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MEMORANDUM

September 8, 2008

TO: Rep. Brad Miller, Chairman
Investigation and Oversight Subcommittee

FROM: Majority Staff

Attached is a report on the staff investigation related to the Subcommittee's hearing on "Biobanking: How the Lack of a Coherent Policy Allowed the Veterans Administration to Destroy an Irreplacable Collection of *Legionella* Samples."

Cc: F. James Sensenbrenner Jr.
Ranking Member
Investigations and Oversight Subcommittee

"Biobanking:
How the Lack of a Coherent Policy Allowed the Veterans Administration to Destroy an Irreplacable Collection of *Legionella* Samples."

Staff Report
Subcommittee on Investigations and Oversight
Committee on Science and Technology
U.S. House of Representatives

September 2008

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SUMMARY

Late in the afternoon of December 4, 2006, laboratory staff from the Veterans Administration Pittsburgh Health Service (VAPHS) – based on an order from Dr. Mona Melhem, the associate chief of staff for clinical services, a few minutes earlier – in less than three hours destroying a unique collection of *legionella* and other isolates that had been collected by two prominent infectious disease researchers over their almost three decades of research.

The destruction was the culmination of an acrimonious process that resulted in the closing of the nationally acclaimed Special Pathogens Laboratory by the VAPHS, the firing of Dr. Victor Yu, its long-time chief of infectious disease, and the involuntary resignation of Dr. Janet Stout, the other researcher and director of the laboratory. But it occurred only after a number of false statements about the existence of the collection were made by Dr. Melhem to the VAPHS officials just hours before final steps were to be taken to facilitate transfer to a laboratory at the University of Pittsburgh for continued use by the researchers.

Such a collection of many disease strains that has been built over the years can never be replaced. It was particularly valuable because it was not a simple collection of disease strains, but correlated microbiologic factors to clinical outcomes. Researchers around the country and the world were outraged at this action by the VA. Hundreds signed a petition asking for an independent investigation. The Subcommittee decided to examine this event, not just for what it would tell us about how such a unique collection could be destroyed, but for what we could learn about the Federal policies for management of bio-materials collections across the government.

It is very common for researchers who have left one laboratory for another to take their collections with them if there are no other researchers in the first laboratory who are interested in continuing that work. This was certainly true of this collection. But while the research side of the VAPHS was attempting in good faith to transfer the collection, Dr. Melhem appeared determined to destroy it before such a transfer could take place, even to the point of making false statements to her supervisors.

What Committee staff uncovered in its investigation was that the VAPHS had no clear, written policies in place to determine what to do with such collections and to protect biospecimens collected with federal funds. The processes the VAPHS appeared to have used in the past which involved the Research Compliance Committee in these situations appear to have been ad hoc and were not used in this instance. But the person who ordered the destruction of this collection did so without any consultation with the head of the research office or the Research Compliance Committee.

After the destruction was completed, Dr. Melhem tried to justify her action by claiming that a research official had approved it months before. That official denied ever having done that. Michael Moreland, the medical center director at the time, doesn't remember having given her such an order on December 4 and didn't appear to have a clear idea about what was contained in the collection. Both of them are now taking the position that it wasn't really a

"research" collection, despite the fact that dozens of peer-reviewed papers had come out of the laboratory over its 25 years of existence.

Additionally, we found years of management neglect by the board of directors at the Veterans Research Foundation of Pittsburgh – which included top officials at VAPHS -- that resulted in minimal knowledge of its funded projects and extremely sloppy financial practices. The Research and Development Committee at VAPHS also did not appear to have adequate control over and knowledge of its approved research projects. This failure to institute and follow clear procedures spilled over into the process for closing the SPL and the various investigations into its finances and Dr. Yu. VA procedures and conflicts-of-interest guidance were violated; conclusions were drawn without adequate documentation; and Dr. Yu was not allowed to respond to serious allegations about non-compliance with research protocols. It appeared that the most important thing to the VAPHS hierarchy was to close the lab and rid itself of Dr. Yu and Dr. Stout quickly by whatever manner necessary.

It is breathtaking that a federal health agency official would order the destruction of a human tissue specimen collection without discussing it with and receiving approval of the agency's research officials. It is even more breathtaking that the top officials at the VAPHS and the Veterans Affairs Department have taken no formal action since to make sure that such an action never occurs again.

These events point to a broader problem. Although scientists at other federal agencies assured the staff that such an action would never occur at their laboratories, we found that there are no clear policies across federal agencies for the control and disposition of biomedical collections. In the case of the Veterans Affairs Department, Committee staff found some policies at the agency level requiring the banking of all human tissues collected for research, but no one in Pittsburgh seems to be aware of them, and they produced no written policies of their own in response to a document request.

To date, the National Institutes of Health (NIH) and more specifically the National Cancer Institute (NCI) are the furthest along in developing a biobanking policy, which was hastened after a scandal uncovered the sale of specimens by one of their researchers. NCI's guidelines recommend open and transparent policies for biospecimen retention, establishing points during the study to review the collection, and that biospecimens be advertised for transfer to other institutions if they can no longer be maintained by the original host institution or if there is no further interest in using the materials there. For biospecimens used in research, the guidelines state "...permanent storage generally is preferred...."[1]

Based on its work, the staff recommends that the Committee consider legislation directing the Office of Science and Technology Policy be directed to establish an interagency effort to create a core set of policies for the handling, maintenance and disposition of biomedical collections. Taxpayers spend millions of dollars supporting research that creates valuable and unique research resources. It is incomprehensible that there are no policies in place to ban

[1] NCI Best Practices; p. 16 (Sections C.1.2 and C.1.3).

arbitrary and capricious management decisions by administrators without any assessment of the value of the collection and its potential use in other research.

The work of Dr. Yu and Dr. Stout cannot be recovered. However, the work of the thousands of other professionals working at the VA or other Federal agencies or building collections with Federal money should not be subject to similar mishandling simply because they run afoul of a powerful administrator in their management chain.

INTRODUCTION

At 3:40 p.m. on December 4, 2006, the police at the Veterans Administration Pittsburgh Health System (VAPHS) unlocked the doors of the Special Pathogens Laboratory (SPL) in Building 2. Five VAPHS employees entered: Cheryl Wanzie, the chief technologist for the clinical microbiology laboratory; Kevin Frank, a lab supervisor; and Joseph Crowley and Tina Cozza, lab employees and Dr. Dmitriy Gutkin, the lab's director.[2] According to the police report, these employees had been ordered by Michael Moreland, then VAPHS director, to "remove all lab specimens from the second floor."[3] The employees, however, had received their direct orders from Dr. Mona Melhem, assistant chief of staff for clinical support, who told them that Mr. Moreland had ordered the immediate destruction of the specimens by close of business on that day.

Before that order was given, however, Dr. Melhem had asked Ms. Wanzie about the status of the isolates in the laboratory. Ms. Wanzie said nothing had been done to them since closure of the SPL in July because she considered them to belong to the research office. Dr. Melhem then told Ms. Wanzie that Mr. Moreland wanted them destroyed by the end of the day. Ms. Wanzie did not call the research office to check if its chief concurred with that directive, but "just followed orders."[4] Dr. Melhem also called Mr. Frank and told him to go to the SPL lab, "bag everything up and get rid of it by the end of the day."[5] In approximately two hours, the employees had taken all of the biological materials that constituted a 25-year collection of *legionella*, *klebsiella* and other isolates and environmental specimens compiled by Dr. Victor Yu and Dr. Janet Stout, two of the nation's premier *legionella* researchers, thrown them in biohazard containers and given them to the VAPHS contractor for disposal as biohazards.[6]

The Committee's investigation revealed no clear evidence that Mr. Moreland had ordered the destruction of those isolates on that day or on any other day[7] and that the VAPHS assistant chief of staff for research and development – who was in charge of the collection – was actively working to transfer it to the University of Pittsburgh and was unaware of any order to destroy the collection. What is clear is that (1) the destruction was ordered by Dr. Melhem within minutes of receiving an e-mail informing her that Dr. Stout had set up an appointment on December 5 with the VAPHS' research compliance officer to begin "de-identifying" the isolates prior to transfer and (2) Dr. Melhem made numerous false statements to her staff and to VAPHS officials and

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[2] Dr. Gutkin was identified in the police report as "Dimtriy Gutky." There is no indication that Dr. Gutkin himself participated in the destruction of the collection, although he certainly was aware of it. Veterans Affairs VA Police Uniform Offense Report, UOR # 06-12-04-1540, Dec. 4, 2006.

[3] *Ibid.*

[4] Committee staff interview with Cheryl Wanzie, July 11, 2008.

[5] Committee staff interview with Kevin Frank, July 11, 2008.

[6] Committee staff interviews with Cheryl Wanzie, Kevin Frank, Tina Cozza and Joseph Crowley, July 10-11, 2008; memorandum from Kevin Frank to Dr. Mona Melhem, Dec. 5, 2006.

[7] The Committee asked for all documents relating to this order, but the Department said it had none, and reported that Dr. Melhem said the order came in a conversation between Dr. Melhem and Mr. Moreland. Mr. Moreland said he had no memory of telling anyone to destroy the isolates on Dec. 4, 2006, but thought they were destroyed earlier. Committee staff interview of Mr. Moreland, July 11, 2008.

ordered actions that violated agency and VAPHS procedures to accomplish this destruction of human tissue specimens.

Dr. Melhem's motivations are unclear. She told Committee staff she was simply trying to accomplish what she had already "committed" to in an e-mail minutes earlier to Dr. Ravij Jain, the VAPHS chief of staff, and to Mr. Moreland: that the isolates had been destroyed. In her view, "It was the right thing to do."[8] But in her interview with Committee staff, she also expressed personal animosity toward both Dr. Yu and Dr. Stout and made several unsubstantiated allegations.[9]

What is evident is that the destruction was the climax of a highly charged process that had begun early in 2006 when high-level VAPHS officials decided to close the Special Pathogens Laboratory, which had been in operation for over 25 years, without following any of the procedures it had previously used to close laboratories. During the process, they made decisions before determining all of the facts; blamed others for sloppy financial and research practices which had been in place for years at both the VAPHS and the Veterans Research Foundation of Pittsburgh (VRFP); convened a two-member "independent" board of investigation to justify closing the laboratory that included one person intimately involved in the SPL controversy; kept the assistant chief of staff for research and development uninformed about the disposition of the collection; and, most importantly of all, allowed a research collection to be destroyed without any institutional process on the orders of one person. Subsequently, the VAPHS claimed the destruction was proper because the isolates were not a "research" collection, although dozens of peer-reviewed articles had resulted from the groundbreaking work of the SPL.[10] For example, just this year, the Department adopted a water system testing protocol for its national hospital system that was a direct result of the work of the SPL.[11]

When it was discovered that this collection had been destroyed outside of the normal processes and based on misrepresentations, not a single VAPHS official took steps to make sure that such destruction could never occur again. These events were so unprecedented that hundreds of infectious disease researchers signed a petition requesting an investigation. It was like a "book burning," said Dr. David Snydman, an infectious disease expert at Tufts Medical Center, who had collaborated with Drs. Stout and Yu and had lost samples from his patients housed in the collection.[12]

Committee staff has interviewed numerous scientists and physicians from other federal agencies and academia. While it is clear that formal protocols governing the disposal of research collections are surprisingly rare, none of them indicated that such a destruction would have happened in their institutions. But this event -- bizarre and rare as it may have been -- destroyed much of the life's work of two scientists. It points to a critical need for the federal government

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[8] Committee staff interview with Dr. Mona Melhem, July 10, 2008.

[9] Several VAPHS officials had strong, negative opinions of Dr. Yu. See, *e.g.,* Committee staff interviews of Dr. Mona Melhem, Dr. Steven Graham and Dr. Frederick DeRubertis, July 10-11, 2008. But Dr. Melhem even suggested that Dr. Stout might poison the water supply. Committee staff interview of Dr. Melhem, *supra.*

[10] See, e.g., Committee staff interview of Mr. Moreland, *supra.*

[11] VHA Directive 2008-010, "Prevention of *Legionella* Disease."

[12] "Researchers Protest Destruction of Bacteria Collection," *NatureNews,* http://www.nature.com/news/2008/080320/full/news March 20, 2008.

and individual agencies to establish clear policies for the protection of its researchers and the biospecimen collections that they have accumulated, often at significant taxpayer expense.

HOW DID THIS HAPPEN?

The critical events that led up to the fateful day of December 4, as determined from documents provided by the VAPHS, Dr. Yu and Dr. Stout and Committee staff interviews, are as follows:

The Special Pathogens Laboratory was closed on Friday, July 21, 2006. After that, Dr. Yu, Dr. Stout and the lab's technicians could not enter the laboratory without permission and a police escort. According to VAPHS documents, all clinical and environmental specimens that were in the process of being tested and/or cultured were removed, as was a refrigerator belonging to the clinical microbiology laboratory and the research collections of Dr. Nina Singh and Dr. Robert Muder, infectious disease clinicians who had used SPL's resources for their research.[13] Although the lab facilities were under the auspices of the research office and most of the equipment was purchased by funds from the Veterans Research Foundation of Pittsburgh, Dr. Melhem appeared to have assumed control because clinical *legionella* specimens from VAPHS patients were tested and cultured there.

Beginning in August of 2006, Dr. Yu and Dr. Stout expressed concern about the safety of the isolates they had left in the laboratory. Dr. Stout described them as representing "30 years of work" and including "isolates that were collected for study over many years. In addition to our own research, we have assisted other investigators over the years by providing these unique and well-characterized isolates to them for their investigations." If the freezers in the now-closed laboratory were shut off, the collection would be lost. She later told Dr. Ali Sonel, the current VAPHS assistant chief of staff for research, that her "future research depends on this collection." Dr. Yu described it as a "treasure trove of isolates."[14]

Both Dr. Yu and Dr. Stout received assurances from Dr. Steven Graham, the former assistant chief of staff for research and development, and Dr. Sonel, who assumed those responsibilities in September of 2006, that they would assist in transferring the isolates to the University of Pittsburgh's molecular genetics and biology laboratory.[15] Dr. Melhem was aware of the process as she was copied on some of the e-mails and also had an "in person" meeting with Dr. Sonel during which he discussed the plan to de-identify and transfer the isolates.[16] But Dr. Melhem also talked to Dr. Graham (although he was no longer the research chief) about disposing of the collection. Dr. Graham described Dr. Melhem as "very anxious to get rid of those samples," but he told her it was not a good idea, and that efforts were underway to de-

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[13]Telephone interview with Dr. Janet Stout, Sept. 3, 2008.

[14] E-mail entitled "Re: Material Transfer Agreement - Special Pathogens Lab isolates," from Dr. Stout to Dr. Sonel, Oct. 5, 2006; e-mail entitled "Re: My research equipment," from Dr. Stout to Dr. Yu, Aug. 12, 2006, and forwarded to Dr. Graham, Dr. DeRubertis and Dr. Muder in an e-mail from Dr. Yu entitled "Re: Invaluable isolates for research," Aug. 15, 2006.

[15] See, e.g., e-mail entitled "Re: Invaluable isolates for research," from Dr. Graham to Dr. Yu, Aug. 15, 2006 (1:53 p.m.); e -mail entitled "Re: Material Transfer Agreement – Special Pathogens Lab isolates," from Dr. Sonel to Dr. Stout (cc: Nicholas Squeglia, Dr. Melhem and Dr. Ravij Jain), Oct. 5, 2006.

[16] E -mail entitled "Re: Material Transfer Agreement – Special Pathogens Lab isolates," from Dr. Sonel to Dr. Stout (cc: Nicholas Squeglia, Dr. Melhem and Dr. Ravij Jain) Oct. 5, 2006; e-mail entitled "Re: SPL Samples" from Dr. Sonel to Dr. Jain, Dec. 6, 2006 (7:50 a.m.).

identify the collection and transfer it.[17] The task of facilitating the transfer was delegated by Dr. Sonel to Barbara Strelec, then the research compliance officer. During November, e-mails between Ms. Strelec and Dr. Stout made clear that they were both working on getting the paperwork done to facilitate the transfer, although neither one had ever done such a transfer. The work appears to have been delayed by general confusion about the necessary forms and vacation, conference and holiday schedules.

The isolates remained intact and identifiable in November when a University of Pittsburgh graduate student was granted access to the SPL and the isolates to complete his research.[18] On November 28, 2006, Ms. Strelec and Dr. Stout agreed to meet on December 5 at 10 a.m. to work on the de-identification process.[19] Because no one was allowed to enter the SPL without a police escort, on December 4 at 2:34 p.m., Dr. Sonel e-mailed Dr. Jain to "confirm that it is OK for Janet Stout and Sue Mietzner [a former SPL employee] to complete their inventory under police supervision tomorrow." Ms. Strelec would review the samples they requested and "we will proceed with releasing the samples that are deidentified. We will have them sign a statement that they will not use any serial number or another key to attempt to reidentify any subjects. Please let me know if you have any concerns about this approach."[20]

At 3:06 p.m., Dr. Jain agreed, but included Dr. Melhem on his e-mail "in case she would want someone from the Lab to be there also."[21] Three minutes later, Dr. Melhem responded that "Per Mr. Moreland's orders, all the freezers were cleaned out. The freezers are turned in."[22] Drs. Sonel and Jain were bewildered since they had been under the impression for months that they were attempting to transfer isolates that they were now told didn't exist. Dr. Melhem's statement appeared to be backed up by an e-mail minutes later from Mr. Moreland who said that it was his understanding that:

> The refrigerators were reviewed, there were samples, but that the samples were from work that was not authorized and was in fact redone outside the special path lab (i.e., the company that redid samples and completed in another lab and we paid for) . . . . so, the samples and material from the refrigerators was disposed of and the refrigerators returned to VA inventory.[23]

In retrospect, it is evident that Mr. Moreland was discussing the environmental samples being processed in the SPL at the time of closure that were later re-processed by a private company, but no one appeared to understand that at the time. This e-mail was followed by an e-

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[17] Committee staff interview with Dr. Graham, *supra*.

[18] Committee staff telephone interview with Dr. Stout, Sept. 4, 2008.

[19] E-mail entitled "Re: Transfer of Isolates," from Ms. Strelec to Dr. Stout, Nov. 28, 2006. That meeting was confirmed again in an e-mail entitled "Re: Transfer of Isolates," from Ms. Strelec to Dr. Stout, Dec. 4, 2006 (9:04 a.m.)

[20] E-mail entitled "SPL Samples," from Dr. Sonel to Dr. Jain, Dec. 4, 2006 (2:34 p.m.)

[21] E-mail entitled "RE: SPL Samples," from Dr. Jain to Dr. Sonel (cc: Dr. Melhem) Dec. 4, 2006 (3:06 p.m.)

[22] E-mail entitled "RE: SPL Samples," from Dr. Melhem to Drs. Jain and Sonel (cc: Mr. Moreland), Dec. 4, 2006 (3:09 p.m.)

[23] E-mail entitled "Re:SPL Samples," from Mr. Moreland to Drs. Jain, Melhem and Sonel, Dec. 4, 2006 (3:22 p.m.). It appears that Mr. Moreland was referring to the clinical specimens from VAPHS patients and the water samples that were being tested in the SPL at the time of closure and were sent to another laboratory for completion. Only one refrigerator was returned to the VA inventory because it was the only one owned by the VA.

mail from Dr. Jain to Mr. Moreland and Drs. Melhem and Sonel, stating that Dr. Stout should be denied access to the SPL because "there are no materials left for them to review." That e-mail included a mysterious paragraph that Dr. Jain denies authoring, and no one else admits writing.[24] It allegedly described how and why the samples were destroyed.

> They have already destroyed all the computerized documents and evidence that would have supported the VA in the latest decisions concerning the Special Pathogens labs, during their last visit (Janet and Dr. Yu), under the pretext of "tagging" their equipment to be transported to the university.
>
> Since then, and as discussed with Mr. Moreland and Dr. Steve Graham, then the ACOS for research, a decision was made to get rid of all the infectious agents in that lab, in preparation for it to be demolished.[25]

These alleged facts and chronology in this paragraph, however, did not match the actual events. There is no evidence that Dr. Stout and Dr. Yu destroyed any computerized documents and evidence during a visit to tag equipment while Dr. Graham was the head of research – or at any other time. The "tagging" visit appears to have occurred on October 6 under police supervision and a month after Dr. Graham left that position.[26] Dr. Graham also has denied agreeing to the destruction of the collection.[27]

In his responsive e-mail, Dr. Sonel expressed surprise that he had not been made aware of this destruction and his concern that the "normal process" of involving the Research Compliance Committee had not been used.

> I don't think we were ever made aware of the samples being destroyed. Since the activities that generated the samples included research, albeit unauthorized, our normal process would have been to involve the Research Compliance Committee prior to destroying specimens derived from human subjects as we have done in the past. In addition a representative of the RCC has been present in the past to observe and verify sample or data destruction processes required by the RCC. The last I had spoken to Dr. Melhem in September, they were in the freezer in her lab during my visit there and I discussed with her our prior conversations regarding potential release of samples with certain safeguards. (emphasis added)[28]

While Dr. Sonel refers to a "normal" process, the Subcommittee was not provided any relevant documents concerning that process. Committee staff subsequently discovered VA documents that appear to require the deposit of biospecimens retained for research into tissue

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[24] Committee staff interviews with Dr. Jain, Dr. Sonel and Dr. Melhem, July 10, 2008.
[25] E-mail entitled "RE: SPL Samples," from Dr. Jain to Mr. Moreland and Drs. Melhem and Sonel, Dec. 4, 2006 (3:40 p.m.).
[26] E-mail entitled "RE: Yu equipment purchased through VRF" from Dr. Sonel to Dr. Yu (cc: Mr. Squeglia and Drs. Jain, Graham, DeRubertis and Stout), Oct. 5, 2006. Dr. Yu was told to report to the VA police office to obtain access.
[27] E-mail entitled "RE: SPL Samples" from Dr. Sonel to Dr. Jain, Dec. 6, 2006.
[28] E-mail entitled "RE: SPL Samples" from Dr. Sonel to Dr. Jain (cc: Mr. Moreland and Dr. Melhem), Dec. 4, 2006 (4:36 p.m.)

banks.[29] In a directive dated March 31, 2003, the collection and banking of biospecimens were put "under the jurisdiction" of local Institutional Review Boards (IRB) and Research and Development (R&D) Committees.[30] The Department has not yet responded with information explaining the status of this policy. Nor does it appear, after reviewing minutes from the VAPHS IRB and R&D Committee meetings, that these policies were put into effect.[31] (An expanded discussion of this issue follows in a later section of this report.)

But the isolates had not been destroyed prior to 3:09 p.m. on December 4 when Dr. Melhem sent her e-mail. However, by approximately 6 p.m., Dr. Stout's and Dr. Yu's 30-year research collection was gone.[32] As Mr. Frank wrote the next morning, ". . . all frozen isolates that you referred to were discarded. We personally met the Environmental Service people (Kathy Long), boxed up the waste, and sent it to Bio-Ox to be incinerated."[33]

In the meantime, Dr. Sonel was trying to decide what to tell Dr. Stout. First, Ms. Strelec called Dr. Stout and told her that the "front office" had put the "process" on hold. By 5:44 p.m., Dr. Stout e-mailed Dr. Sonel to ask why the meeting had been cancelled. Dr. Sonel said he would update her "soon regarding this request," but didn't mention that the isolates had been destroyed.[34] On Dec. 5, Dr. Jain told Dr. Sonel that Drs. Melhem and Dmitriy Gutkin of laboratory services would provide a memo describing the process "followed to move the samples or to dispose of them." Dr. Yu and Dr. Stout should be referred to Dr. Melhem with "any questions" they might have about the isolates.[35]

Later that day, Dr. Melhem sent an undated, unsigned memorandum to Drs. Jain and Sonel, stating that "[p]er the instructions of Mr. Moreland and Dr. Graham (ACOS, R&D), an inventory of all of the freezers in the SPL was conducted after which clinical specimens (approximately 10 percent) were sent to the microbiology lab for processing; Dr. Nina Singh's liver transplant specimens were saved for future studies (approximately 30 percent) and specimens "without clear labels or accompanied by appropriate paperwork were discarded according to biohazard and infection control protocols" (approximately 60 percent). No time frame for all of these activities was given in the memo, but in a subsequent response from the VA, Dr. Melhem said she "believed" it was written "on or around July 19, 2006." However, it is undisputed that no destruction occurred or was ordered at that time.[36]

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[29] VHA Directive 2000-043. November 6, 2000. Accessed September 3, 2006, at http://www.vbri.org/Research/documents/TissueBanking.pdf. The Directive states that it was to expire on October 30, 2005.

[30] VHA Directive 1200. "Banking of Human Biological Specimens Collected From Veterans for Research." Veterans Health Administration, Department of Veterans Affairs, Washington, D.C. March 31, 2003; pp. 1-3. See Sections 2(b) and 3(h). The Directive indicates it was to be recertified at the end of March 2006.

[31] Yet the Standard Operating Procedures for the VAPHS Subcommittee on Human Studies (the IRB), approved January 18, 2005 and again November 14, 2007, both make reference to the Directive from 2000.

[32] Committee staff interviews with Cheryl Wanzie, Kevin Frank, Tina Cozza and Joseph Crowley, July 10-11, 2008; E-mail entitled "Frozen Isolates" from Kevin Frank to Dr. Melhem. Dec. 5, 2006 (8:41 p.m.).

[33] *Ibid.*

[34] E-mail entitled "Re: Material Transfer Meeting Cancelled?" from Dr. Stout to Dr. Sonel, Dec. 4, 2006 (5:44 p.m.); e-mail entitled "Re: Material Transfer Meeting Cancelled?" from Dr. Sonel to Dr. Stout, Dec. 4, 2006 (6:34 p.m.)

[35] E-mail entitled "RE: SPL Samples" from Dr. Jain to Dr. Sonel (cc: Mr. Moreland and Dr. Melhem), Dec. 5, 2006 (11:18 a.m.)

[36] Undated memorandum to Drs. Jain and Sonel, attached to e-mail entitled "SPL.doc" from Dr. Melhem to Drs. Jain and Sonel and Mr. Moreland, Dec. 5, 2006 (11:42 a.m.) SPL staff remained in the laboratory until July 21, 2006.

Moreover, as Dr. Sonel stated in a subsequent e-mail to Dr. Jain, "Dr. Graham denies agreeing to destruction of the samples."[37] Dr. Graham also told Committee staff that his conversation with Dr. Melhem about the isolates did not occur until a few months ago.[38] And there also were samples belonging to Dr. Muder which were removed from the SPL in July and were not listed.

Dr. Sonel expressed his "disappointment" that as head of the research and development side of VAPHS, he was

> . . . not given an opportunity to process this through the RCC [Research Compliance Committee], which I feel would have been the due process even if the end result may have been to destroy the samples. The samples and their proposed fate (to deidentify and release) was discussed in person with Dr. Melhem in September . . . . I sincerely hope we can avoid such a confusion and I would truely [sic] appreciate being kept in the loop if data or specimen destruction is considered when it may be linked to approved or non-approved research. (emphasis added)[39]

No one from the VAPHS could summon up the courage to tell Dr. Stout of the destruction of the isolates. As part of a process of appealing Dr. Stout's 30-day suspension, Dr. Yu and Dr. Stout received information in early January that the research collection had been destroyed.[40]

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[37] E-mail entitled "RE: SPL Samples" from Dr. Sonel to Dr. Jain, Dec. 6, 2006. In an interview with Committee staff, Dr. Graham recalled a conversation with Dr. Melhem in the fall of 2006 in which she appeared "very anxious" to get rid of the isolates. Dr. Graham told her it was not a good idea, and that the Research Compliance Committee was working to de-identify the isolates for transfer. Committee interview with Dr. Steven Graham, July 10, 2008.

[38] Committee staff interview with Dr. Graham, *supra.*

[39] E-mail entitled "RE: SPL Samples" from Dr. Sonel to Dr. Jain, Dec. 5, 2006 (4:40 p.m.)

[40] Letter from Drs. Yu and Stout to Drs. Jain, Graham and DeRubertis requesting verification of the status of the non-*legionella* isolates in their collection, specifically the 400 *klebsiella* isolates, referring to previous letter of Jan. 17, 2007, requesting verification of destruction of *legionella* isolates.

CLOSURE OF THE SPECIAL PATHOGENS LABORATORY

Troubles for the SPL can be traced back almost one year prior to the destruction of the collection that had been contained in that lab. In early January of 2006, Dr. Yu asked Dr. Melhem for a raise for Dr. Stout, who was on the payroll of the clinical microbiology laboratory. Dr. Stout was by that time a well-respected and published infectious disease researcher. The request, and the participation of Dr. Yu in making the request, seems to have sent Dr. Melhem on a path towards closing the lab. Dr. Melhem responded by asking for a spreadsheet of patient workload and control point expenditures for the Special Pathogens Laboratory,[41] and soon decided that she wasn't getting enough clinical value for Dr. Stout's salary.[42] Dr. Graham then began a review of the SPL's funding.[43] He immediately raised questions about a $100,000 unrestricted educational grant from Binax Inc.[44] On April 20, Dr. Melhem met with Dr. Stout and said she was going to pull all the VAPHS clinical work from the SPL and move Dr. Stout into the clinical microbiology lab. [45] On May 1, Dr. Melhem transmitted the same information to Drs. Jain, Graham and DeRubertis even though the financial review of the SPL's activities requested two days before by the executive committee of the board of the Foundation had not yet begun.

On May 2, Mr. Moreland sent Dr. Yu a list of actions Dr. Yu was to take and procedures to follow in operating the SPL. If that was not done, his Foundation accounts were to be frozen.[46] It is not clear whether Dr. Yu complied with the entire list. But the "limited financial review" of the SPL submitted by James Baker, VAPHS chief financial officer, on June 15 concluded most of the SPL's income did not come from research grants, but from testing services provided to VA and non-VA customers and that the *legionella* study approved by the research and development committee in December of 2005 was actually a business. Baker recommended that the Foundation board make a determination about continuation of the study, questioned both the Binax and E-Sun Technology grants and recommended tighter financial controls over grants. He also made an unsupported allegation that no entity within the VAPHS wanted to take responsibility for the laboratory.[47]

There is no doubt that Dr. Yu had been allowed to run the SPL for years without significant outside oversight or review and with the full approval of the Foundation's executive director. However, because all of the billings and receipts were handled by the Foundation, there was little or no evidence of actual misuse of funds. Nor did the board meet to determine that the

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[41] E-mail entitled "Special Pathogens Data FY04-05.xls" from Cheryl Wanzie to Dr. Melhem, Jan. 11, 2006.
[42] The Subcommittee requested documents on any review of the SPL that had occurred after 2000. No documents were provided dated prior to 2006.
[43] Memorandum entitled "Re: Delineation of Current Research Activity" from Dr. Yu to Dr. DeRubertis (cc: Drs. Graham and Jain), March 29, 2006.
[44] E-mail entitled "Victor Yu" from Dr. Graham to Dr. DeRubertis (cc: Dr. Jain), April 4, 2006.
[45] E-mail entitled "Special Pathogens FTE and Janet Stout," from Dr. Yu to Dr. Jain and Mr. Moreland, May 1, 2006.
[46] Memorandum entitled "Re: Supervision of Activities in the Special Pathogens Laboratory," from Mr. Moreland to Dr. Yu, May 2, 2006.
[47] "Veterans Research Foundation of Pittsburgh Limited Financial Review Accounts of Dr. Victor Yu," June 15, 2006.

lab should be closed. Nonetheless, the result of the review was that Dr. Jain told Dr. Yu on July 5 that the lab would be closed. According to Dr. Yu, the reasons given were confusing: the lab did not perform research, but another allegation was that payment from non-VA customers for testing services were paying for research which was not approved by the Institutional Review Board.[48] Dr. Stout and the clinical work the SPL had done for VAPHS would be transferred to the clinical microbiology laboratory, all non-clinical work would end in five days, and the SPL employees would be terminated.[49]

Two days later, after 25 years of operation, Dr. Yu was told that the employees would be terminated that day, and his other accounts would be frozen until October 1 so that any deficit from the *legionella* study would be covered by those accounts.[50] (Dr. Yu subsequently requested and received a 10-day reprieve on the closing date.) On July 10, Dr. DeRubertis raised concerns about work done in the SPL by two other researchers. "The closure of the SPL will have consequences for the current clinical Infection Control, and research activities of VAPHS and its ID [infectious disease] division," Dr. DeRubertis wrote, asking who was going to provide these services.[51]

After the abrupt decision by Mr. Moreland and Drs. Jain and Graham to immediately close the established laboratory of two of its most recognized researchers, it is undisputed that chaos erupted. Dr. Yu refused to stop taking samples to analyze and told the lab staff to continue processing them in hopes that he could somehow save his laboratory.[52] Dr. Stout made arrangements with the head of laboratory services to move equipment to the clinical lab on July 25, but he went on vacation, and Dr. Melhem then ordered that it be done on July 19 and the locks changed on July 21, telling everyone that the entire building was to be demolished within weeks. Dr. Jain was also pushing to close the lab quickly. Mr. Moreland caused further disruption by instituting a Board of Investigation whose members insisted on deposing SPL employees as they were trying to finish their work.[53] Guards were placed at the doors so employees could not leave. Dr. Stout went to the emergency room for several hours with cardiac-related symptoms, but returned and took out 49 boxes of research papers, which were later found to include some patient records.[54]

In the end, the laboratory was closed on July 21, and Dr. Yu, VAPHS's chief of infectious disease for 28 years, was fired for refusing the order of Dr. Derubertis to stop

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[48] E-mail entitled "Written justification for closure requested" from Dr. Yu to Dr. Jain and Mr. Moreland (cc: Dr. DeRubertis), July 12, 2008. No written document was forthcoming. Dr. Yu has stated to Committee staff that all of his research was properly approved. Telephone interview of Dr. Yu, Sept. 7, 2008.

[49] Memorandum entitled "Special Pathogens Laboratory" from Dr. Jain to Dr. Yu, July 5, 2006.

[50] E-mail entitled "Legionella Lab Closeout Plan.doc" from Nicholas Squeglia to Dr. Yu (cc: Drs. Graham, Jain and DeRubertis), Jul7 7, 2006.

[51] Memorandum entitled "Closure of the Special Pathogens Lab (SPL" from Dr. DeRubertis to Dr. Melhem, July 10, 2006.

[52] Deposition of Dr. Victor Yu before the Board of Investigation, July 21, 2006, pp. 42-43.

[53] E-mail entitled "Obstacles to Completion of Legionella responsibilities" from Dr. Yu to Dr. DeRubertis (cc: Drs. Jain and Stout, members of Congress and the American Legion), July 21, 2006. According to the VA Handbook, the Board's authority extends only to employees. VA Handbook 0700, Chap. 4(B)(3-4). After July 21, SPL employees would no longer be under the Board's authority.

[54] See, *e.g.,* Notes of Dr. Janet Stout on July 12, 2006, meeting with Drs. Gutkin and Melhem and attached documents; letter entitled "Proposed Removal" from Dr. Melhem to Dr. Stout, Aug. 18, 2006.

processing samples. Dr. Stout was placed on administrative leave and faced a removal action. But the Revco refrigerator belonging to the Foundation remained in operation, and the Yu/Stout isolate collection remained intact inside until December 4.

Following the firing of Dr. Yu, the research compliance officer was tasked with a "publications audit" of Dr. Yu's research articles over the past 10 years. There were two drafts, the final one of which concluded that Dr. Yu had conducted unapproved research. Dr. Yu was not given any opportunity to respond, and has subsequently pointed to numerous errors in the report.[55] The Research Compliance Committee met on September 5, 2006, discussed the report and decided to close Dr. Yu's "science only" (no human subjects) study because the "continuing review for this study had lapsed."[56] This was not accurate as the study had been reviewed by the Research and Development Committee and was approved through December 11, 2006.[57]

The reasons for the haste in closing a lab that had been operating 25 years and produced groundbreaking research which improved VA patient care remain unclear. What is evident is that VAPHS officials made a decision to close the lab and had no intention of working with Drs. Yu and Stout to resolve any questions about its practices and operations before doing so. Dr. Yu had been told a decade earlier that he could bill non-VA customers for testing their samples through the VRFP, and no one ever changed that directive. The excuse that Dr. Melhem gave about the building being demolished within weeks was a red herring. When Committee staff visited the VAPHS in July of 2008, the building was intact, and at least one other laboratory was operating in it. Except for the loss of the isolate collection, its handwritten catalog and some computer terminals, the Special Pathogens Laboratory premises look just as they did when the staff was locked out – Christmas and other cards and family photos are still on the walls; books are in the bookshelves; and unused, but still operating, refrigerators hum in the background.

In the meantime, Dr. Stout and Dr. Yu have opened a second special pathogens laboratory and are trying to rebuild their careers.

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[55] Committee staff telephone interview with Dr. Yu, Sept. 7, 2008.
[56] Minutes of the Research Compliance Committee, Sept. 5, 2006.
[57] Expedited approval was granted on Dec. 12, 2005, and reported to the full committee on Jan. 25, 2006. VAPHS, Protocol History for "Various Studies Examining Treatment, Prevalence and Eradication of Legionella."

HISTORY OF THE SPECIAL PATHOGENS LABORATORY

The Special Pathogens Laboratory (SPL) was established at the Pittsburgh Veterans Affairs Medical Center in 1981 as a special microbiology laboratory to respond to endemic hospital-acquired Legionnaires' disease at that hospital. It was under the direction of Dr. Victor Yu, then chief of infectious disease and the microbiology lab. Later Dr. Janet Stout became the director. It was established by the Central Office of the Veteran Affairs Department (VA). Originally, the staff included three microbiologists funded by the Department. In addition to perfecting techniques to determine the presence of the *legionella* bacteria in human isolates, Dr. Yu, Dr. Stout and other researchers discovered the link between the presence of the bacteria in hospital water systems and hospital-acquired Legionnaires' disease. This work ultimately resulted in a protocol adopted by the VA system in 2008 for the annual testing of the water systems in all VA hospitals.[58] Most recently, Dr. Stout worked with the American Society of Heating, Refrigerating and Air-Conditioning Engineers on its proposed standard entitled "Minimizing the Risk of Legionellosis Associated with Building Water Systems." The standard could result in requiring certain building owners to establish *legionella* auditing and prevention programs.[59]

In addition to its work for the Pittsburgh Veterans Affairs Medical Center (VAMC), because of its expertise, the SPL began providing services to other VA centers and non-VA hospitals. On June 30, 1995, a meeting was held at the VAMC to "finalize the mechanism for billing of microbiological testing performed at the Special Pathogens Laboratory and Clinical Microbiology Laboratory." According to a memo from Dr. Yu, cost estimates for *legionella*, checkerboard antibiotic synergy and mycobacteria testing were provided. It was decided that compensation for all *legionella* testing services would be deposited in the Veterans Research Foundation of Pittsburgh, and on a quarterly basis, payment would be made to the "Hospital Care Appropriation" for VA institutional costs. Services provided to other VA Medical Centers would be paid through an "expenditure transfers" account. A "sharing agreement", which normally would be used to provide services to outside parties, was determined to not only be "unnecessary, but unwieldy, given that requests for testing are usually sporadic and total funds received from 'regular' users is well below $25,000 annually."

Marketing of services was also discussed, and it was "the understanding of the group" that advertising was permissible if it was done through the VRPF Corporation. Advertising fliers were to be drafted.[60]

Although Dr. Yu had requested that the SPL be designated as a national VA reference laboratory, it was decided that *legionella* reference testing could be accommodated through the existing structure of the Special Clinical Resource Center of the Pathology and Laboratory

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[58] VHA Directive 2008-010, "Prevention of *Legionella* Disease."
[59] ASHRAE Guideline 12-2000.
[60] Memo from Dr. Yu to William Boyle, Raymond Laughlin and Ron Michaels (cc: Thomas Capello, Dr. Ernest Urban, Dr. Martin Sax and Jack Rihs) July 5, 1995. According to Dr. Yu, these fliers were never drafted. Deposition of Dr. Victor Yu, July 21, 2006, p. 55.

Medicine Services instead of establishing a separate unit.[61] This set-up was acknowledged by Dr. Graham, the former assistant chief of staff for research, who stated in July of 2006 that "Years ago, the VAMC gave him a lab with technician support to provide clinical services to VAMCs and non-VAMCs for culturing the Legionnaire disease pathogen." Dozens of peer-reviewed articles resulted from the researchers' work on *legionella* and other infectious bacteria. Dr. Yu was the recipient of an award by the Infectious Disease Society of America for the Best Original Article in 2003 involving his work on the effective use of penicillin for some infections. Dr. Graham inaccurately claimed in 2006 that Dr. Yu and Dr. Stout had "no active research protocol for some time," although one had been approved in December of 2005.[62]

[61] Memo entitled "Establishment of a VA Reference Laboratory," from Dr. Yu to Dr. Urban, July 3, 1996; memo entitled "VA Reference Laboratory, As per memo from Dr. Yu, dated June 3, 1996," from Dr. Gurmukh Singh to Dr. Urban, June 4, 1996.

[62] VAPHS, Protocol History for "Various Studies Examining Treatment, Prevalence and Eradication of Legionella."

FOUNDATION OVERSIGHT

Over the years, the SPL brought in significant amounts of funds to the Pittsburgh foundation from its sale of testing services and research funds. It is clear from the Foundation's records, however, that the board of directors – which included the Pittsburgh VA's medical director, its chief of staff, and its assistant chief of staff for research and development – paid very little attention to how those funds were accounted for or what research was being undertaken. The board only met annually until 2003 when it met biannually for two years. The receipt and disbursement of funds were left to the judgment of the Foundation's executive director, who was also the chief administrative officer of the VAMC's research and development office, and he appears to have paid little attention. Co-mingling of funds from one project to cover shortages in another project was common and approved.[63] The board appears to never have taken any recorded votes, even when it changed the by-laws, so it is unclear when and if "official" actions were taken.[64] Accounts in deficit were brought to the board's attention, but little action was taken, even when the entire foundation had a deficit of over $600,000.[65]

In 2005, the board reviewed revised bylaws that permitted an executive committee. Without a vote approving those bylaws and without the policy for the committee -- which was to be presented at the next board meeting -- a three-member committee met in April of 2006 to discuss Dr. Yu's accounts. First it requested an audit. Then on June 30, it decided to disband Dr. Yu's laboratory, allegedly based on the results of the "audit", from which the committee determined "that this program no longer meets the goals" of the VRFP. No further explanation was given. It was to be done as soon as possible, and the employees would be fired.[66] It is unclear whether the executive committee had that authority, since the lab was established by the VA, and the facilities were under VAPHS control, not the Foundation's. The Foundation basically operated as a financial conduit.

The alleged "audit" was actually a "limited financial review" by James Baker, the VAPHS' chief financial officer (CFO) and was quite incomplete. During the review, the CFO interviewed only one VAPHS official, which was Dr. Melhem. The CFO concluded that $27,000 in clinical supplies may have been misused by the SPL based on unverified costs estimates and questioned Dr. Stout's work and expenses, without ever interviewing her. Based

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[63] See, *e.g.,* Committee staff interview of Nicholas Squeglia, July 11, 2008

[64] According to the minutes of the board of directors, Veterans Research Foundation of Pittsburgh, for Sept. 28, 2005, revised bylaws were distributed and discussed which permitted the establishment of an executive committee. No other details, including membership, were provided, and no vote is recorded. However, a policy for that committee was to be presented to the board at its next meeting. But before the next meeting, an "executive committee" of three members met to discuss Dr. Yu's accounts and order an audit. Minutes of "Executive Committee Meeting," April 28, 2006.

[65] See, *e.g.,* minutes of board of directors, Veterans Research Foundation of Pittsburgh, April 26 and Sept. 23, 2004, and Sept. 28, 2005. Ironically, at the meeting where the deficit was mentioned, the board asked for an edit of a draft self-evaluation form on board performance which included the following in its "Roles and Responsibilities": "The board is exercising appropriate fiscal oversight, including ensuring that financial controls are in place, approving the annual operating budget, ensuring that the budget reflects priorities, and monitoring financial performance during the year." Minutes of board of directors, *supra,* Sept. 28, 2005.

[66] Minutes of the executive committee, VRFP board of directors, April 28 and June 30, 2006.

only on Dr. Melhem's statements, he concluded that the clinical support, medical specialty and research elements of the VAPHS were not willing to accept responsibility for the SPL. There is no evidence that he met with the heads of the medical specialty or research offices.

The CFO noted that $900,000 of the SPL's income had come from testing revenues without mentioning that this source of income was approved for years, and the Foundation had been designated as the conduit. He acknowledged also that the Foundation had a practice of allowing researchers to "borrow" funds from projects not in deficit to cover projects in deficit – as Dr. Yu had done. He then gave his opinion – without the benefit of hearing from the VAPHS research office and while admitting that research was actually being published by SPL staff – that the *legionella* study was a business receiving free space from the VAPHS, and that the Foundation board of directors should review its activities and determine whether it was a "relevant research study" or a business. If it was a business, it should be shut down.[67]

There is no evidence that the Foundation board ever met to consider the limited financial review, the closure of the SPL or to hear from Dr. Yu or Dr. Stout. Nor did the executive committee, which immediately decided to close the laboratory.

The careless management of the Foundation by its board and officers over the years was especially evident in the following "precepts" adopted by the board in September of 2006, none of which appeared to be in place previously:

A. All research must be conducted within the scope of a VAPHS R&D Committee-approved research study.
B. Agreements in support of the approved research must be in the form of a memorandum of understanding, contract, CRADA or clinical trial agreement as approved by the VA technology transfer office.
C. All investigators must submit a signed conflict of interest statement for each research or educational activity.
D. Financial oversight to assure funds and expenditures of such funds are linked to an R&D Committee-approved project.[68]

What is most disturbing about the Foundation board's behavior is not that it decided at some late date to operate in a more professional manner, but that it turned on Dr. Yu, blamed him for operating under the lackadaisical system that the board itself and its executive director had not only tolerated, but encouraged, for many years and then demanded that the lab be shut down immediately for not meeting standards that had not yet been adopted. There is no indication that any other researcher was subjected to such a review.

But the Committee's investigation indicates that it was not the limited financial review or any other investigation that resulted in this precipitous closure of a prestigious laboratory that had been in existence for more than 20 years. In April, Dr. Melhem had told Dr. Stout that she intended to move all clinical work from the SPL to her clinical microbiology laboratory. On May 1, Dr. Melhem told Drs. Graham, Jain and DeRubertis that she intended to take that action

[67] Baker, James, "Veteran Research Foundation of Pittsburgh, Limited Financial Review, Accounts of Dr. Victor Yu, June 15, 2006, pp. 3-6.
[68] Minutes of the board of directors, VRFP, Sept. 18, 2006.

by July 1. "I can wait till the audit is completed if this will make it easier for you. I believe this is the right thing to do. It will save all of us a lot of trouble in the long run," she wrote in her e-mail.[69] There is no evidence that anyone objected.

[69] E-mail entitled "Re: Draft of Yu memo for your comments," from Dr. Melhem to Drs. Graham, Jain and DeRubertis, May 1, 2006.

THE INVESTIGATIONS OF DR. YU

After the Foundation's executive committee decided to close the Special Pathogens Laboratory, Mr. Moreland initiated two additional investigations of Dr. Yu. Both began as reviews of the Binax grant. The internal Board of Investigation set up by Mr. Moreland violated many of the procedures set up by the Department's guidelines, including going far outside of the scope of its charge. The agency's inspector general conducted a standard investigation, but the local U.S. Attorney's office refused to prosecute either criminally or civilly.

Additionally, the research office initiated a review of publications review of Dr. Yu to attempt to determine if Dr. Yu's research had the proper IRB approvals. A draft report stated that Dr. Yu had conducted research without the proper approvals, but Dr. Yu – who did not know of the existence of the report and was never consulted – in a review requested by the Committee has stated that the report was rife with errors and misrepresentations.

A. The Board of Investigation

In his limited financial review of Dr. Yu's accounts at the Foundation, Mr. Baker did not raise any questions about the $100,000 Dr. Yu had received from a company named Binax. None of the money had been spent except for the 10 percent administration fee taken by the Foundation. Nonetheless, on July 19, 2006, Mr. Moreland decided to convene a Board of Investigation (BOI) to look into all aspects of the research, financial arrangements and agreements that may have existed between the SPL and Binax.[70] He named David Cord of the VAPHS Human Resources Office as chair, and Dr. Graham as a member.

Dr. Graham's appointment was in clear violation of VA Handbook 0700 on Administrative Investigations which directs that the members of a board of investigation "must be objective and impartial, both in appearance and in actuality . . . . should not have had direct involvement in matters that are being investigation, and should not supervise or have close personal relationships with any individual whose conduct is a subject of the investigation."[71] Not only was Dr. Graham a member of the board of the Foundation which was the recipient of the Binax grant and head of the research office, but he also was the person who had suggested that the grant be investigated because it was "questionable."[72] He was intimately involved in facilitating the closure of the SPL, and the day after he was appointed, Dr. Graham reported to the director of the Office of Research Oversight for the VA's Atlantic region that he was investigating an unspecified instance of research noncompliance – an issue for which he would have been responsible -- that had been uncovered by the financial review of Dr. Yu's accounts.[73]

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[70] Memorandum entitled "BOARD OF INVESTIGATION" from Mr. Moreland to David Cord and Dr. Graham, July 19, 2006.

[71] "Administrative Investigations," VA Handbook 0700, July 31, 2002, Chapter 3(B)(2)(b), p. 3-1.

[72] E-mail entitled "Victor Yu" from Dr. Graham to Drs. DeRubertis and Yu, April 4, 2006. Dr. Graham incorrectly stated in that e-mail that Dr. Yu's *legionella* study had not been reviewed since 1996 even though the most recent approval occurred in December of 2005.

[73] [73] E-mail entitled "Pittsburgh VA research lab closing" from Dr. Min-Fu Tsan, director, VA Office of Research Oversight Mid-Atlantic Region, to Tom Puglisi, VHACO, July 14, 2006. The Committee asked for documents relating to a conflict-of-interest review of the BOI members, but was told there were none.

And shortly after Mr. Cord was appointed to the BOI, Mr. Moreland contacted him to tell Mr. Cord that Dr. Yu had violated a direct order from Dr. DeRubertis.[74] This was not within the scope of the BOI charge, but it found its way into the BOI report, another violation of the Handbook.[75] The Handbook also suggested an odd number of members to a board to facilitate decision making and strongly suggested that the board be a fact-finding body only and not provide recommendation because "a focus on developing recommendations may tend to distract AIB members from their primary role as objective factfinders."[76] Mr. Moreland ignored this guidance.

On August 4, 2006, the charge to the BOI was amended to direct the members to "investigate any potential breach of security and/or patient privacy by any employee associated with" the SPL.[77] This was the result of an allegation that Dr. Stout had removed research records from the SPL that contained patients' private information.

The final report – issued on August 11 – went far beyond the scope of the two charge letters in its facts, determinations and recommendations. The BOI found that the Binax funds were untouched. No research was underway with those funds because additional funding from other parties had not been obtained. But the BOI did not limit its conclusions to the charge regarding Binax. It went on to state that Dr. Yu had not obtained continuing reviews on his *legionella* study, although it had been re-approved in 2005. It also concluded that the SPL was not involved in MRSA research, although a collection of MRSA isolates belonging to Dr. Muder, another infectious disease researcher, were removed from the SPL when it was closed.[78] The report went into great detail about the over $500,000 the lab was expected to generate from testing environmental samples for *legionella*, but claimed it was not financially self-sufficient.

The BOI also stated that Dr. Yu had disregarded orders in July from Dr. Jain and Dr. DeRubertis to halt testing environmental samples from outside sources and opined on the role of special reference laboratories while denying that the SPL was a special reference laboratory.

Concerning Dr. Stout's privacy violations, the BOI disregarded her testimony that she had told the SPL staff not to box up any material that contained patient information and determined that she had committed a security breach and provided false testimony by stating that the boxes were taped shut.

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[74] E-mail entitled "Re: Hopkins request for their results (fwd)" from Mr. Moreland to Drs. DeRubertis and Jain and Mr. Cord, July 24, 2006.

[75] "The Scope statement of the Charge Letter provides the outer boundaries of the investigation. . . . While the Convening Authority may provide additional direction to the AIB during the course of the investigation by any means, changes in the scope of the investigation must be documented by an amendment to the Charge Letter." (emphasis added) VA Handbook 0700, *supra,* Chap. 3(C)(3). The Committee was informed by the VA that the only change to the charge was to add the allegation against Dr. Stout.

[76] VA Handbook 0700, *supra,* Chap. 3(C)(6)(c).

[77] Memorandum entitled "Board of Investigation" from Mr. Moreland to Dr. Graham and Mr. Cord, Aug. 4, 2006.

[78] [78] Memorandum entitled "Closure of the Special Pathogens Lab (SPL" from Dr. DeRubertis to Dr. Melhem, July 10, 2006. Dr. Yu also said previous MRSA research had been approved. Committee staff interview with Dr. Yu, Sept. 7, 2008.

In its conclusions, the BOI made recommendations that for the most part were not related to the original charges. These included proposals for disciplinary action against Dr. Yu for violating a direct order from his supervisors; for closure of the lab because it was running a deficit and was doing fee service work; and a thorough audit of all the records of the SPL and the VAPHS' Research and Development Committee and Institutional Review Board to determine if there was "serious research noncompliance that meets reporting criteria."[79] Except for the recommendation concerning Dr. Stout's security violation, none of these recommendations were within of the scope of the charge letters.

B. The Inspector General's Investigation

At the same time, Mr. Moreland tasked the BOI with investigating the Binax grant, he sent a letter to the VA Inspector General requesting a review of the same grant and other "irregularities" on the initiative of Drs. Graham and Jain.[80] The letter was sent on July 18 and alleged that there were concerns that "Dr. Yu had misused or diverted some of his project funding."[81] The next day, Mr. Moreland convened the Board of Investigation to examine the same alleged irregularities in Dr. Yu's Binax account.

But Dr. Graham already knew the Binax money had not been used by Dr. Yu. Dr. Jain had forwarded Dr. Graham's e-mail to Mr. Squeglia and asked about the amount still remaining in the Binax account and the length of time the funds had been there.[82] Mr. Squeglia replied an hour later that "the funds are still in the account.... Total received is $100,000. Administrative assessment of 10% was charged and yields balance of $90,000." The funds were received in $10,000 increments approximately every month between September 2004 and May 2005.[83]

In the end, the Office of the Inspector General reported to Ms. Terry Gerigk Wolf (Mr. Moreland's successor as Director of the VAPHS), that there was no diversion or misuse of Dr. Yu's grants, but that the purchase of a database service by the Pittsburgh VAMC from a company owned by Dr. Yu was a possible criminal violation, and that his acceptance of an honorarium from Binax for presentations made in Europe was a "possible violation" of the Department's standards of conduct.[84]

With regard to the issue that was the original reason for seeking the IG's involvement, an interview with a Binax company official indicated that the $100,000 fund had "no strings

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[79] Memorandum entitled "BOARD OF INVESTIGATION" from Mr. Cord to Mr. Moreland, Aug. 11, 2006.
[80] "Nick [Squeglia] and I are concerned that no expenditures have been charged against the Binax account.... This raises questions as to who did the work in the scope of this agreement and from what sources were they paid?" E-mail entitled "Concern Regarding Binax Account" from Dr. Graham to Dr. Jain (cc: Mr. Squeglia and Michele Michaels), July 14, 2006; E-mail from Moreland to Nealon and Dr. Jain. Subject: "Re: Concern regarding Binax account." July 14, 2006 (1:12 PM).

[81] Gelles, Lynnette. "Comprehensive Report of Investigation." Pittsburgh Resident Agency, Office of the Inspector General, Department of Veterans Affairs, Pittsburgh, Pennsylvania. August 27, 2007; p. 1. Hereafter cited as *IG Report.*
[82] E-mail from Dr. Jain to Dr. Graham (cc: Squeglia and Michele Michaels). Subject: "RE: Concern regarding Binax account." July 14, 2006 (12:47 PM).
[83] E-mail from Mr. Squeglia to Dr. Jain and Dr. Graham (cc: Michele Michaels). Subject: "RE: Concern regarding Binax account." July 14, 2006 (1:47 PM)
[84] *IG Report, supra;* Letter from Jeffrey G. Hughes, Special Agent in Charge, Northeast Field Office, Office of the Inspector General, Department of Veterans Affairs, Newark, New Jersey, to Terry Gerigk Wolf, Director, VA Pittsburgh Medical Center. February 11, 2008; p. 1.

attached," and was for developing a rapid test kit for pneumonias similar to the kit Binax had developed -- with the help of the SPL -- to quickly identify if a patient was infected with the predominant strain of *Legionella*. Binax had also paid Dr. Yu's expenses and an honorarium (totaling $4,107.48) to attend conferences in Germany and Spain.[85]

The Inspector General requested a review from the VA Office of General Counsel on the facts it had collected regarding Binax. The Counsel's office in Philadelphia responded that, while Dr. Yu had not sought an opinion on the propriety of accepting the honorarium, it has no process for approving such a request. Further, criminal prosecution would be called for only if Dr. Yu served on VA Pharmacy and Therapeutics Committees or had procurement authority. Neither situation applied.[86]

Finally, the allegation concerning E-Sun Technologies and Dr. Yu concerned the purchase of access to a website -- antimicrobe.org -- by the Pittsburgh facility. The period of service covered 18 months and the cost was $16,500.[87] IG interviews with VAPHS staff determined that the local Contracting Officer was not aware that E-Sun was Dr. Yu's company and that the website was an E-Sun product, and therefore Dr. Yu had benefited from a conflict of interest. Dr. Yu appeared to be involved in the preparation of a Justification for Other than Full and Open Competition needed for the purchase order. But the librarian who asked for the subscription did know of the conflict, and the purchase orders at issue were approved without passing through some of the appropriate checks in the purchasing system.[88]

This purchase was the only allegation presented for consideration to the Office of the United States Attorney for the Western District of Pennsylvania for possible criminal prosecution. The Assistant U.S. Attorney declined to do so stating that it was not clear that Dr. Yu knew the proposed transaction was prohibited. The documentation made it clear that the librarians who prepared the purchase orders were aware of Dr. Yu's interest in E-Sun, yet proceeded to approve the order. Since Dr. Yu gave the agency a free year's subscription before seeking payment, he could not be shown to have "taken advantage" of the VA. In the end, "Without some evidence of unjust enrichment or fraudulent activity, a . . . prosecution of Dr. Yu is rendered more problematic by his long-standing international reputation . . . ." The criminal branch did, however, recommend that a civil recovery of the funds might be justified due to the conflict of interest.[89]

But the civil branch of the U.S. Attorney's office also declined prosecution. The Assistant U.S. Attorney doubted he could convince a judge or jury that Dr. Yu knowingly violated regulations and detailed the multiple failures of VA employees that allowed the

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[85] *IG Report*; pp. 5-6.
[86] *Ibid.*; p. 6.
[87] *Ibid.*; p. 3.
[88] *Ibid.*; pp. 3-5.
[89] Letter from Mary Beth Buchanan, United States Attorney, and Leo M. Dillon, Assistant U.S. Attorney, U.S. Department of Justice, Western District of Pennsylvania, Pittsburgh, Pennsylvania, to Jeffrey G. Hughes, Special Agent in Charge, Northeast Field Office, Office of the Inspector General, Department of Veterans Affairs. October 11, 2007.

transactions to proceed which would undercut the Government's case. He recommended additional training for VAPHS procurement and contracting employees.[90]

C. The Publications Review

VAPHS administrators now claim that their decision to destroy the SPL biospecimens was based on the fact that the specimens were not collected as part of an approved research protocol. This determination appears to be based on a review of Dr. Yu's publications conducted by the Research Compliance Committee staff.[91] Initially drafted by Research Compliance Officer Stacey Edick in the summer of 2006, it was redone by Education and Compliance Coordinator Barbara Strelec when Dr. Sonel asked for an update.[92]

Like all of the other investigations and reviews undertaken by the VAPHS concerning Dr. Yu, this audit raises more questions that it answers. The original drafters of the report attempted to compare Dr. Yu's publications with protocols approved by the Research and Development and IRB Committees. Ms. Strelec told Committee staff because it was difficult to be sure about whether the work represented human subjects research solely from the discussion of methods and data in the papers, she said that her revisions attempted to make the report "less conclusive."[93] Several things are clear, however: (1) the records of the R&D and IRB committees were incomplete and therefore not reliable as supporting documentation, but even this incomplete documentation indicated that some of the research was approved; and (2) and Dr. Yu was not given the opportunity to rebut the statements in the report in violation of the VAPHS' own guidelines.

According to the June 2005 policies for the Research Compliance Committee, Dr. Yu should have been afforded "...an opportunity to respond in writing to all instances of non-compliance uncovered during the course of an audit prior to consideration by the RCC. Investigators may refute audit findings."[94] Dr. Yu, who did not have a copy of the audit until it was provided to him by the Committee, maintains that he does indeed have documentation for all of his research.[95]

The publications chosen for audit were selected by searching the PubMed database[96] for Dr. Yu's name in articles appearing during the previous decade. All references other than journal manuscripts were removed from consideration. A total of 39 articles were reviewed by Ms.

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[90] Letter from Mary Beth Buchanan, United States Attorney, and Paul E. Skirtich, Assistant U.S. Attorney, U.S. Department of Justice, Western District of Pennsylvania, Pittsburgh, Pennsylvania, to Jeffrey G. Hughes, Special Agent in Charge, Northeast Field Office, Office of the Inspector General, Department of Veterans Affairs. February 5, 2008.

[91] The Board of Investigation recommended that "[t]he Research Compliance Office should conduct a thorough audit of all the records of the Special pathogens Laboratory and records of IRB and R/D committee approval and determine what approvals were necessary...." Cord, David P.. Memorandum to Michael E. Moreland. Subject: "BOARD OF INVESTIGATION." August 11, 2006; Recommendation 5 [p. 12]. However, the audit probably began before the delivery of the Board's report, as July 26, 2006 appears on some printouts.

[92] Committee staff interview with Barbara Strelec, July 10, 2008.

[93] Interview with Strelec, *supra.*

[94] Policies of the VA Pittsburgh Healthcare System Research Compliance Committee, June7, 2005; p. 6.

[95] Telephone communication with Dr. Yu, September 7, 2008. He also provided a "Response to Publication Audit," September 5, 2008.

[96] PubMed is a National Library of Medicine database with citations to articles in the scientific literature.

Strelec.[97] At the same time, the Coordinator for the IRB, Kathy Parks, reviewed all "IRB and R&D records", where Dr. Yu was listed as principal investigator, providing eight items (one of these was a study at the University of Pittsburgh). Ms. Strelec then attempted to match the published works with the research protocols. Ms. Strelec indicated to Committee staff that she was operating under a "hard deadline" of September 5, 2006, for completion of the audit.[98]

On September 8, Dr. Sonel forwarded an "updated draft" of the report, including "additional IRB documentation... from prior to 2001..." to Dr. Jain.[99] Dr. Sonel submitted the report in full to Dr. Jain on September 11. In his e-mail, Sonel states that Yu "...clearly has conducted human subjects review at VAPHS without prior approval from the IRB and/or R&D Committees on a number of occasions."[100] His comment is similar to Item 1 in Part IV, "Summary."[101] Ms. Strelec provided the Committee staff a copy of the audit as she submitted it on September 5, and denied being the author of the "Summary" in the September 11 version.[102] It is also interesting to note that a reference in the earlier version of the report noting that all discussion of data collection involved items before the enactment of the Health Insurance Portability and Accountability Act (HIPAA) [103] was removed in the later version sent to Dr. Jain.[104] HIPAA introduced significant changes in the regulations governing the oversight of research involving human subjects, and studies that were acceptable before HIPPA are now subject to more rigorous scrutiny.

From the documents submitted to the Subcommittee in response to Mr. Miller's requests, it is not possible to determine if the papers in the *Publication Audit* indeed represent research activities that were not considered by the VAPHS approval process. Indeed, not all of the protocol histories for Dr. Yu's 11 projects identified by Ms. Park were submitted by the Department to the Subcommittee. Of those that were provided, they show that Dr. Yu appeared to be complying with the requirements and was receiving appropriate reviews. It is not clear if the supporting documentation is in the correct files at VAPHS; the Publication Audit itself states that, "[i]t is uncertain if the VAPHS Office of Research is in possession of all pertinent research records due to the move from the University Drive facility in July 2005."[105]

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[97] Strelec, Barbara. Publication Audit, Human Research Protection Program, VA Pittsburgh Healthcare System. September 5, 2006; p. 1. Hereafter cited as *Strelec Audit.*

[98] Committee staff interview with Barbara Strelec, *supra.*

[99] E-mail from Sonel to Jain (cc: Strelec and Squeglia). Subject: "Dr. Yu Publication Audit." September 8, 2006 (5:08 PM).

[100] E-mail from Sonel to Jain (cc:Strelec and Squeglai). Subject: "RE: Dr. Yu Publication Audit." September 11, 2006 (12:51 PM).

[101] *Ibid.*; p. 19.

[102] Interview with Strelec, supra.

[103] *Strelec Audit*; p. 17.

[104] *Publication Audit*; p. 18.

[105] *Ibid.* For the protocol entitled "Various Studies Examining Treatment, Prevalence and Eradication of *Legionella*," there is a wide gap between the "initial review" by the R&D Committee on October 1, 1998, and the "continuing review" on January 25, 2006. At that last review, the R&D Committee voted 11-0 top continue the protocol and established the next review for December 11, 2006. The protocol history only reflects by dates on the "ITEMS REVIEWED" that the study had received expedited approval on December 12, 2005." VAPHS Protocol History. "Various Studies Examining Treatment, Prevalence and Eradication of *Legionella.*" Printed August 8, 2008. This document was submitted by the Department on August 22, 2008. Yet in their earlier submission of May 30, 2008, the Department submitted a Project Data Sheet for the same study. Attached there was a sheet entitled "Abstract," which shows "Last Update: 9/26/06." This sheet references "annual updates" for 2001 and 2002 that also do not appear in the protocol history. Project Data Sheet. Project Title" "Various Studies Examining Treatment, Prevalence and Eradication of *Legionella.*" Apparently printed September 26, 2006. Submitted by the Department of Veterans Affairs on May 30, 2008, Book 2, Tab 6B.

Dr. Stout, too, had one protocol related to the "Exposure Assessment for Community-Acquired Legionnaires' Disease." Initiated in 2001, the protocol history demonstrates regular reviews until its closure in 2003. Indeed, it is one case where biospecimens came up for discussion, as one of the IRB members argued that informed consent forms were required for sputum samples that would be coming to Pittsburgh for analysis (even though no identifiable patient information would be included).[106] While there is not enough information to be able to tell if any of the biospecimens destroyed on December 4 were collected under the terms of these protocols, there was no attempt to make such a determination.

[106] VAPHS Protocol History. "Exposure Assessment for Community-Acquired Legionnaires' Disease." Printed August 6, 2008; p. 8.

THE STATUS OF FEDERAL BIOBANKING POLICY

The SPL's biospecimen collection was an early version of a growing trend in medical and public health studies. According to the National Cancer Institute (NCI), "Human specimens... have emerged as a critical resource for basic and translational research in cancer as they are a direct source of molecular data from which targets for therapy, detection, and prevention are identified and molecular taxonomies of cancer are derived."[107] At the SPL, Dr. Yu devoted significant effort to correlating a particular sample to the medical history of its source,[108] and that merger offered valuable new insights into how to combat infections. These so-called "biobanks"[109] are a growing trend in biomedical research, and the federal government is likely to find itself with increasing investments in such projects. The destruction of the SPL collection, however, demonstrates how quickly such investments can be lost without a strong policy framework.

Proper management of a scientific collection requires more than drawing a blood sample, writing the patient's name on the vial, and placing it in a freezer. Yet the Committee staff has not been able to find fully developed collections management policies.[110] In response to the Subcommittee's first document request to the Department for its policies,[111] the only two relevant documents dealt with assuring that donors give appropriate informed consent, not the maintenance or disposition of the collection.[112]

No mention of a policy for dealing with collection disposal emerged during staff interviews with VAPHS staff, although Dr. Sonel referred to one in his e-mails.[113] Recently, however, the Subcommittee staff found a VA document entitled "Banking of Human Research Subjects' Specimens."[114] The Directive makes it VA policy that "...human biological specimens,

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[107] *National Cancer Institute Best Practices for Biospecimen Resources*, National Cancer Institute [Bethesda, Maryland: National Institutes of Health]. June 2007, p. 1. [Hereinafter cited as *NCI Best Practices*]

[108] "Critical to the success of biorepositories is the clinical annotation of tissue and serum specimens. The annotation of these biospecimens with clinical data - disease staging, severity, progression, treatment and outcomes measures - heightens their value in translational research, particularly, in biomarker discovery." Reis, Steven E. *et al.* "Clinical and Translational Science Award Proposal." University of Pittsburgh. March 2006, p. 116. Accessed August 28, 2008 at https://www.ctnbestpractices.org/networks/nih-ctsa-awardees/university-of-pittsburgh-pittsburgh-pa/preview_popup/file.

[109] "Biobank" is the term applied to a research activity where "...data originating from microorganisms are linked with human clinical information with the ultimate aim of improving healthcare by increasing the quality of biomedical research." De Paoli, Paolo. "Future of Biobanking in Microbiology for Medical Research," *Future Microbiology* (2008) 3(1); p. 79.

[110] The Smithsonian Institution's policy considers "...the deliberate development, maintenance, preservation, documentation, use, and disposition of collections." "Collections Management," Directive 600 [Washington: Smithsonian Institution]. October 26, 2001; p. 1.

[111] Letter from Rep. Brad Miller, Chairman, Subcommittee on Investigations and Oversight; to Secretary of Veterans Affairs James Peake. May 13, 2008; p. 4.

[112] It is, of course, vital that it be carried out properly: "...[W]hen sourced bio-repositories consist of samples, which are badly collected, processed, stored or annotated, the end result of a complete experiment based on these samples can be of no better quality, despite the sophisticated techniques or analytical method chosen to perform the research." Ringman, P.H.J.; Dinjens, W.N.M and Oosterhuis, J.W.. "Biobanking for Interdisciplinary Clinical Research," *Pathobiology* (2007) 74, p. 239. Careful attention to obtaining *informed* consent is also required.

[113] Dr. Fred DeRubertis, the vice president of the medical service specialty line, stated in his interview that he did not know of Dr. Yu's collection. Committee Staff interview, July 11, 2008. See also the discussion regarding the role of the Research Compliance Committee in considering collection disposition earlier in this report.

[114] VHA Directive 2000-043. November 6, 2000. Accessed September 3, 2006, at http://www.vbri.org/Research/documents/TissueBanking.pdf. The Directive states that it was to expire on October 30, 2005. Yet the Standard Operating Procedures for the VAPHS Subcommittee on Human Studies, approved January 18, 2005 and November

as well as the linked clinical data collected as part of research projects conducted by VA investigators in VA facilities or approved off-site locations, are maintained at VA approved tissue banks."[115] Existing research protocols were to be brought into compliance during required IRB continuing reviews.[116] A later Directive that apparently replaced the 2000 statement states that research protocols and consent forms had to explicitly detail "...all potential use/disposition of collected specimens," and collection and banking activities were specifically assigned to the jurisdiction of the IRB and the R&D Committee at the hosting VA facility.[117] The staff reviewed the minutes from the VAPHS Subcommittee on Human Studies (the IRB) and protocol histories detailing the consideration of research protocols that might be associated with the biospecimens stored in the SPL. There is no indication that the IRB applied this policy. Dr. Stout told the Committee staff that she was never made aware of these requirements when her *legionella* protocol came up for its required continuing review in 2005.[118] This policy appears to fill much of the vacuum that contributed to the loss of the *legionella* collection. The Department has been asked to determine whether the Directive remains in force.

The National Institutes of Health, another agency with large biospecimen collections[119], appears to be the most advanced in developing protocols for biobanks. The Deputy Director for Intramural Research issued an interim memorandum making discussion of the expected collection strategy, use and proposed disposition a required element for any research protocol contemplating the use of biospecimens.[120] An ad hoc Science Directors Subcommittee on Biorepository Practices and Guidelines was established and charged to study the state of biospecimen management at NIH.[121] Their new "Guidelines for Human Biospecimen Storage and Tracking within the NIH Intramural Research Program" were approved by the NIH Steering Committee on June 7, 2008.[122]

NIH drew from the experience of the National Cancer Institute (NCI), which began its own evaluation in 2002. The Institute sought out best practices in biospecimen management. It published the results from this work in June 2007, seeking to "...establish and document transparent policies governing the retention of biospecimens, data, and records pertaining to informed consent and the identity of research participants...."[123] NCI's guidelines recommend open and transparent policies for biospecimen retention, establishing points during the study to review the collection, and that biospecimens be advertised for transfer to other institutions if they

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14, 2007, both make reference to this Directive. It was not submitted to the Subcommittee by the Veterans Administration in response to Chairman Miller's request for documents.. It does not appear on the Department website publications section.

[115] *Ibid.*; p. 1.

[116] *Ibid.*; p. 2 (Section 4b).

[117] VHA Directive 1200. "Banking of Human Biological Specimens Collected From Veterans for Research." Veterans Health Administration, Department of Veterans Affairs, Washington, D.C. March 31, 2003; pp. 1-3. See Sections 2(b) and 3(h). The Directive indicates it was to be recertified at the end of March 2006.

[118] Telephone interview with Dr. Stout, September 3, 2006.

[119] Dr. Michael Gottesman, Deputy Director for Intramural Research at NIH, said that a survey of NIH biospecimen collection undertaken at the outset of the review identified some 23 million biospecimens in total. The number is expected to rise to 30 million. Telephone interview, July 31, 2008.

[120] Gottesman, Michael. Memorandum to Clinical Research Protocol Principal Investigators, Clinical Research Protocol Associate Investigators and NIH IRB Chairs. Subject: "Research Use of Stored Human Samples, Specimens or Data." June 12, 2006. Accessed September 4, 2008 from http://ohsr.od.nih.gov/info/pdf/DDIRmemorandum.pdf.

[121] Minutes of the Human Subjects Research Advisory Committee, National Institutes of Health. March 9, 2007; pp. 4-5.

[122] Attachment to E-Mail from Gemma Flamberg, Senior Legislative Analyst, National Institutes of Health, Department of Health and Human Services. Subject: "biospecimen policy." July 31, 2008 (2:38 PM).

[123] *NCI Best Practices*, Section C.1.3, p. 16.

can no longer be maintained by the original host institution or if there is no further interest in using the materials there. For biospecimens used in research, the guidelines state "...permanent storage generally is preferred...."[124]

At the Centers for Disease Control and Prevention (CDC), informal discussions regularly take place in the various laboratories to decide what to do with biospecimens left behind when a researcher retires.[125] CDC tends to retain all biospecimens it collects unless it has duplicates; that led to the decision to build a central repository for collections that would require long-term storage.[126]

How did other policies address the situation represented by the SPL collection? The NCI Best Practices include a "Principle for Responsible Custodianship," which includes advertising the availability of those biospecimens that are no longer needed for research or that a facility cannot maintain.[127] CDC's Dr. Nicholson indicated that collections identified as valuable would not be destroyed.[128] Collections in its central repository are reviewed annually; transfer to other CDC collections or other institutions must be offered before disposal.[129] Similar processes were described in policies from other scientific disciplines, such as the Smithsonian Institution's National Museum of Natural History,[130] the National Plant Germplasm System of the Department of Agriculture[131] and the United States Botanic Garden:[132] Dr. Sonel believed that this peer review should have been exercised by the Research Compliance Committee in the case of the SPL collection. But in the end, it was Dr. Melhem who made the decision.

Four years ago, the Office of Science and Technology Policy (OSTP) convened a working group on agency scientific collections. Because the group's remit covered a diverse set of collections (NASA's lunar samples, NIH's biospecimens and reagents, historical artifacts at the National Park Service), its recommendations will be broad and general.[133] The Committee staff recommends that OSTP be tasked to develop a focused policy for biospecimen collection management, building on the work that has already been done. Biobanking cannot succeed if its basic policy structure is honored more in the breach than the observance.

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[124] NCI Best Practices; p. 16 (Sections C.1.2 and C.1.3).

[125] Telephone interview with Dr. Barry Fields, *Legionella* Lab Chief, Centers for Disease Control and Prevention, Atlanta, Georgia. August 1, 2008.

[126] Telephone interview with Dr. Janet Nicholson, Senior Advisor for Lab Science, Coordinating Center, Center for Disease Control and Prevention, Atlanta, Georgia.

[127] *Ibid.*

[128] *Ibid.*

[129] *CDC and ATSDR Specimen and Data Bank Policy.* Office of the Chief Science Officer, Office of the Director, Centers for Disease Control and Prevention. CDC-GA-1999-02. December 1999; p. 11.

[130] Smithsonian Institution Directive 600, *loc. cit.*; p. 14.

[131] *Manual of Procedures for the National Plant Germplasm System*, Agricultural Research Service, Department of Agriculture. June 2005; pp. 17-18.

[132] *Collections Management Plan and Curatorial Policies for the United States Botanic Garden*, Washington, D.C.. August 30, 2007; pp. 11-15. See Section 3.3 for policies on deaccessioning.

[133] Telephone interview with Dr. Jim Vaught, July 29, 2008. According to the co-chair, Scott Miller of the Smithsonian Institution, the group is trying to complete the draft of its report to transmit to the member agencies for review and comment. Telephone interview with Scott Miller, July 21, 2008.

CONCLUSION

The deliberate and secret destruction of a biospecimen collection that has been used to advance the detection and treatment of infectious diseases with significant mortality rates is a great loss, not only to the researchers who so carefully compiled it, but to the future patients who will not have the benefit of continuing research. It is a particular travesty because it was done by a federal health agency charged with protecting the health of our nation's veterans, and it appears to have been driven by nothing more than petty personality conflicts.

In the future, such action should never be taken again. Personality conflicts should have no role in managing federal programs, in our health care systems or in decisions to maintain biospecimen collections. Hopefully, the Veterans Affairs Department will finally take the necessary steps to make sure that it doesn't happen again.