

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

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(810 Words)

Good morning, Mr. Chairman and members of the Subcommittee and thank you for this opportunity to discuss issues regarding the closure of the Special Pathogens Laboratory (SP Lab) at the VA Pittsburgh Healthcare System (VAPHS).

them that it would be difficult or impossible for any human specimens to be transferred, but it might be possible to transfer bacterial specimens to another institution. This would require a Materials Transfer Agreement that must be endorsed by the accepting institution and approved by the VAPHS administration. At that time, the new laboratory was not operational, so I considered it premature to consider the issue further. I did communicate this desire to transfer these specimens to the Research Administrative officer. I have no direct knowledge of the destruction of specimens on December 4, 2006.

At the request of the Subcommittee, I have also been asked to comment on the efforts of a schizophrenia researcher who left VAPHS in 1995 to transfer specimens. In 1998 and 2000, requests were submitted to my predecessor as ACOS for Research to transfer human cerebrospinal fluid and blood specimens that were obtained under an approved IRB protocol to another institution. The ACOS for Research denied the request

In July 2006, I met with the Director of VAPHS, the Chief of Staff, and the Research Administrative Officer regarding the Lab's closure. The concern was raised that there may be biohazardous material in the lab that could constitute a safety hazard. The Director asked the Research Administrative Officer and me to address this problem. To the best of my knowledge, the Research Administrative Officer and the Biosafety Officer subsequently entered the laboratories and disposed of all cultures still growing in incubators, as well as biological agents and chemicals stored in 4° refrigerators. Specimens kept in the -70° freezers were not disposed of at that time.

In August 2006, I was contacted by the former SP lab staff scientist and the Director of the SP Lab regarding the possible transfer of equipment and reference specimens from the Lab. I informed the SP Lab Director that equipment bought by the Veteran's Research Foundation of Pittsburgh remains the property of the Foundation and regulations allow equipment to be transferred only to another VA medical center or VA Foundation. I informed

asked the Lab Director to comply with the requirements for IRB and R&D committee review of his research program. The VAPHS Director directed that an audit be conducted of the Lab's accounts in the Veterans Research Foundation of Pittsburgh. I understand the VAPHS Director later decided to close the Special Pathogens Laboratory, although I did not participate in any meetings where this was discussed.

The results of this foundation financial audit and review of additional documents by the Research Service suggested the strong likelihood that that the Lab had conducted research without proper approval from an IRB or the Research and Development Committee. The VAPHS Director, the VA Office of Research Oversight were informed of these concerns. The VAPHS Director convened a Board of Investigation on which I served. I referred the matter to the VAPHS Research Compliance Committee for further investigation and action.

My name is Dr. Steven Graham and I am Director of the Geriatric Research Educational Clinical Center at VAPHS and Professor of Neurology at the University of Pittsburgh. I served as Associate Chief of Staff (ACOS) for Research at VAPHS from July 2002 until September 2006. I am prepared to discuss my involvement and knowledge of the SP Lab's closing and related issues.

In March 2006, I participated in a meeting with the senior VAPHS leadership regarding the Lab. At that meeting, serious questions were raised about the Lab's lack of peer-reviewed research grants and whether approved research was being conducted in the laboratory. There were also questions about the extent to which the Lab's activities supported veterans' health care. In April 2006, I met with the SP Lab's Director and VAPHS senior leadership to discuss these concerns. At the meeting, the Lab Director was asked to provide a list of institutions and companies for whom the lab was performing studies, the number of VA studies, and a list of all research studies approved by the Institutional Review Board (IRB). We

upon the advice of VA Regional Council and VA's Office of Research and Development (R&D). The transfer request was not compatible with VHA Directive 2000-043 regarding Banking of Human Research Subjects Specimens. Another investigator at VAPHS agreed to take custody of these samples and they remain at VAPHS to this date.

This concludes my statement. I am prepared to answer any questions the Subcommittee may have.