Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Research Irregularities
VA Medical Center
Durham, North Carolina

Report No. 06-02682-53

January 2, 2007

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations
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DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, VA Mid-Atlantic Health Care Network (10N6)

SUBJECT: Research Irregularities, VA Medical Center, Durham, North Carolina

Purpose

The Department of Veterans Affairs (VA), Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) received a report from the Durham VA Medical Center Director advising that a VA without compensation (WOC) employee falsified a patient's signature on a research consent form. The purpose of our review was to assess whether the medical center's Institutional Review Board (IRB) properly investigated the research breach and whether appropriate corrective actions were taken to resolve the issues.

Scope and Methodology

We reviewed the Director's letter to the OIG and documentation of the IRB investigation, recommendations, and actions. We also discussed the issues with staff knowledgeable about the event.

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

Background and Results

In March 2006, during a routine audit of research studies, medical center staff identified several irregularities related to a VA approved research study entitled, "Study of Familial Primary Open Angle Glaucoma." Specifically, the medical center's auditors noted the similarity of the signatures of the research subject and that of the person obtaining consent. The subject's signature from a clinical consent signed that same day was compared to the signature on the research consent and found to be substantially different. The medical center's IRB promptly suspended the study and reported the incident to the VA Office of Research Oversight (ORO) and the Office of Human Research protection (OHRP). The IRB appointed a special subcommittee on April 13, 2006, to further investigate the consent form breach and other compliance issues. The

subcommittee subsequently determined, and the WOC employee admitted, that the signature on the consent form was falsified by the employee. The WOC employee's VA appointment was terminated in June.

Members of the IRB also met with the primary investigator to provide guidance on bringing the study into compliance with human studies criteria. The IRB requested that the investigator: (1) review the previous IRB recommendations and identify items that had been completed, (2) provide a plan of action to bring the study into compliance, and (3) provide a detailed plan for oversight of the study. The primary investigator failed to submit a protocol meeting VA IRB standards.

On October 25, the IRB completed its investigation of the case, which included review of multiple research study and compliance documents. The IRB terminated the study and notified the primary investigator on November 3. The IRB also advised that the following actions were required:

- Report the Health Insurance Portability and Accountability Act (HIPAA) violation to the VA Information Officer.
- Send a letter of apology to the research subject whose name was falsified on the consent form.
- Notify ORO and OHRP of the final disposition of the study.
- Dispose of blood samples obtained during the study.

We were notified that, as of December 14, 2006, all actions had been completed.

Conclusion

The medical center appropriately disclosed the research irregularities to responsible oversight authorities, and the IRB had taken reasonable actions to address and resolve the issues. The medical center director concurred with our findings. We consider the issue closed.

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

Appendix A

OIG Contact and Staff Acknowledgments

OIG Contact	Victoria H. Coates Director, Atlanta Office of Healthcare Inspections 404 929-5962

Appendix B

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