Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Importation of Blood Products for Research Purposes
New Mexico VA Health Care System
Albuquerque, New Mexico

Report No. 07-03025-32 **November 30, 2007**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations
Call the OIG Hotline – (800) 488-8244

Executive Summary

The VA Office of Inspector General (OIG) reviewed allegations that a principal investigator (PI) at the New Mexico VA Health Care System (the system) crossed the Mexican and Canadian borders to obtain blood samples for research. Additionally, the complainant alleged that researchers obtained blood samples from used needles. The OIG conducted a review to determine the validity of the allegations.

We substantiated that researchers transported blood samples obtained in two protocols across the Mexican border into the United States without the appropriate Customs Declarations and without Institutional Review Board (IRB) approval. We did not substantiate the allegation that researchers obtained blood samples from Canada and transported the specimens across the border. We also did not substantiate that researchers obtained blood specimens from used needles.

During the review, we identified several compliance issues in both protocols. The concerns consisted of the use of an unlicensed physician to conduct certain diagnostic interviews and to draw blood without disclosing this to the IRB; irregularities in the de-identification of the informed consent documents; unavailability of medical records for some subjects to support pre-existing diagnoses qualifying the subjects for the study; failure to obtain approval from either the IRB or the Office of Research and Development (ORD) for conducting research activities internationally; and the use of a tissue bank not approved by the VA.

Therefore, we recommended that management suspend the two protocols pending the implementation of corrective actions which included verifying that subjects recruited for both protocols met criteria for the studies, making all verification documents available to the OIG, and notifying the journals publishing any data from either protocol of this finding; and auditing all active protocols of the named PI to ensure compliance with human subjects' protections policies and regulations.

We also recommended that management ensure all unlicensed physicians engaged in research activities have a scope of practice and are in compliance; ensure research protocols that conduct activities internationally have appropriate IRB and ORD approval, and comply with Federal regulations; comply with Veterans Health Administration Handbook 1200.1, *The Research and Development Committee Handbook*; and comply with Medical Center Memorandum 151-9 in establishing a research audit plan, conducting regular audits, and reporting findings.

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

TO: Director, Veterans Integrated Service Network (10N18)

SUBJECT: Healthcare Inspection – Importation of Blood Products for Research Purposes, New Mexico VA Health Care System, Albuquerque, New Mexico

Purpose

The VA Office of Inspector General (OIG) received an anonymous complaint with allegations that a principal investigator (PI) at the New Mexico VA Health Care System (the system) crossed the Mexican and Canadian borders to obtain blood samples for research. The complainant further alleged that researchers obtained blood samples from used needles from the system laboratories. The OIG conducted a review to evaluate the complaint.

Background

The system is a Level 1 tertiary referral center, located in Albuquerque, NM, which is authorized to operate 310 beds. It is one of seven medical centers located in Veterans Integrated Service Network (VISN) 18. The system maintains an active research program involving human subjects, which conducts both biomedical research and social science research. Research studies follow specific plans for implementation known as protocols. Biomedical protocols focus on medical drugs or devices, health prevention or promotion, therapeutic interventions, Phase I oncology trials, and bench research. Social science research is more descriptive, frequently utilizing questionnaires and interviews. Each protocol may involve multiple researchers (known as investigators), but each must have one PI who maintains ultimate responsibility for the protection of human subjects enrolled in the protocol. In research protocols conducted at more than one site, each site must have a PI.

Research protocols conducted at VA medical centers or by VA investigators must be approved by both an Institutional Review Board (IRB) and by the Research and Development (R&D) Committee. In multi-center trials, the IRB and R&D Committee at

each involved site must separately approve the protocol. In this case, the system utilizes the affiliate IRB at the University of New Mexico, and in accordance with VA policy, maintains its own R&D Committee.

Special protections are in place for research involving the banking or collection of human research subjects' specimens, including genetic studies. Veterans Health Administration (VHA) Directive 2000-043, *Banking of Human Research Subjects' Specimens*, November 6, 2000, states: "It is imperative that human research subjects donating the specimens receive the highest level of protection possible and that any questions or any legal or ethical ambiguities always be resolved in favor of the human research subject." This directive also requires that any projects collecting or storing human biological tissue specimens utilize VA-sponsored tissue banks.

Further, while a person may ship a biological product for investigational *in vitro*[1] diagnostic use only (21 C.F.R. 312.60) into the United States, these specimens must be declared to customs officials and certain labeling is required. Human body fluid specimens of 7 to 15 milliliters require labeling with an appropriate descriptive name of the product, a statement of intended use, and a statement that the specimen is negative for human immunodeficiency or Hepatitis B or that it was not tested for these diseases by a Food and Drug Administration (FDA) approved test.

The OIG received an anonymous complaint that alleged that a PI directed researchers at the system to cross the border into Mexico to obtain blood and transport the blood back across the border. The complainant further alleged that researchers went to the laboratory at the system to obtain used needles containing small blood samples and used these samples in research.

Methodology

To investigate the allegations, we conducted a site visit from August 27–31, 2007, at the system. While onsite, we inspected 80 rooms in three buildings housing research offices and laboratories, looking for refrigerators that contained blood products. We photographed blood samples found in the PI's laboratory and obtained documents from the laboratory describing the type of testing performed. Nine individuals were interviewed, including blood bank officials, phlebotomists, the Compliance Officer, the named PI, and other researchers working on the PI's protocols.

We examined documentation pertaining to protocols involving the named PI, including IRB files, grant submissions, position descriptions for researchers involved in the PI's studies, and documents pertaining to the PI's accounts at the affiliated nonprofit corporation. This included all source documents for expenditures and travel vouchers.

[1] *In vitro*, is Latin for "in glass," meaning in an artificial environment such as a test tube; the opposite of *in vivo*, meaning inside the body.

We reviewed audits performed by nonprofit corporation personnel on protocol consent forms and obtained lists of all subjects enrolled in the PI's protocols. These were compared with documents submitted to the IRB listing the number of subjects recruited for each protocol involving the PI.

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

Results

We substantiated that blood samples obtained in two protocols (hereafter Protocol 1 and Protocol 2) were transported across the border into the United States from Mexico. However, we did not find that commercial blood products were imported for research purposes. Our inspection of 80 laboratories and offices revealed 35 refrigerators in research areas or offices. Two refrigerators contained blood products. One laboratory refrigerator contained tools for blood analysis, and one refrigerator contained five bags of plasma for a documented research study. The plasma did not originate from Mexico, nor did our inspection disclose the existence of any other commercial blood products which appeared to originate from Mexico.

Additionally, the complainant alleged that researchers obtained blood products and samples from Canada, which were transported across the border for use in research. We could not substantiate this allegation. Expense vouchers submitted to the nonprofit organization did not reveal trips to a Canadian location for research related purposes. No supplies for obtaining blood samples were purchased, and no receipts for international transportation of specimens or supplies from Canada were declared in expense reports reviewed by investigators. The complainant provided us with no documentation in support of this allegation. No one we interviewed admitted to traveling to or conducting research in Canada. Therefore, we did not substantiate this allegation.

However, we did find irregularities in the recruitment process, verification of inclusion criteria, informed consent de-identification, and the credentialing and privileging of research personnel involved in the two protocols reviewed. Finally, we note that both protocols involved the banking of tissue specimens from human subjects at an offsite tissue bank not approved by VA for use in these particular protocols.

Protocol 1

Protocol 1 involved the recruitment of Latino families for purposes of identifying genetic tendencies towards a certain illness. The study was Federally funded, with the system acting as a subcontractor to a designated non-VA site. As a multi-center trial, the study involved three other cities in the United States and two research centers in Mexico. The protocol required each human subject enrolled to give a blood sample and a licensed physician to conduct certain diagnostic interviews of the subjects. All of these activities

would be conducted over a 2 to 3 day period. The samples would then be stored in a tissue bank and used by other researchers to study certain disorders. VHA's Office of Research and Development (ORD) had not approved the importation of blood specimens from other countries for either protocol.

The protocol in no way referenced veterans, nor did it disclose system researchers would conduct any research activities outside the United States. VHA Handbook 1200.5, *Requirements for the Protection of Human Subjects in Research*, permits non-veterans to be enrolled in VA-approved research studies only when there are insufficient veterans to complete the study. While this protocol was designed to include family members, which would necessarily include non-veterans, families without any veteran members were also recruited.

The PI submitted an application to the IRB for full review of Protocol 1 on November 26, 2003. This application stated that researchers would recruit subjects through clinical referral, advertisement, and medical record review. It further indicated that "[a]ctivities associated with our portion of this study will be conducted at the Albuquerque VA. It is possible that some interviews and blood draws may have to be conducted at patient homes if they are unable to travel to Albuquerque." Subjects would be paid a total of $125 for two interviews and a blood draw. The application to the R&D Committee at the system stated that a specialist physician would perform the interviews. The IRB approved the protocol on January 5, 2004. The IRB's file contained no documentation that the PI or system investigators would be collecting blood samples outside the United States.

The PI requested that the IRB close the study on December 7, 2005. As of the date of study closure, system researchers had enrolled a total of 46 subjects. In reviewing the PI's files, we found 46 consent forms and data on 50 individuals. Eleven of the consent forms had the same date. On at least nine occasions, interview summary documents recorded the interviews occurred in Juarez, Mexico. A travel voucher dated January 16, 2005, was submitted for reimbursement to the nonprofit corporation "for taking the government car into Juarez . . . to see a subject for the Latino Genetics study."

The interviews were conducted by a social worker and an unlicensed physician, not by a specialist physician as was stated in submissions to both the IRB and R&D Committee. Further, the IRB was informed that only one individual, who was a Certified Laboratory Phlebotomist, would draw blood for the study. That individual did not accompany the researchers to Juarez, Mexico. The unlicensed physician drew blood samples for the research in Juarez. No IRB documents we reviewed disclosed that anyone other than the named phlebotomist would obtain blood specimens from the subjects.

In all nine cases in which documents recorded that interviews were conducted in Juarez, it was also noted that medical records were not available for the subjects. IRB submissions, however, stated that individuals with a previous diagnosis of a certain

disease would be recruited. We found no evidence in the PI's files that documented a previous diagnosis of any disease state for the enrolled individuals. Because medical records were unavailable for these patients, we do not know how the PI determined that these individuals had any medical diagnosis prior to enrollment in the study, nor were we able to independently verify that the subjects recruited met inclusion and exclusion criteria.

Research notes support that blood samples were obtained at the time of the subject interviews. Through our interviews with research personnel, we established that, on several occasions, the blood was transported back into the United States by placing it in a vehicle that was then driven across the border. Research personnel told us they did not declare the blood samples to United States Customs officials. Documents submitted to the IRB for this study did not disclose that blood specimens would be transported from Mexico into the United States by investigators under the authority of the system IRB. The IRB submissions we reviewed did not reference international subject recruitment by system researchers.

Protocol 2

The second protocol (Protocol 2) received IRB approval on June 20, 2005. It involved essentially the same process of interviewing subjects and obtaining blood samples for genetic analysis. The only difference was that it focused on a different disorder. The IRB initially approved recruitment of subjects through clinical referral, advertisement, and medical record review. Also, we were told that subjects were recruited by obtaining identifying information from an organization providing services for patients with a specific disorder. We found documentation that an employee of the an advocacy organization for that disorder received payments of around $600 per month for "discussing design, risks and potential benefits with area clergymen, medical staff and health care workers." Each family member participating in the study would receive a total of $125. The per capita income of Mexico is $7,870; in the United States, it is $26,036. A payment of $125 [in dollars] in Mexico is equivalent to roughly $413 in the United States, as a percentage of per capita income. VHA Handbook 1200.5 requires prospective investigators in their proposal to "substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure or influence on the perspective research subjects . . . ."

On April 20, 2007, the PI submitted a progress report to the IRB, which stated that they recruited subjects through oral presentations at various advocacy and health institutions. There was no reference to individuals being recruited through their clergy. The progress report disclosed that 54 subjects had been recruited for the study. Under the number of subjects recruited at local sites excluding the system but under the authority of the institution's IRB, the PI entered not applicable. We were given no documents suggesting that the IRB knew of or approved the recruitment of subjects from Mexico by investigators under their authority.

We requested all informed consent documents signed by the subjects for this protocol. The study coordinator informed us that the principal site of the research required that copies of the informed consent documents be sent to them; the coordinator also said the site requested that the informed consent documents be de-identified. We examined 37 consent forms in detail, noting that 15 had the names obliterated to the point that identifying information could not be discerned from the consent form. Only one of the consent forms recorded the subject ID number on it; the others were located with documents that recorded subject ID numbers. The remaining 22 consent forms did have identifying information on them. The PI informed the IRB that researchers at other sites would not have access to personal identifiers of the subjects. Specifically, he stated that the "identifiers will be kept at the VA and will never be sent to . . . [the primary research site]." No one we interviewed could explain why some consent forms were de-identified and others were not. However, we were informed that copies of all consent forms had been sent to the primary site for the study.

IRB documents submitted by the PI for Protocol 2 stated that interviews could be conducted at subject's homes if they were unable to travel to the system. On January 14, 2007, one researcher listed Juarez, Mexico, as a destination with use of a Government vehicle. The researcher also submitted a travel voucher including a hotel stay in Juarez, Mexico, as recently as April 14, 2007. On May 19, 2007, and June 3, 2007, a researcher rented a car and obtained approval to take the car into Mexico. These expenses were submitted for reimbursement as part of two separate trips for the purposes of interviewing subjects for Protocol 2. During the trip on May 19, 2007, the researcher submitted a reimbursement request for supplies for obtaining blood samples.

We interviewed the individual submitting this travel voucher. He admitted that he and two other researchers involved in the protocol would go into Juarez to interview subjects at their homes. He estimated that a total of 20 such samples were obtained on different occasions. We received conflicting interview testimony from other individuals concerning the number of times this occurred. There was no dispute, however, that blood was collected in Mexico and subsequently transported in the researchers' vehicle across the border into El Paso. From El Paso, the blood samples were shipped to the institution testing and banking the specimens. This tissue bank was not approved by VA for use in this protocol.

During interviews, we were told that on one occasion, United States Customs officials questioned the researchers about the containers of blood samples. They were allowed to cross into the United States, but subsequently received a telephone call from the FDA advising them to discontinue the practice. Information obtained from interviews varied as to whether this practice continued after the phone call from the FDA. We were told that at some point, researchers began using international kits for shipping the blood; these kits were accompanied by an appropriate customs declaration. Documents submitted to the IRB did not disclose research activities would be conducted outside the United States.

Finally, the complainant also alleged that researchers obtained used laboratory supplies and blood samples from the system's laboratory after hours for use in research. We did not substantiate this allegation. Expense vouchers submitted to the nonprofit organization revealed researchers purchased supplies for obtaining blood samples and traveled to the subject location to obtain those samples. The complainant provided us with no documentation in support of this allegation. No one we interviewed admitted to utilizing any used laboratory materials for research purposes. We therefore did not substantiate this allegation.

Additional Deficiencies Identified in the Compliance Program

Because of the deficiencies identified in this report, we chose to examine the system's compliance program to determine whether the system identified problems prior to our site visit. Under system policy, the Research Compliance Officer (RCO) is a member of the R&D Committee and is responsible for developing and continually reviewing policies and procedures for the Human Research Protection Program to ensure compliance with current regulations. The RCO works in a dual capacity, which allows two-thirds of the position's time to the compliance and business integrity officer role and one-third of the position's time to the RCO role.

System policies state that audits of medical records, research protocols, consent forms and like documents will be conducted by the Research Service to evaluate the facility's compliance with National Committee for Quality Assurance Accreditation standards, in addition to all applicable Federal rules and regulations. The RCO, in conjunction with the Research Service must develop an audit plan and schedule. The policy further states that periodic compliance audits will be conducted to ensure adherence to Research Compliance Program requirements and to assist in the reduction of identified problem areas. Audit and monitoring results would be submitted to the system Compliance Steering Committee.

Despite this policy, we find that a dedicated RCO for Research Services did not exist at the time of our review. Without this position, the system could not ensure that research conducted met compliance standards. The system Compliance Officer had not audited any protocols during an 8-month tenure and did not believe that such audits were a responsibility of the current position or of the predecessor. Further, the system Monitoring & Auditing Plan for fiscal year 2007 did not include a plan for the Research Service. Without an annual plan for monitoring and auditing, Research Service compliance with regulations cannot be assured.

The nonprofit agency pays for a position (classified as without compensation on VA rolls) in Research Service that is utilized to conduct audits of research protocols. However, a review of all audits conducted in calendar year 2006–2007 revealed only one quarterly audit of two consent forms without deficiencies for Protocol 2 and none for

Protocol 1. Protocol 2 contained 54 subjects. We found no evidence that any other aspects of the study were reviewed. Based on the limitations of the audit for this protocol, investigators cannot be assured that quarterly audits conducted in Research Service accurately reflect a state of compliance with VHA and Federal regulations.

Conclusions and Recommendations

While not substantiating that researchers used blood specimens obtained improperly from used needles for research purposes, we did find that researchers at the system transported blood specimens across the border between the United States and Mexico without the appropriate Customs Declarations and without IRB approval. We further identified numerous compliance issues in the two protocols reviewed, including the use of an unlicensed physician to conduct certain diagnostic interviews and to draw blood without disclosing this to the IRB; irregularities in the de-identification of the informed consent documents; unavailability of medical records for some subjects to support pre-existing diagnoses qualifying the subjects for the study; and failure to obtain approval from either the IRB or the ORD for conducting research activities internationally. Finally, the use of a tissue bank not approved by the VA for this protocol did not comport with VHA policies and procedures. Weaknesses identified in the compliance program prevented the system from identifying many of these issues prior to our review.

In addition to violations of regulations, policies and procedures, we further found payments made to subjects in Juarez and the use of clergy to assist in recruitment of subjects raised significant ethical questions in the conduct of these two protocols. The IRB had approved a sum of money for subject participation on the understanding that system researchers were conducting their activities, including subject recruitment, within the United States. The IRB had not determined whether $125, equivalent to $413 in the United States as a percentage of per capita income, might be viewed as a coercive sum of money in Juarez, Mexico. Further, given the special influence clergy may have over parishioners and the fact that this particular recruitment method was not disclosed to the IRB, we believe that the ethics of such an arrangement may be questionable.

We therefore made the following recommendations:

Recommendation 1. The VISN Director will require the System Director to suspend both Protocol 1 and Protocol 2 pending the implementation of recommendations 2 and 5 in this report.

Recommendation 2. The VISN Director will require the System Director to verify that subjects recruited for both protocols identified in this report met the inclusion and exclusion criteria for the studies and will make all documents used for this verification available to the OIG upon request. If documentation is not available to verify inclusion or exclusion criteria for this study, the System Director will identify all publications

resulting from either of these protocols and notify the journals publishing any data from either of these protocols of this finding.

Recommendation 3. The VISN Director will require the System Director to ensure that all unlicensed physicians engaged in research activities at the system have an appropriate scope of practice and comply with that scope of practice in the conduct of research activities.

Recommendation 4. The VISN Director will require the System Director to ensure that all research protocols at the system that conduct any research activities internationally have appropriate IRB and ORD approval, and comply with applicable Federal regulations.

Recommendation 5. The VISN Director will require the System Director to audit all active protocols of the named PI to ensure compliance with applicable human subjects' protections policies and regulations.

Recommendation 6. The VISN Director will ensure that the System Director requires that research quality assurance comply with VHA Handbook 1200.1, *The Research and Development Committee Handbook*.

Recommendation 7. The VISN Director will require the System Director to comply with Medical Center Memorandum 151-9 in establishing a research audit plan, conducting regular audits, and reporting findings as required by the policy.

Comments

The VISN and System Directors agreed with the findings and recommendations and generally provided acceptable improvement plans. (See Appendixes A and B, pages 11–18, for the full text of comments.) With regard to Recommendation 7, while they did not provide a research audit plan, along with a timeline for conducting regular audits and reporting findings as required by local policy, we will follow up on all planned actions until they are completed.

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

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 15, 2007

From: VISN Director (10N18)

Subject: **Review of Research Activities, New Mexico VA Health Care System, Albuquerque, New Mexico**

To: Director, Dallas Healthcare Inspections Division (54DA)

Thru: Director, Management Review Office (10B5)

I concur with the findings from the OIG review of research activities and with the actions plans developed by the New Mexico VAHCS. If you have any questions, please contact my Executive Assistant, Joan Funckes, at 602-222-2692.

Patricia A. McKlem

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

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

OIG Recommendations

Recommendation 1. The VISN Director will require the System Director to suspend both Protocol 1 and Protocol 2 pending the implementation of recommendations 2 and 5 in this report.

Concur **Target Completion Date:** Completed

Recommendation 2. The VISN Director will require the System Director to verify that subjects recruited for both protocols identified in this report met the inclusion and exclusion criteria for the studies and will make all documents used for this verification available to the OIG upon request. If documentation is not available to verify inclusion or exclusion criteria for this study, the System Director will identify all publications resulting from either of these protocols and notify the journals publishing any data from either of these protocols of this finding.

Concur **Target Completion Date:** 11/30/2007

Recommendation 3. The VISN Director will require the System Director to ensure that all unlicensed physicians engaged in research activities at the system have an appropriate scope of practice and comply with that scope of practice in the conduct of research activities.

Concur **Target Completion Date:** Completed

Recommendation 4. The VISN Director will require the System Director to ensure that all research protocols at the system that conduct any research activities internationally have appropriate IRB and ORD approval, and comply with applicable Federal regulations.

Concur **Target Completion Date:** Completed

Recommendation 5. The VISN Director will require the System Director to audit all active protocols of the named PI to ensure compliance with applicable human subjects' protections policies and regulations.

Concur **Target Completion Date:** 2/15/2008

Recommendation 6. The VISN Director will ensure that the System Director requires that research quality assurance comply with VHA Handbook 1200.1, *The Research and Development Committee Handbook.*

Concur **Target Completion Date:** 1/31/2008

Recommendation 7. The VISN Director will require the System Director to comply with Medical Center Memorandum 151-9 in establishing a research audit plan, conducting regular audits, and reporting findings as required by the policy.

Concur **Target Completion Date:** 1/31/2008

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

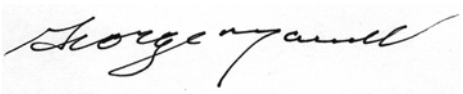
Date: October 11, 2007

From: Director, New Mexico VA Health Care System (501/00)

Subject: **Review of Research Activities, New Mexico VA Health Care System, Albuquerque, New Mexico**

To:

I concur with the findings from the OIG research activities review. Attached are responses with action plans as appropriate for each recommendation.



GEORGE MARNELL

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

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

OIG Recommendations

Recommendation 1. The VISN Director will require the System Director to suspend both Protocol 1 and Protocol 2 pending the implementation of recommendations 2 and 5 in this report.

Concur **Target Completion Date:** Completed

Protocol 2 has been suspended by the IRB (Human Research Protection Committee-HRRC). After an extensive audit of Protocol 2, the IRB withdrew approval for Protocol 2 and required that all research activities for this study cease on September 18, 2007. In a letter to the investigator dated September 19, 2007 - "Notification of Termination of HRRC Approval" referring to Protocol 2, the IRB determined that the violations discovered during the IRB audit of Protocol 2 met the definition of continuing non-compliance and were therefore to be reported to the Office of Human Research Protections (OHRP) and the sponsor NIH (which has already occurred). The IRB also determined that, due to multiple violations and the inability to distinguish which subjects may have been recruited inappropriately, all data collected by the VA Albuquerque site, including blood specimens sent to the NIH repository, could not be used and were to be destroyed immediately. Verification that this has occurred is pending within 60 days of the termination letter.

Protocol 1 was closed December 8, 2005 with no activity on this study after this date. An IRB audit of this study was recently completed and will be presented to the same IRB subcommittee which reviewed the audit and made the recommendations for termination of Protocol 2. This will occur on October 16, 2007.

Recommendation 2. The VISN Director will require the System Director to verify that subjects recruited for both protocols identified in this report met the inclusion and exclusion criteria for the studies and will make all documents used for this verification available to the OIG upon request. If documentation is not available to verify inclusion or exclusion criteria for this study, the System Director will identify all publications resulting from either of these protocols and notify the journals publishing any data from either of these protocols of this finding.

Concur **Target Completion Date:** 11/30/2007

The IRB audit of Protocol 2 could not clearly identify whether inclusion or exclusion criteria were met for all subjects. This was one reason why the IRB terminated Protocol 2 and has requested that all data and blood specimens be destroyed immediately along with notification of the OHRP and the NIH. An extensive IRB audit of Protocol 1 has already been completed and will be presented to the IRB on October 16, 2007. Similar concerns regarding inclusion and exclusion criteria for subjects in Protocol 1 exist. Speaking to the PI, and performing a Medline search has not identified any published reports from these studies to date. As mentioned, the IRB has requested that all data and blood samples from Protocol 2 be destroyed. This study is ongoing so it is likely that the research data from our site can be removed prior to publication of results from the larger study. The NMVAHCS research office in conjunction with the IRB will request assistance from the NIH identifying any pending publications which may include data from Protocols 1 and 2 acquired from our site. If such publications are identified, the NMVAHCS research office in conjunction with the IRB will notify the appropriate journals of the findings.

Recommendation 3. The VISN Director will require the System Director to ensure that all unlicensed physicians engaged in research activities at the system have an appropriate scope of practice and comply with that scope of practice in the conduct of research activities.

Concur **Target Completion Date:** Completed

There are currently no unlicensed physicians performing research in the NMVAHCS. Effective September 4, 2007 the Associate Chief of Staff, Research Service for the NMVAHCS began reviewing and initialing off on the position descriptions for all facility personnel engaged in research activities to ensure that they meet current requirements for scopes of practice of unlicensed research personnel. In the case of an unlicensed physician, a scope of practice will be written, reviewed, and approved by the ACOS for Research, the Chief of Staff and the Director.

Recommendation 4. The VISN Director will require the System Director to ensure that all research protocols at the system that conduct any research activities internationally have appropriate IRB and ORD approval, and comply with applicable Federal regulations.

Concur **Target Completion Date:** Completed

A review of current active protocols completed by 10/5/07 shows that there are currently no international research projects. Any future projects involving international research will have ORD and IRB approval, and comply with Federal regulations. As noted in the OIG report and our IRB audits, Protocol 1 and Protocol 2 were not approved for international research. The development of a more rigorous research audit plan as outlined in the response to Recommendation 7 below should help insure that future non-compliance in the conduct of international studies will be avoided.

Recommendation 5. The VISN Director will require the System Director to audit all active protocols of the named PI to ensure compliance with applicable human subjects' protections policies and regulations.

Concur **Target Completion Date:** 2/15/2008

The research program of the named PI is undergoing review by our IRB. Audits are currently underway on selected studies of the PI at the direction of the IRB. Additionally the PI has been required by the IRB to conduct self audits on all studies prior to receiving continuing approval to conduct research. Selected results of these self audits will be spot checked by the IRB. This investigator has 20 active studies. Audits on all of the investigator's studies will need additional time to complete so a deadline of 2/15/2008 is set to meet this recommendation.

Recommendation 6. The VISN Director will ensure that the System Director requires that research quality assurance comply with VHA Handbook 1200.1, *The Research and Development Committee Handbook.*

Concur **Target Completion Date:** 1/31/2008

The R&D Committee adopted the guidelines in the revised VHA Handbook 1200.1 at the April 12, 2007 meeting of the R&D Committee. A site visit by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) is scheduled for November 19, 2007, as part of the VA Research accreditation process, and our facility will receive feedback concerning our program. At our R&D Committee meeting scheduled for October 11, 2007, a subcommittee was appointed to review the issues of research non-compliance in Protocols 1 and 2. It is expected that recommendations from this subcommittee will serve to strengthen research quality assurance at our facility and help to ensure compliance with VHA Handbook 1200.1.

Recommendation 7. The VISN Director will require the System Director to comply with Medical Center Memorandum 151-9 in establishing a research audit plan, conducting regular audits, and reporting findings as required by the policy.

Concur **Target Completion Date:** 1/30/2008

Audits will be performed that are in compliance with Medical Center Memorandum 151-9 and appropriately documented.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Andrea Buck, M.D., J.D., Medical Consultant (202) 565-8496
Acknowledgments	Linda DeLong, Director Karen Moore, Associate Director Richard Cady, Investigator Roxanna Osegueda, Program Analyst

Appendix D

Report Distribution

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