Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Patient Care, IRB, and Research Oversight Issues at a VA Medical Center

Report No. 08-01515-199

July 20, 2010

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The purpose of this review was to evaluate allegations related to inadequate oversight of human subjects' research and improper Institutional Review Board (IRB) actions that resulted in patient harm at a VA medical center.

We found no evidence that the index patient was harmed as a result of his removal from Protocol X, nor did we find that an oncologist made medical decisions that negatively impacted the patient's life. We also determined that the IRB acted within its authority to question the tumor staging of the index patient, and notified the appropriate individuals of needed actions. The IRB notified the principal investigator (PI) of Protocol X's suspension in a timely manner and engaged in ongoing communication with the PI about the status of the study and the participants.

We substantiated that responsible managers did not assure adequate oversight of human subjects' research activities. We noted that some deficiencies identified by external review groups still existed at the time of our review, and we found that documentation of PI annual reports and IRB continuing reviews was inadequate. We also questioned some management decisions related to peer review, study audits, and provider reprivileging.

We recommended that the PI annual report and continuing review documentation is completed in accordance with VHA Handbook 1200.5, and that Professional Standards Board members receive training on the options available when reprivileging employees. The VISN and Medical Center Directors agreed with our findings and recommendations and provided acceptable improvement plans.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, Veterans Integrated Service Network

SUBJECT: Healthcare Inspection – Patient Care, IRB, and Research Oversight Issues at a VA Medical Center

Purpose

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) received allegations related to inadequate oversight of human subjects' research and improper Institutional Review Board (IRB) actions that resulted in patient harm at a VA Medical Center (the medical center).

The purpose of our review was to determine whether the allegations had merit.

Background

All VA institutions that perform federally-funded or supported research must file a Federalwide Assurance (FWA) stating that the institution and its IRB will comply with the Federal Common Rule, a set of regulations governing research involving human subjects. IRBs are groups of experienced researchers who review protocols for the purpose of ensuring that human subjects are protected as required by Veterans Health Administration (VHA) policy and Federal regulations. VHA Handbook 1200.5, *Requirements for the Protection of Human Subjects in Research,* adopted July 15, 2003, and updated on July 31, 2008, outlines policy for compliance with the Common Rule's requirements for the ethical conduct of research involving human subjects. In VHA, the IRB is a subcommittee of the Research and Development (R&D) Committee, and all research projects must have both IRB and R&D Committee approvals.

In December 2007, a complainant made multiple allegations related to the care of a cancer patient (index patient), IRB improprieties, and research oversight issues. After we began evaluating the allegations, we identified what appeared to be a pattern of substantial research protocol violations by a specific principal investigator (PI) related to not only the index patient's protocol, but to additional research protocols as well. To

adequately evaluate the complainant's allegations and the IRB's response, we found it necessary to examine this PI's research activities over several years. This report outlines historical details that provide a context for understanding the cultural environment in the medical center's Research Service, the PI's relationship with the IRB, and the medical center's response to non-compliance events relative to this PI.

The PI is an academic and clinical oncologist with an extensive list of scholarly articles and publications to his credit. In July 2006, a research coordinator notified the IRB that the PI was enrolling patients in two protocols (A and B) who did not meet inclusion/exclusion criteria. These criteria allow some people to participate in a clinical study and disallow others, and are based on such factors as age, gender, type and stage of disease, previous treatment, and other medical conditions. These criteria help produce reliable results so that researchers can answer the questions they plan to study.[1] Patients enrolled in research studies are typically subjected to strict treatment regimens designed around the protocol. If patients are improperly included in studies, which by definition means that they will be excluded from other treatment regimes which may be more appropriate, patients could be harmed. In addition, non-adherence to inclusion/exclusion criteria raises issues about the credibility of the data.

In response to the research coordinator's allegation, the medical center initiated an Administrative Board of Investigation (ABI). The ABI made recommendations related to the auditing, management, and/or suspension of the PI's existing unmonitored (investigator-initiated) studies. In addition, the ABI made recommendations relative to Human Subjects Protection (HSP) training for research staff, IRB composition and follow-up of protocol deviations, notification of research funding sources and oversight bodies, and other administrative issues. The medical center's research compliance officer (RCO) audited Protocol A and confirmed protocol violations related to inclusion/exclusion criteria. Protocol A was suspended.

Following the suspension of Protocol A, the RCO was directed to audit the PI's other two investigator-initiated clinical studies involving human subjects. The RCO found similar violations related to Protocol B; this study was suspended. The third protocol had only one subject who was disenrolled prior to treatment, so no action was needed.

A VISN review team completed an investigation in the fall of 2007. That report noted multiple deficiencies related to this PI's research studies including incomplete documentation, inadequate reporting of protocol deviations, and non-adherence to inclusion/exclusion criteria. To address quality of care and patient safety concerns, the VISN team recommended peer reviews be conducted on questionable cases. In addition, the VISN team identified and made recommendations related to IRB functioning and other administrative activities.

[1] The Rockefeller University Hospital. www.rucares.org. Retrieved April 24, 2009.

Medical center managers secured three VHA oncologists (external to the medical center) to conduct quality peer reviews of a selection of the PI's cases. The peer reviewers completed 40 peer reviews

The findings of these quality peer reviews were protected under 38 U.S.C. 5705. This protection allows managers to use peer review results for quality management and improvement purposes, but prohibits those results from use in disciplinary actions. In this case, medical center managers had to secure management, or unprotected, peer reviews to use in administrative proceedings. The medical center had difficulty arranging for these management reviews; ultimately, this process took about 18 months to complete. Pending completion of the management reviews, the PI continued to conduct research in his monitored studies and treat patients in the oncology clinic.

Before completion of the management reviews, the IRB received a complaint that the PI was enrolling patients in protocols X and Y who did not meet inclusion/exclusion criteria. The IRB took action to suspend both protocols. The sequence of events regarding Protocol X is detailed below and is the basis for the complainant's letter to the OIG.

Scope and Methodology

We visited the medical center over several weeks in 2008. We interviewed the complainant by telephone prior to our first visit. While onsite, we interviewed the Medical Center Director, the Chief of Staff (COS), the Associate COS for R&D (ACOS/R&D), the IRB chairman, the Chief of Primary Care & Subspecialty Medicine (PC&SM), research study coordinators, members of the oncology staff, the index patient's wife, and others with direct knowledge related to these allegations. We reviewed the patient's medical record, research protocol X and its associated reporting documents, IRB meeting minutes, external review reports of R&D Service, VHA Handbooks (1200.1 and 1200.5), and local policies pertinent to the case. We consulted with a VHA oncologist and a VHA radiologist from other VA medical facilities to assist us in evaluating the tumor staging issue at the center of the complainant's allegations.

We also reviewed the medical records of 40 (of 112) random patients enrolled in 12 of the PI's protocols and identified 13 patients with lung or head and neck cancer that may not have met inclusion/exclusion criteria for participation in their respective research studies. In addition to questionable tumor staging, we also identified patients who had abnormal electrocardiograms or functional disabilities that should have excluded them from participation in their respective protocols, but they were enrolled nonetheless. We obtained external peer reviews of these 13 cases, the results of which were turned over to the Medical Center Director for his information and action, as indicated. We do not discuss those cases further.

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

Issue 1: Complainant's Allegations

The allegation involved protocol X, a Phase 2[2] research study. Protocol X was a double-blind[3] placebo-controlled clinical trial sponsored by a pharmaceutical company. The PI was a medical oncologist who also treated cancer patients in clinic.

The complainant made multiple allegations related to the care of a cancer patient (index patient), IRB improprieties, and research oversight issues. The complainant specifically requested that the OIG address the following concerns:

- Was the index patient harmed by the IRB's administrative decision to remove him from protocol X?
- Did a medical center oncologist (referred to as oncologist B in the remainder of this report) make medical decisions that [negatively] impacted the index patient's life?
- Was it a conflict of interest for oncologist B, who was a member of the IRB, to question the medical judgment of the PI [in regard to the index patient]?
- How did the IRB determine that the PI's medical judgments were wrong?
- Did the IRB have authority to order the reassignment of the index patient (thereby altering his treatment plan), and was it appropriate to transfer the case to oncologist B, who was an IRB member and who was involved in the IRB decision?
- Was it acceptable for the IRB to delay communicating its patient-specific concerns about the index patient to the PI for 8 months?
- Did responsible managers assure adequate oversight of human subjects research?

Sequence of Events

Protocol X received initial IRB approval in the fall of 2005, and the PI began enrolling patients in the study in early 2006. Shortly after the PI began enrolling patients the IRB received a complaint alleging that at least one subject enrolled in Protocol X may not have met criteria to participate in the study. The RCO and two staff oncologists conducted reviews which suggested that the index patient did not meet the inclusion/exclusion criteria for the study because he actually had Stage IV lung cancer.

[2] The stage in which drug effectiveness is determined preliminarily in patients with the targeted medical condition. www.chemotherapy.com/glossary/terms.jsp

[3] A research design plan that controls for experimenter effects and the influence of demand characteristics. Neither the experimenter nor the research participants know, until after data collection, which experimental treatment has been applied to which individuals.

Based on the review results, the IRB chairman instructed staff to withhold the index patient's study medication.

The PI thought this decision could potentially harm the patient as long as he continued to receive radiation treatment. Although the PI documented that he was unsure whether the index patient was receiving the study medication or the placebo, he ordered the study medication to be administered anyway following a conversation with the sponsoring drug company. However, nursing staff refused to administer the study medication.

Five days later, the IRB suspended Protocol X and another of the PI's protocols (Protocol Y and notified the PI of the decision the same day. The IRB also notified the appropriate oversight entities and the study sponsor. The PI responded that four patients (including the index patient) could be harmed from stopping study interventions, and submitted information to the IRB stating that, in the PI's opinion, the index patient had Stage III lung cancer.

In late April, the IRB requested that the Chief of PC&SM review the clinical care of patients enrolled in the two suspended studies. The Chief of PC&SM assigned a staff oncologist to review the cancer-specific care of these patients. Based on these reviews, the Chief of PC&SM reassigned three patients, including the index patient, to other oncologists. In May the sponsoring drug company terminated the study.

The Chief of PC&SM responded to the PI's concerns, indicating that because the study was double-blinded, and the efficacy of the experimental drug was by definition unknown, no conclusion could be reached that the patient was harmed by discontinuation of study medication.

Case History

In January 2007, the index patient presented to the primary care clinic with a complaint of bronchitis. A pulmonologist diagnosed "probable neoplasm"…after a chest x-ray and computed tomography (CT) scan showed a mass in the right lung. A fibroptic bronchoscopy confirmed the diagnosis of invasive squamous cell[6] carcinoma of the lung. The PI, who was a board-certified oncologist, initially described the tumor as "extensive" with the cancer as Stage IIIA "at minimum," and noted that surgical removal was not an option. To determine the stage of the cancer, the PI ordered a Positron Emission Tomography (PET) scan[4] in February. The PET scan revealed findings compatible with metastatic tumor involvement. The CT scan, completed without contrast in January had not revealed this abnormality. The PI recommended a combination of radiation and chemotherapy, and the patient was enrolled in Protocol X.

[4] PET scans detect biochemical processes in the body that may indicate disease before the appearance of anatomical changes that other imaging studies may detect.

In early March, the PI initiated a combination of chemotherapy and radiation along with the study medication (or placebo). The patient remained on chemotherapy, radiation, and the study medication until the end of March without any reported signs of esophagitis or dysphagia (difficulty swallowing). Three days later, the PI documented that he did not think the PET scan results justified the conclusion that the cancer had metastasized to other parts of the body. Six day later, the study was suspended following concerns about potential protocol violations.

One week later, the PI documented that the IRB ordered the patient placed under the care of a different oncologist, and as a result, the patient did not receive the total number of planned radiation treatments. Per the new oncologist's suggestion, the next cycle of full dose chemotherapy would be scheduled 6 weeks after completion of the radiation (which occurred on March 26). Between May and August the patient continued to receive chemotherapy for squamous cell lung cancer.

In late November, the index patient presented to the emergency department (ED) with a complaint of acute onset neck swelling, but he did not report symptoms of esophagitis. The patient reported similar episodes of neck swelling in the past with the most recent episode 3 weeks earlier. The patient was admitted, and on November 30, requested that the PI evaluate him even though his care had been transferred to another oncologist. The patient was discharged home 5 days later. The next day, the PI documented his belief that local progression of the disease was responsible for these symptoms.

In late December, the patient was admitted to the medical center with an altered mental status.[5] He went into respiratory and cardiac arrest on hospital day (HD) 1 and was intubated,[6] resuscitated, and transferred to the intensive care unit in critical condition. On HD2, staff documented the patient's deteriorating kidney function, evidence of seizure activity, and non-responsiveness to pain. On HD3, the critical care attending physician wrote that the patient had near total obstruction of the superior vena cava[7] and that the prognosis was "horrible." The resident physician documented discussion of the patient's prognosis with the family, who requested a Do Not Resuscitate (DNR) order. The patient subsequently expired on HD4. The autopsy, which was limited to the chest cavity, found "…death apparently caused by local extension of primary tumor." The PI related the findings to the patient's family per their request in late January 2008.

[5] A general term closely linked to a variety of other descriptors of mental status, including confusion, delirium, stupor, and coma.
[6] The insertion of a tube into the patient's airway to allow mechanical ventilation.
[7] The principal vein draining the upper portion of the body.

Inspection Results

Allegation (a): Quality of Patient Care

Complainant's Question: Was the index patient harmed by the IRB's administrative decision to remove him from protocol X?

We found no evidence that the index patient was harmed by his removal from Protocol X. Because the index patient was enrolled in a double-blind clinical trial, the PI could not have known whether the patient received the experimental treatment or the placebo. If the patient received the placebo, then removal from Protocol X could not have caused harm. Given that there was a 50-percent chance the patient did receive the experimental treatment, we consulted a VHA hematologist/oncologist and a VHA radiologist to assess whether the patient's tumor was properly staged and whether he received the appropriate treatment based on the staging.

Our oncologist consultant reported that the index patient's PET scan was consistent with metastatic or Stage IV lung cancer, and the radiologist consultant independently reviewed the PET scan and also gave the opinion that it was consistent with metastatic disease. While a PET scan alone is not diagnostic of metastatic cancer, the medical record did not reflect that these results were considered or that additional testing was done to definitely establish the presence or absence of metastasis. As the autopsy was confined to the chest cavity, we cannot say with certainty whether the patient's cancer had metastasized.

Further, our oncologist consultant believed that establishing the presence or absence of metastatic disease was important because appropriate treatment for Stage IIIA lung cancer differs from that of Stage IV. Stage IV disease is typically not curable, so patients are generally offered palliative chemotherapy and radiation. These are not given at the same time because of the increased risk of toxicity (such as esophagitis or pneumonitis[8]) without possibility of a cure. Stage IIIA patients, however; do receive these therapies concurrently because of a greater possibility of benefit. We therefore concluded that by being enrolled in Protocol X, the index patient may have received treatment that was inappropriate for his cancer stage, and which could have exposed him to unnecessary side effects. We found no evidence that the patient was harmed by the decision to remove him from protocol X.

Furthermore, we determined that the IRB's "administrative decision" to suspend the protocol (thus removing the patient from the study) was appropriate. The IRB took this

[8] Inflammation of the lung tissue.

action based on a pattern of continuing non-compliance as evidenced by the VISN report, and ABI findings.

Complainant's Question: Did oncologist B make medical decisions that [negatively] impacted the index patient's life?

We did not find that oncologist B made medical decisions that negatively impacted the patient's life. After the index patient's reassignment, oncologist B's treatment met the standard of care for Stage IV cancer. Approximately 4 months after his removal from the study, the patient was seen in Oncology Clinic by the PI. At that time, the PI documented, "Physical exam is essentially unchanged. He [the patient] looks robustly healthy. He seems to be doing quite well." He was admitted to the hospital briefly in November and then discharged home. We spoke with the patient's wife who told us that he had been doing fairly well and had not voiced any particular complaints after he was removed from the clinical trial. She advised that he was tired from chemotherapy but "held his own" until shortly before his death.

Allegation (b): Improper IRB Actions

Complainant's Question: Was it a conflict of interest for oncologist B, who was a member of the IRB, to question the medical judgment of the PI?

We found no evidence that oncologist B, who was a member of the IRB, had a conflict of interest when he questioned the medical judgment of the PI. Oncologist B, along with another medical center oncologist, provided the clinical expertise needed for the IRB to make an informed decision about whether the patient qualified for the study. IRB minutes show that oncologist B recused himself from IRB deliberations and from the subsequent vote to remove the patient and suspend the study.

Complainant's Question: How did the IRB determine that the PI's medical judgments were wrong?

Two staff oncologists and the RCO completed reviews of the allegations. We concluded that the IRB's use of the RCO audit and oncologists' clinical reviews was an appropriate method to evaluate whether the index patient met the inclusion/exclusion criteria for study participation.

Complainant's Question: Did the IRB have authority to order the reassignment of the index patient (thereby altering his treatment plan), and was it appropriate to transfer the case to oncologist B, who was an IRB member and who was involved in the IRB decision?

We found no evidence that the IRB ordered reassignment of the patient's care to oncologist B. The IRB did not order reassignment of the patient's care; rather, the IRB

referred the case to the Chief of PC&SM for clinical review. The Chief of PC&SM assigned the patient's care to oncologist B, a decision which was within his discretion. As stated earlier, we found no conflict of interest relative to oncologist B's role on the IRB and his clinical care of this patient. While we were unable to locate documentation that oncologist B discussed the case and treatment plan with the PI, this consultation would have been a professional courtesy rather than a clinical requirement.

Complainant's Question: Was it acceptable for the IRB to delay communicating its patient-specific concerns about the index patient to the PI for 8 months?

We did not substantiate the allegation that the IRB did not communicate its concerns about the index patient to the PI for 8 months. Documents in the IRB files and from the patient's medical record, reflects multiple communications regarding the IRB's concerns.

Based on the number and content of communications, we concluded that the PI knew, or should have known, the IRB had concerns about the staging of the index patient's tumor well before 8 months, as alleged.

Allegation (c): Human Subjects Research Oversight

Complainant's Question: Did responsible managers assure adequate oversight of human subjects' research?

We determined that responsible managers did not assure adequate oversight of human subjects' research. Previous external reviews of this PI's activities and of the entire Research program found protocol violations, reporting deficiencies, and other documentation issues.

In addition to the VISN review, the Office of Research Oversight (ORO) conducted a visit in July 2007, to evaluate the effectiveness of the IRB and R&D Committees and to assess current compliance with Federal regulations and VHA policies regarding the conduct of research. ORO identified program deficiencies including the appointment of IRB and R&D Committee members, the completion of continuing reviews, the content of IRB minutes, and the reporting of certain adverse events to ORO.

In addition, the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) identified some deficiencies in research oversight when they visited the medical center in November 2007. AAHRPP is the entity responsible for accrediting human research programs in VHA. During this site visit, AAHRPP found the medical center's Research program did not fully comply with 55 of 76 elements reviewed. The medical center addressed 28 of those elements; however, 27 remained deficient. Standards not met by the medical center included failure to have and follow a written policy and procedure for addressing allegations and findings of non-compliance with human research protections. Specifically, AAHRPP indicated that the medical center's response "did not address the concern that the organization did not report serious

or continuing non-compliance to the IRB, appropriate organizational officials, and all applicable federal agencies." AAHRPP gave the medical center a status of Accreditation Pending, permitting managers to submit additional action plans to ensure correction of the remaining deficiencies. These responses were submitted to AAHRPP in July and September 2008; AAHRPP accredited the program on December 2008.

During our review, we found problems related to PI annual reports, IRB continuing reviews, and other documentation issues. According to policy, IRBs must conduct continuing reviews not less than once per year on previously approved protocols to ensure ongoing compliance with Handbook 1200.5 (38 CFR 16.109(e)). So that IRBs may be updated on the status of ongoing research projects, investigators are required to submit progress reports at least annually as part of the continuing review process. In addition, the R&D Committee is responsible for ensuring the effective operation of the research program and making appropriate recommendations to the Medical Center Director based on the Committee's oversight and evaluation of the Research program. The R&D Committee must review and approve each research project initially and at least annually thereafter in accordance with VHA Handbook 1200.1.

We reviewed 36 randomly selected IRB files for 5 PIs' protocols. While eight files complied with documentation and reporting requirements, we found that the remaining files were deficient in one or more of the following areas:

- No PI-generated progress reports.
- Missing continuing reviews; in some cases, continuing reviews were not documented as far back as 2005.
- No evidence of R&D Committee approval, as required.

We further noted that some IRB files did not consistently include all of the required documents or reflect the continuity of process from study approval to continuing review to study closure, as appropriate. Due to the previous review team findings and our independent confirmation that some of the conditions still existed, we concluded that on some projects, managers had not assured the level of oversight needed to ensure protection of human subjects.

Issue 2: Decision-Making and Follow-up Actions

During our evaluation of the adequacy of Research oversight, we identified several conditions resulting from dubious management or committee-level decisions which served to complicate and protract the investigation and resolution of issues.

Peer Review Process. Managers elected to pursue protected peer reviews in response to the ABI and VISN reports despite indications that administrative actions would likely be

indicated. By taking this action, managers essentially confirmed, on a large scale, what they already knew – that some oncology patients may not have been receiving the appropriate treatments because they were enrolled in certain research protocols for which they did not meet inclusion/exclusion criteria. When managers determined that unprotected quality reviews would be needed, they had difficulty securing the services, as follows:

- The handful of readily available oncologist-peer reviewers had already been "exhausted" during the protected peer review process and ABI.

- Peer review assignments are often a collateral duty and can take substantial time to complete; therefore, prospective peer reviewers with clinical responsibilities can be reluctant to commit the time.

- Unprotected peer reviews can be used in disciplinary actions, and as such, could be used as evidence in subsequent legal proceedings. Many providers do not want to testify against a colleague.

The medical center provided us with extensive documentation of their efforts to secure peer reviewers for the unprotected review process, including elevating the problem to the VISN level. The VISN Chief Medical Officer also had difficulty securing the needed peer reviewers, and the entire process took about 18 months to accomplish. Anecdotally, we have heard other VHA medical facilities express similar concerns that unprotected peer reviews can be difficult to arrange. This condition suggests that VHA should evaluate the need for a rotating "pool" of peer reviewers to meet this need.

Management Decision Regarding Monitored Studies. The ABI's recommendation stated, "After completion of a review of ongoing and perhaps previously conducted studies, the medical center needs to consider whether [the PI] should be conducting clinical research in the facility, and if so, under what conditions." The Medical Center Director responded by ordering audits of all of the PI's current unmonitored studies, but did not require audits of the monitored studies.

Management's assumption that sponsor-monitored studies were not at risk for substantial protocol deviations was inaccurate. We found multiple instances where sponsor documentation of their site visit compliance reviews consisted of a simple statement denoting no evidence of deviations. In these cases, there was no documentation of clinical reviews directed at compliance with inclusion/exclusion criteria. In fact, we were told that some sponsor representatives did not have clinical backgrounds and could not adequately judge the comprehensiveness of assessments or compliance with inclusion/exclusion criteria. For this reason, we believe that managers improperly excluded monitored studies from their internal audits, possibly to the detriment of patient care.

Reprivileging of PI. In early 2008, the Professional Standards Board (PSB) granted clinical privileges to the PI for the full 2-year reprivileging period despite knowing that an ABI had been completed and unprotected peer reviews were in process. It is unclear why the PSB did not exercise the option to reprivilege the PI for 6 months pending the completion of the unprotected reviews. The results of those reviews, received in June 2008, could have changed the PSB decision as to the level of privileges granted, or whether the PI should be reprivileged at all.

Conclusion

We found no evidence that the index patient was harmed as a result of his removal from Protocol X, nor did we find that oncologist B made medical decisions that negatively impacted the patient's life. We also determined that the IRB acted within its authority to question the staging of the index patient and refer the case to the Chief of PC&SM for further evaluation. We did not identify any conflict of interest issues, and reassignment of the index patient to oncologist B was a reasonable intervention given the staging and treatment concerns at the center of this case. The IRB notified the PI of Protocol X's suspension in a timely manner and engaged in ongoing communication with the PI about the status of the study and the participants.

We substantiated the complainant's concern that responsible managers did not assure adequate oversight of human subjects' research activities. We noted that some deficiencies identified by external review groups still existed at the time of our review, and we found that documentation of PI annual reports and IRB continuing reviews was inadequate. We also questioned some management decisions related to peer review, study audits, and provider reprivileging.

Recommendations

Recommendation 1. We recommended that the VISN Director ensure that the Medical Center Director requires compliance with PI annual report and continuing review documentation in accordance with VHA Handbook 1200.5.

Recommendation 2. We recommended that the VISN Director ensure that the Medical Center Director assures that PSB members receive training on the options available when reprivileging employees.

Comments

The VISN and Medical Center Directors agreed with our findings and recommendations and provided acceptable improvement plans. We will follow up on the planned actions related to Recommendation 1 until they are completed. Based on evidence provided by the medical center, we consider Recommendation 2 closed.

(original signed by:)
JOHN D. DAIGH, JR., MD
Assistant Inspector General
for Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: April 27, 2010

From: Director, VA Healthcare Network

Subject: Healthcare Inspection – Patient Care, IRB, and Research Oversight Issues,

To: Office of Inspector General

VHA CO 10B5 staff

1. Please find the attached response from the VAMC Director. All recommended action items have been completed and I recommend that this Health Care Inspection Report be closed.

2. Please contact the VISN Research Compliance Officer with further questions.

(original signed by:)

Director

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: April 27, 2010

From: Director/CEO, VA Medical Center

Subject: Healthcare Inspection – Patient Care, IRB, and Research Oversight Issues,

To: Office of Inspector General

VHA CO 10B5 staff

1. Please find my attached response to the above named healthcare inspection. All recommended action items have been completed and I recommend that this Health Care Inspection Report be closed.

2. Please contact me with further questions.

(original signed by:)

Director

Appendix B

Medical Center Director Comments

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 1. We recommended that the VISN Director ensure that the Medical Center Director requires compliance with PI annual report and continuing review documentation in accordance with VHA Handbook 1200.5.

Concur **Target Completion Date:** Completed

Action: In calendar year 2008 Compliance Audit was completed and reported to the IRB with the next report due 2011. There were no recommendations for follow up action in the 2008 report to include monitored and unmonitored studies. Consent Form Reviews and Continuing Reviews were completed in 2008 and annually thereafter with the last report submitted to the IRB in March 2010. The PI annual report was last submitted in March 2010. IRB minutes, Consent Form and Continuing Review summary data collection tool are attached for your review. Annual reviews are documented and recorded in the IRB data base.

Recommendation 2. We recommended that the VISN Director ensure that the Medical Center Director assures that PSB members receive training on the options available when reprivileging employees.

Concur **Target Completion Date:** Completed

Chairperson Professional Standards Board discussed options available when reprivileging employees for whom there are concerns about their practice. Focused Professional Practice Evaluation may be initiated; the provider's privileges may be extended for the period of time of the Focused Professional Practice Evaluation or if the practice is egregious other administrative action taken. These actions were demonstrated in October 2009 minutes.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Victoria H. Coates Director, Atlanta Office of Healthcare Inspections (404) 929-5961
Acknowledgments	Annette Robinson, Team Leader Audrey Collins Dorothy Duncan Idell Graham Deborah Howard Tishanna McCutchen James Seitz Marilyn Stones Carol Torczon Susan Zarter

Appendix B

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