

**STATEMENT OF
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DEVELOPMENT
VA PITTSBURGH HEALTHCARE SYSTEM
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
COMMITTEE ON SCIENCE AND TECHNOLOGY
SUBCOMMITTEE ON INVESTIGATIONS AND
OVERSIGHT
U.S. HOUSE OF REPRESENTATIVES**

SEPTEMBER 9, 2008

(805 Words)

Good morning Mr. Chairman and members of the Subcommittee. I would like to thank you for providing this opportunity to discuss the events surrounding the disposal of various samples from the now-closed Special Pathogens Laboratory (SP Lab) at the VA Pittsburgh Healthcare System (VAPHS). My name is Dr. Ali Sonel

and I am the Director of the Cardiac Catheterization Laboratories and the Associate Chief of Staff (ACOS) for Research and Development at VAPHS.

To provide some context, VAPHS is home to one of the largest research programs in the nation with over \$24 million in annual research expenditures and 276 active research protocols, including 165 human research participant protocols, conducted by 120 investigators. Fostering scientific research and ensuring the safety, rights and welfare of research participants through compliance with local, state, and national regulatory requirements for protection of human subjects are critical to our mission of serving America's veterans.

In September 2006, I became the ACOS for Research. Prior to this time I was not involved with the closure of the SP Lab. The SP Lab Director did not contact me to request a transfer of any biological samples or specimens. The only request I received for transferring any specimens or samples was made by another member of the SP Lab

staff in October, 2006. This researcher inquired about potentially transferring biological isolates derived from human subjects and related environmental samples, referencing an earlier discussion with the prior ACOS for Research. After discussing this request with the Chief of Staff, I asked the researcher to present us with any required paperwork for such a transfer. In order to better understand the request, I also asked our Research Compliance Office to determine what items specifically were being requested for transfer, their condition and whether or not such a transfer would be permitted by existing regulations. However, I did not receive any formal paperwork or materials transfer agreements. A meeting was arranged at the end of November between the VAPHS Research Education and Compliance Coordinator and SPL staff members so the SPL staff could identify and catalog the samples and specimens in question. This meeting was scheduled for December 5, 2006.

On December 4, I sent an email to the Chief of Staff to confirm that there were no administrative barriers for this

meeting to take place. The Chief of Staff responded positively and included the ACOS for Clinical Support on the email string to confirm. The ACOS for Clinical Support indicated at 3:09 PM on December 4th that the freezers containing the samples were cleaned out and the freezers were returned. The Chief of Staff concluded that there were no materials left for SP Lab staff to review and suggested that they be directed to the ACOS for Clinical Support if they had any further questions. At that point, I asked the Research Education and Compliance Coordinator to cancel the meeting with the SPL staff and directed them to the ACOS for Clinical Support for any further inquiries.

There were no policies specific to VAPHS as of December 4, 2006 with regard to disposition of tissue or data repositories in a situation where the investigator is no longer authorized to conduct research. VHA Handbook 1200.5 stipulates that if an investigator leaves a VA facility, the original research records must be retained at the institution. VA Handbook 6300.1 further notes, "The

records and information collected and created by VA personnel in the conduct of official business belong to the federal government and not to the employee(s) who initiated their collection or creation.”

On October 19, 2007, VAPHS Research Data Security and Privacy policy was issued, outlining local policies regarding the security of research information. This policy, which was written based upon guidance provided by the Office of Research Oversight and the Office of Research and Development, clearly states that "VHA research data belongs to the VA". The policy describing our procedures related to the disposition of research collections, states that "any data to be retained, reused, or shared for future studies, must be housed in a data repository and that the creation of the repository requires the development of policies and procedures that must be approved by the VAPHS IRB and Research and Development Committee.”

VAPHS is currently developing a comprehensive policy addressing the handling and disposition of research data

and collections, including situations where the investigator's appointment was terminated or in cases where research data or specimens were collected without proper regulatory approvals, thus constituting serious non-compliance.

Thank you again for your time, Mr. Chairman. I am prepared to answer any questions you may have.