technologists

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[1] VHA Handbook 1200.05, "*Requirements for the Protection of Human Subjects in Research,*" July 31, 2008.
[2] VHA Handbook 1200.05.
[3] VHA Handbook 1058.3, "*Assurance of Protection For Human Subjects in Research,*" May 10, 2007.
[4] VHA Handbook 1200.05.

noticed that an internal patient log was missing, they reported concerns to managers in December 2007. The facility Acting Chief of Staff (ACOS) questioned Dr. A, who admitted conducting the research. Dr. A told the ACOS that based on education he received while employed at the VA [redacted] Health Care System (HCS), his research was exempt. The ACOS told Dr. A what he was doing was considered research, instructed him to stop the activity, and informed him he could not continue to analyze data or publish any of his findings or information gathered. The facility ACOS notified the facility Compliance Officer who contacted the headquarters ORO office and was referred to the Midwest Regional ORO Office. The facility Director notified the VA Assistant Chief, Research and Development Officer of the incident in a memorandum dated January 9, 2008, and identified facility actions that had been taken. [redacted] Dr. A, the facility provided special training to all staff regarding prohibition of research outside of established research programs, protocols, and approvals.

We contacted the VA [redacted] HCS and confirmed Dr. A was employed there as a without compensation [redacted] from June 30, 2005, through March 2, 2007. He did not submit any protocols through their IRB but did take the physician-required research training. The training states that any research must go through an IRB. Therefore, Dr. A's explanation that his research was exempt based on prior training was not accurate. While at the facility, Dr. A had completed VA privacy training that also stresses research rules and regulations in relation to patient privacy and consent.

Another [redacted] (Dr. B) was listed as a co-author on the research poster presentation. When we interviewed Dr. B, he denied ever conducting research or being a part of Dr. A's study but did admit that Dr. A had mentioned the research to him. Dr. B stated he did not report the research because he did not feel it would be appropriate since he was not in a position of authority and only [redacted] (Due to a separate event, the facility did not [redacted].

Issue 2: Response from the Office of Research Oversight

We concluded that the facility and ORO responded appropriately when they learned of Dr. A's research.

ORO is the primary office in VHA for overseeing the responsible conduct of research and investigating alleged research improprieties.[5] In a February 1, 2008, memorandum to the facility Director, the Midwestern Regional ORO Director acknowledged receipt of the facility's description of the incident. The ORO Regional Director replied that the facility's actions taken in response to the incident appeared to be appropriate, and for that reason, ORO would close the case. VA Regional Counsel had instructed the facility to preserve records and information related to the "research" until they

[5] VHA Directive 1058, *"The Office of Research Oversight,"* February 9, 2009.

received further notification. The memorandum also instructed the facility to continue to sequester any data collected in this case.

The ORO Director explained to us that they prioritize cases they investigate, and, since no patient harm occurred, they agreed with the facility's actions and closed the case.

Issue 3: Presentation of Research Findings

We substantiated that Dr. A presented the unauthorized research findings as a poster presentation [redacted] Neither ORO nor the facility was aware that Dr. A had submitted his research findings. The DHHS investigator reported to us that Dr. A had also submitted a chapter for a book that may have included the research results. DHHS blocked that chapter from publication.

Based on information obtained from the printout of the poster presentation, we validated the findings were presented at [redacted] We found the abstract for the poster presentation [redacted]

The poster presentation listed a facility medical media employee as a contact. We interviewed the medical media supervisor who informed us that a staff member did develop the poster for Dr. A. At that time, there was not a requirement to obtain supervisory approval before processing a medical media request. The medical media employee was not aware of any wrongdoing. The facility has changed the medical media request form to include the signature of the requestor's supervisor.

Dr. A did not receive VA funding [redacted] but did use facility medical media staff time and resources.

Conclusions

Dr. A had been appropriately credentialed and privileged for his assignment at the facility. We were concerned that Dr. A might seek employment through contract agencies at other VHA facilities and attempt further research. We found his name in the VA Outlook mail system as an employee [redacted] VA Medical Center, [redacted] Dr. A did enter data into VetPro on January 1, 2009. However, managers at [redacted] informed us that he was never hired because he was not board certified in [redacted] and when they checked references with the facility, were told they would not rehire. We verified that Dr. A had contacted the VA [redacted] HCS via email May 29, 2009, sent his curriculum vitae, and inquired about research opportunities in [redacted] Based on their prior experience, he was not considered for employment. We also called the VA Medical Center in Poplar Bluff, MO because a private institution in that community was listed on the poster presentation. Dr. A had never been employed there. Finally, because it was listed on his resume, we contacted the [redacted]

HCS and determined that he was on contract beginning February 9, 2005. We were unable to determine when his contract expired due to lost records.

Dr. A has since been convicted and sentenced for fraud by DHHS. He is now on the DHHS Exclusions List so would not be eligible for employment at any VA facility.

Because the facility had notified appropriate research oversight when they were aware of the situation and undertaken corrective actions to prevent similar occurrences, we recommend administrative closure.

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Office of Healthcare Inspections