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Closeout for M93110057

This case was brought to OIG's attention by institution officials. We were informed that the institution[1] had completed an inquiry into allegations against a faculty member[2] in connection with the conduct of his biohazardous research. We deferred our investigation until the institution had completed its investigation and adjudication and resolved the subsequent appeal, grievance, and arbitration. We then initiated our own investigation and concluded that both the institution and the faculty member failed to act responsibly in the conduct and oversight of the biohazardous research. However, because of the circumstances in which these failures occurred, we ultimately concluded that neither the faculty member nor the institution committed misconduct in science.

The attached investigation report and letters from the National Science Foundation to the faculty member and institution officials constitute the closeout for this case.

cc: Investigations, IG

[1] [redacted]

[2] Dr. [redacted], a faculty member in the Department [redacted] at the institution.

M93-57

NATIONAL SCIENCE FOUNDATION
4201 WILSON BOULEVARD
ARLINGTON, VIRGINIA 22230

nsf

OFFICE OF THE
GENERAL COUNSEL

July 10, 2000

[redacted]
General Counsel
Office of the General Counsel
[redacted] University
[redacted]

RE: OIG Case M93110057

Dear Mr. [redacted]

Thank you for your response dated June 27, 2000. The agency has reviewed the Office of the Inspector General's final report, submissions filed by [redacted] University and submissions by Dr. [redacted] While there is no finding of misconduct in science against the University, questions remain concerning the effectiveness of the oversight structure of biohazardous research at [redacted] University. After careful review of all the relevant reports and documentation, particularly the documentation concerning the viability and operations of the biosafety committee during the past year, the National Science Foundation (NSF) has decided to take the following remedial actions concerning the University:

1. [redacted] University is required to submit supporting documentation with any proposal sent to NSF relating to biohazardous research. That documentation must include (a) a statement of whether the research was required to be reviewed by [redacted]'s biosafety committee (b) documents evidencing the biosafety committee's approval of the proposed research agenda and (c) documents evidencing the biosafety committee's rationale for its approval for the particular proposal. In this regard, NSF's Division of Grants and Agreements will monitor internally your compliance with this action.

Telephone (703) 306-1060 FAX (703) 306-0149

2. The University must reimburse NSF for $5,000 in REU funds that were not spent as intended. Accordingly, please send a check made payable to:

National Science Foundation
Attn: Cashier, Room 295N
Division of Administrative Services
4201 Wilson Boulevard
Arlington, VA 22230

These remedial actions will be in effect for 3 years from the date of this letter. Please advise the appropriate University departments and officials effected by this action. Thank you for your continued cooperation.

Sincerely,

[redacted]

Assistant General Counsel

cc: Dr. [redacted]
DFM

NATIONAL SCIENCE FOUNDATION
4201 WILSON BOULEVARD
ARLINGTON, VIRGINIA 22230

nsf

OFFICE OF THE
GENERAL COUNSEL

July 10, 2000

[redacted] University
Department of [redacted]

REF: OIG M93110057

Dear Dr. [redacted]

Thank you for your response dated June 8, 2000. The agency has reviewed the Office of the Inspector General's final report, submissions filed by [redacted] University and your submissions. While we make no finding of misconduct in science against you, the National Science Foundation (NSF) has decided to take the following remedial actions to ensure that any NSF-funded biohazardous research is conducted in a safe manner:

1. You are required, in connection with any NSF-supported biohazardous research, to submit copies of any representations or promises you have made in order to obtain biohazardous materials. Accompanying these documents should be a detailed description of your efforts to comply with those representations. These materials should be sent to the NSF program supporting your research.

2. You are required, in connection with any NSF-supported biohazardous research, to submit documentation establishing that your biohazardous research has obtained any necessary approvals and authorizations through either the University's biosafety committee or any other entity whose approval or authorization is required. Further, documentation establishing that the hazardous nature of the research has been sufficiently posted and the appropriate individuals notified of the nature of the hazards involved in the research is also required.

Telephone (703) 306-1060 FAX (703) 306-0149

NSF's Division of Grants and Agreements will monitor internally your compliance with these actions. These remedial actions will be in effect for 3 years form the date of this letter.

Thank you for your continued cooperation.

Sincerely,

[redacted]

Assistant General Counsel

cc: Mr. [redacted]
Office of the General Counsel
DFM

Confidential

Office of Inspector General

Investigation Report

OIG Case M93110057
Part I of IV

August 2, 1999

REPORT OF AN INVESTIGATION INTO ALLEGATIONS OF MISCONDUCT IN SCIENCE

SUMMARY

The Office of Inspector General (OIG) at the National Science Foundation (NSF) has determined that both the subject of this case and his University did not act responsibly in the conduct and oversight, respectively, of biohazardous research. Because of the circumstances described in this report, we concluded that neither the subject nor the University committed misconduct in science. Nonetheless, we have recommended remedial steps that we believe are necessary to protect public safety and to ensure that the circumstances of this case do not arise again.

We concluded that the University did not establish, or operate with, an adequate oversight structure for biohazardous research. Although responsible University officials were aware of the nature of the subject's research for 3 years, the University did not review it or provide responsible oversight. We also concluded that the University's HIV Investigation Committee did not follow up on the University Inquiry Report's findings about the University or attempt to resolve conflicting information pertinent to the case provided by the subject and University administrators. We recommend that NSF take the following remedial actions concerning the University:

1. Send the University a letter describing its expectations for the safe conduct of biohazardous research and the need for effective oversight of potentially dangerous research by competent university administrators.

2. Require the University to ensure that its review and oversight procedures are consistent with those of other institutions. To accomplish this, the University should consult with and seek the advice of other institutions' committees or administrations that have successful safety processes and review and approval procedures. The University should submit a report on its efforts to NSF, and provide a copy to NSF's Office of Inspector General. The report should include descriptions of its processes for ensuring and providing oversight and review. It should describe the qualifications of the administrators and committee members appointed to manage these processes. NSF should determine whether the report adequately addressed the problems described in this report and whether the University's plan and personnel can adequately protect public safety.

   Until the report is approved by NSF, NSF should require the University to submit documentation with any proposal submitted to NSF that describes whether the project

was required to be reviewed by a safety committee, and, if required, shows that the project has been approved by that committee. Copies of the documentation and approvals (and the rationale for the approvals) are to be submitted to NSF with copies to NSF's Office of Inspector General.

Alternatively, if the University determines that the magnitude of the required remedial effort is disproportionate to the funding the University receives for biohazardous research, the University may decide that it is not cost effective to comply with the requirements specified above to conform with federal expectations for safely conducting biohazardous research. If the University decides that it is unable or unwilling to comply with these requirements, the University should immediately: (a) inform NSF of its decision; (b) cease conducting biohazardous research; and (c) no longer apply for further federal funding in this area.

3. Require the University to reimburse NSF for $5,000 in REU funds that were not spent as intended.

We also concluded that the subject violated the commitments he made in order to obtain biohazardous materials. We recommend that NSF take the following actions with regard to the subject to ensure that his biohazardous research is conducted in a manner that protects public safety and ensures University oversight:

1. Send the subject a letter describing NSF's expectations for the safe conduct of biohazardous research and the need for coordinating potentially dangerous research with university administrators. NSF should explain that, had the subject committed the same acts at a university with responsible oversight, it would consider his actions to be misconduct in science.

2. Require that, in connection with any NSF-supported activity, the subject submit copies of any representations or promises he has made in order to obtain biohazardous materials. He should accompany those documents with a written description of his plan for complying with them. These materials should be sent to the NSF program supporting the subject's research, with copies provided to NSF's Office of Inspector General.

3. Require as part of the conditions of any NSF-supported activity, that the subject describe, in every progress report, the steps he has taken, and will continue to take, to ensure that proper notification of his research and its hazard potential is posted, and that his research has received the proper oversight. This requirement should be in effect for 3 years from the final disposition of this case.

Background

Dr. [redacted] (the subject) is a tenured professor in the Department of [redacted] [redacted] University (the University), in [redacted] Since his arrival in 1989, he has received funding for numerous research efforts from the University, contracts transferred from his former institution, and from NSF. NSF award [redacted] and the supplements to that award provided the federal support for the research that was the focus of this investigation. While conducting research pursuant to this grant, the subject used various human bloodborne pathogens in a multi-user facility located within the University's biology department. Faculty, students, and research technicians used the facility. Its access was not generally restricted.

In February 1993, in connection with an application to an internal funding committee, questions were raised within the University as to the propriety of the subject's use of this facility and whether his use of it had been properly disclosed to, and reviewed and approved by, the University. Questions were also raised as to whether other facility users were exposed to bloodborne pathogens, including Human Immunodeficiency Virus (HIV), without their knowledge.

Since at least 1988, NSF has instructed grantee institutions that they "have full responsibility for the conduct of" research conducted with NSF funds.[1] There are four primary sources of guidance for the conduct of recombinant DNA and biohazardous research in connection with NSF-supported research: the *National Institutes of Health (NIH) Guidelines for the Conduct of Recombinant DNA Research*,[2] the *Center for Disease Control (CDC)-NIH Biosafety in Microbiological and Biomedical Laboratories*,[3] the *Occupational Safety and Health Administration (OSHA) Occupational Safety and Health Standards*,[4] and NSF's *Grant General Conditions (GC-1)*.[5] This case is characterized by a lack of awareness of and compliance with the guidelines and information in these documents by the University, and the subject's disregard for his own commitments to ensure proper oversight of his research.

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[1] NSF Grant General Conditions (*GC-1*, 10/88), Art. 1(a). The award letter notes the applicability of the *GC-1*, see Tab 28.

[2] 51 Fed. Reg. 16,958 (1986). A summary of the relevant *Guidelines* is provided in Appendix 1.

[3] Department of Health and Human Services Publication No. (NIH) 88-8395, 2d Ed. (May 1988).

[4] 29 C.F.R. § 1910 (1992).

[5] NSF *GC-1*, 10/88, Art. 1(a), Art. 28.

The University's Inquiry and Investigation

The Inquiry

In March 1993, the University began an inquiry into the subject's use of HIV.[6] The August 1993 Inquiry Report made recommendations with regard to the subject and the University, and suggested systemic reforms in the University's research review and approval procedures.[7] The University decided that "the initial inquiry was not adequate" and that there should be "a full investigation of this matter."[8] On 25 October 1993, nearly a month after the University began its investigation, the inquiry committee submitted an addendum to its report citing "new" allegations and "new data"; the committee said that, if it had known about the new allegations and data at the time, it would have recommended "further investigation of possible misconduct" by the subject.[9]

The HIV Investigation

On 1 October 1993 the University convened the "HIV Investigation Committee" "to investigate allegations of improper laboratory procedures against" the subject.[10,11]

After extended deliberations, the Committee found by a preponderance of the evidence that the subject was responsible for:

1. Failure to obtain proper authorization to acquire and/or use certain biohazardous materials. Specifically, these charges refer to an unauthorized signing of a Material Transfer Agreement to obtain [Simian Immunodeficiency Virus (SIV)], use of a recombinant DNA HIV plasmid without [Biosafety Committee (BSC)] approval, and failure to report 1993 use of polio virus and SIV to the [University] Occupational Safety and Health Administration (OSHA) Coordinator;

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[6] 16 March 1993 memo from the Associate Vice President for Academic Affairs to the subject. The inquiry was initially based on a mistaken belief that the subject's work with HIV was supported by NIH. Even though there are no significant differences in the purpose of inquiries conducted pursuant to the misconduct regulations applicable to NIH and NSF grants, the University terminated the "NIH inquiry" on 20 April 1993 but "continue[d] to pursue the matter" and eventually began an investigation. *See* Inquiry Report, Tab 1, p. 1.

[7] *See* Tab 1.

[8] 28 October 1993 memorandum from the Vice President to [redacted] President, University Chapter of AAUP. This investigation was conducted pursuant to NSF's misconduct-in-science regulation, *see* p. i, HIV Investigation Report.

[9] Addendum to HIV Inquiry Report, 25 October 1993, p. 2.

[10] The original complaint was filed by [redacted] Associate Professor of Biological Sciences, on 28 September 1993. [redacted] Professor of Chemistry, also submitted a written complaint on 5 November 1993, at the request of the Chairman of the HIV Investigation Committee. On 16 November 1993, Dr. [redacted] rofessor of Chemistry, Director of the Institute for Biochemistry) provided a written offer of evidence and allegations.

[11] HIV Investigation Report, p. 1. The Report, including the specific allegations, is at Tab 2.

2. Failure to adhere to guidelines recommended by the Centers for Disease Control with regard to experiments carried out with infectious SIV and infectious HIV; and

3. Failure to respond promptly and providing misleading information in response to the University's requests for information concerning use of infectious HIV. Specifically, this charge refers to lying to the [University Biosafety Committee] on February 18, 1993 by denying past use of HIV.[12]

Unlike the Inquiry Report, the HIV Investigation Report placed responsibility for the events upon the subject. The University president[13] accepted the HIV Investigation report and took disciplinary action against the subject, including suspending him without pay and prohibiting him from conducting research or applying for any research funds.[14]

Remarkably, while the HIV Investigation Report discussed systemic problems in the University's research oversight procedures that were also raised in the Inquiry Report, it recommended no action.[15] Although the University took certain steps designed to address the deficiencies in its oversight process, it did not take action to address the performance of those administrators responsible for those deficiencies. Had these administrators executed their responsibilities competently, it is doubtful this case would have arisen—yet one of these same administrators still retains responsibility for these processes.[16]

The subject disputed the findings and actions against him, and pursuant to his rights, sought a determination by an arbitrator. The arbitrator held a full factual hearing at which both sides presented witnesses. The subject's counsel (provided by the American Association of University Professors) provided evidence and expert witnesses on biosafety that the counsel for the University neither effectively cross-examined nor countered with other witnesses.

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[12] HIV Investigation Report, p. iii.

[13] Dr. [redacted] The current president is Dr. [redacted] When he was Vice President, he convened the inquiry and investigation committees, received the reports, and recommended the actions that Dr. [redacted] ultimately took against the subject.

[14] *See* Tab 2, 9 November 1994 letter from the University president to the subject that lists the sanctions imposed on him.

[15] In its response to the draft report (Tab 32, p. 5-6), the University said accurately that it had not charged the Committee with investigating "the University or the Administration. . . . [T]he deficiencies of the administration with regard to biosafety review were pointed out throughout the Committee's report. It was left to the administration and /or the NSF to decide what should be done with this information." It is remarkable that, despite the recommendations in its Inquiry Report and the comments in its Investigation Report, the University took only limited action to correct systemic administrative lapses. It is clear from its response that, even now, several years after these events, it is just beginning to implement critical safeguards. We believe its actions reinforce the need for NSF to ensure the University's responsible management of its oversight process.

[16] The Environmental Health and Safety Director. The Director of ORAD resigned in June 1998 and is currently the Dean of the [redacted] at [redacted] niversity. His replacement was chosen from within the University. (Tab 32, p. 2). The Vice Provost for Academic Affairs retired in January 1997.

The arbitrator concluded that the evidence did not support the first allegation, and that the subject's action with regard to the second allegation did not constitute professional misconduct. He did agree that the subject had not provided prompt and clear information about his research. Because he concluded that the University-imposed sanctions were "grossly disproportionate to his infraction,"[17] in June 1996 he ordered the University to

> rescind the discipline issued to the [subject] . . . and compensate him for pay and other benefits lost as a result of his suspension. The University may, instead issue [the subject] a written reprimand for his failure to respond promptly to requests from the [BSC] and other University employees inquiring into his use of infectious HIV.[18]

OIG's Investigation

After the arbitration was completed, OIG reviewed the case. We concluded that the subject's conduct could not be understood without first evaluating the University's oversight procedures. Because the propriety of the subject's actions turns in part on the adequacy of the University's procedures and the actions of University administrators—which the University's investigation addressed only tangentially—we concluded the University could not investigate these matters impartially and we began our own investigation, which included interviews at the University[19] and review of relevant documentation.

We determined that:

1. the University did not discharge its research oversight duties in order to ensure that procedures for review of proposals and research projects were established, disseminated to the appropriate parties, and followed; and

2. the subject did not uphold the commitments he made in order to obtain biohazardous materials and to conduct the research, despite committing to do so.

Because the subject's behavior can only be understood in the context of the University's research oversight structure, we will address that structure in the first part of this report. Our discussion includes instances which, though not directly related to NSF funding, demonstrate that the University's oversight efforts were deficient overall. The second part of this report describes how the subject, in order to obtain deadly pathogens for his NSF-funded research,

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[17] [redacted] The Arbitration Opinion is at Tab 3.

[18] *Id.* at p. 90.

[19] The statements of 17 individuals interviewed by OIG in this case are arranged alphabetically at Tabs 4-22. All October 1996 affidavits referenced in this report are in the form of interview notes taken by OIG, which were reviewed, revised by the witness as he or she felt was necessary, and adopted under oath by the witness as a true, accurate, and complete summary of the interview.

made express commitments to undertake his research in a manner consistent with certain guidelines and standards, which he knew was impossible in the context of the University's deficient oversight structure. Again, we have included discussion of instances not directly related to NSF funding that we believe supports our conclusion about the subject's actions.

The report sets out a summary of the relevant events; examples and quotations illustrating these points are in the accompanying appendices and supporting documentation is found in the tabs attached to the report. While we ultimately conclude that neither the University's nor the subject's conduct in the extant regulatory environment at the University are misconduct in science, we recommend certain remedial actions which we believe should be taken to protect public safety.

University Guidance and Oversight

At the time the subject was submitting the proposals that form the basis for the University's investigation of the subject, the University required that the *Approval of Application for External Grant or Contract* form (the "*Form*") accompany all external proposals as they were circulated internally for approval by University officials. The *Form* required the applicant to declare whether the project involved radioactive materials, research on human subjects or animals, or recombinant DNA (rDNA). A University administrator was to ensure that review and approval were obtained, and that administrator was then to provide a "date of approval" on the *Form*. The *Form* required signatures from the department chairperson, dean, and a grants administrator, "prior to proposal approval by the Director" of the [redacted]—who, in this case, was also the University's Authorized Organizational Representative (AOR). Only after receiving these approvals was the applicant permitted to submit an external application.[20]

Unfortunately, the University publications that explained the oversight process, *A Manual for Externally Funded Projects* (the *Manual*) and the *Research Bulletins* (the *Bulletin*) initially failed to state the University's oversight role clearly, and in later editions mischaracterized it. Specifically, the publications asserted that the PI bore ultimate responsibility for compliance with internal and external oversight requirements. This conflicts with NSF's standard grant conditions described in the *GC-1*, which place ultimate oversight responsibility on the institution.[21,22]

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[20] *See* Tabs 27 and 28 for examples of these *Forms*.

[21] *See* Appendix 2.

[22] The chairman of the Biological Sciences Department shared a similar misconception as recently as May 1997, when he asserted that "he is not an expert in biosafety, and ultimate responsibility rests with the PI." Minutes of BSC Meeting, 29 May 1997, p. 1. However, we are encouraged by the University's current *Biosafety Manual* and *Mission and the Responsible Conduct of Research, Scholarly Activity and Education,* which state that department "chairs are responsible for being knowledgeable about government, university, and sponsor regulations pertinent to work carried out within their departments and for overseeing adherence to these requirements by faculty, staff and students." We believe that our recommendations provide the University an opportunity to demonstrate that its

The Biosafety Committee

Biosafety Committee Function and Structure

The BSC is the oversight committee to which the University assigned rDNA, and subsequently biosafety, oversight functions. We found a disparity of opinions among faculty, BSC members, and University administrators as to what the BSC was, what the scope of its responsibilities were, and what procedures applied to biohazardous materials research. We concluded that the University did not establish and maintain a clear and effective review and approval structure for either rDNA or biohazardous research.[23] Further, at the time of our visit 4 years after the actions by the subject that are the focus of this case, we found that the BSC was still incapable of performing the duties delegated to it by the University in a manner that inspired confidence. Because of its erratic execution of its oversight responsibilities, the University did not provide consistent guidance about its oversight requirements.

Officially, the BSC reviewed only rDNA research until December 1991, when the Vice Provost, prompted by a review of the subject's efforts to obtain biohazardous agents, asked it, and it began to take steps to, cover biohazardous issues. The Director of ORAD said that, in 1986, the BSC had unofficially broadened its authority beyond rDNA to review experiments with certain infectious agents[24]—and while some faculty began to occasionally bring biohazards issues to the BSC, others were unaware of the intended official expansion of the BSC's authority as late as 1993.

For example, the Director of ORAD, who is responsible for BSC oversight, told us that in his view the most "charitable" way to view the University's inconsistent approach to the oversight of hazardous research was to keep in mind that it was a small University, and as it was growing the regulatory environment was changing. The University's staff did not make it their job to keep up with the changes, instead relying upon "collegiality" and "trust and informal discussion." The Director of ORAD pointed out that the "least charitable" way to interpret the University's conduct was to observe that there were "lots of people asleep at the switch." The Director of ORAD made no effort to defend his inattention and inaction, merely observing that he "was there when it came to a head; no one else was willing to take on this task."[25]

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administrators can ensure responsible oversight and are encouraged by its statement in its response that it "is aware of and striving to comply with the NSF Guidelines described in GC-1 . . . ." (Tab 32, p. 3)

[23] Our review of the 1989-1992 committee rosters showed that the committee composition did not meet *Guidelines* specifications (it did not have a community representation). The community representative from 1993-1996 was a University faculty member, an affiliation that the *Guidelines* identify as a disqualifying conflict of interests. *NIH Guidelines for the Conduct of Recombinant DNA Research,* 51 Fed. Reg. *IV-B-2-a* (p.16962) (1988).

[24] *See* Appendix 3.

[25] Tab 14, Notes of 15 October 1996 OIG interview with the Director of ORAD, p. 3.

During the University's investigation, the Director of ORAD explained that

> the problem we have at [the University] is an institutional history of imprecision and informality with regard to compliance with federal regulations. . . . At institutions like [this], because its use of these materials has been relatively low, [it] hasn't been forced to do that but now we are being forced both by internal circumstances and external demands for this activity.[26]

In the course of our investigation, we encountered an astonishing variety of views of the role of the BSC and of oversight responsibilities.[27] We have concluded that the University had no clear, effective oversight structure for identifying, reviewing, and approving research involving biohazardous materials, and its faculty (including BSC members) were unevenly aware of the committee's role or any expansion of it beyond rDNA issues.

Expansion of the BSC's Oversight Role

In a December 1991 memo to the Director of ORAD,[28] the Vice Provost expressed "the need for us to develop policies and procedures in the biosafety area." He instructed the Director of ORAD and the BSC to develop "procedures for handling biological materials with potential health risks that will provide the University with assurances that such procedures, when executed properly, are the safest possible as recognized by the national or international scientific community at large." He specified that "prior review and approval by the BSC" should be part of the procedures. He requested a response by 1 March 1992 "so that we may have a policy in place by the end of the Winter 1992 semester."[29]

In response, the BSC assigned information collection tasks to various members. The BSC met with the subject, whose notes indicate that he explicitly described his work with biohazardous materials and use of a "P-2 facility."[30] At its request, the subject prepared and

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[26] 22 November 1993 testimony of the Director of ORAD to the HIV Investigation Committee, pp. 33-34. He also said, "I wasn't expecting to spend very much time or be directly involved [in biosafety] and that was explicit with conversations that I had between me and [the Vice Provost], that I was not going to be, for example, the RSO at this institution. I was leaving a place to get away from these responsibilities." *Id.* at 34. We are troubled by this statement, which appears to indicate that even at the time he sought the University position, the Director of ORAD was uninterested in actually performing the oversight duties inherent in it.

[27] See Appendix 3.

[28] *See* Tab 23.

[29] *Id.*

[30] P-2 is a biosafety level (BSL);. *see* Appendix 5 for an explanation of BSLs and a description about the BSC's confused understanding of BSLs. *See* Appendix 4 for a further description of the subject's meeting with the BSC, and the BSC's abortive attempt to create new biosafety guidelines. The subject claimed in his second response that this invitation demonstrated his "concerns and [his] efforts to assist the university to ensure biosafety in biohazardous research." (Tab 34, p. 1.) In fact, he knew the university did not substantively respond to the circulation of the draft and it made no active effort to provide oversight. (Tab 2, pp. 9-11, 69.) The subject said the University "agreed with the use of room 304D for the HIV/SIV research project and made the recommendation for [the University] to sign the contract for acquiring biohazardous material warranting BSL2

distributed to BSC members two successive versions of a biosafety manual. Further, in an 18 February 1992 memo to the faculty, the Director of ORAD requested "information on [faculty] use of materials which are either biohazards or have the potential for becoming biohazards in teaching or research at" the University.

However, on the same day the Director of ORAD issued his memo, Nuclear Regulatory Commission (NRC) inspectors appeared on campus, and that "afternoon and evening [the Science Liaison Officer (SLO)[31] and Director of ORAD] began to have to respond to the NRC inspectors."[32] Within days, and at the request of the SLO and the Vice Provost, the Director of ORAD became the chairman of the BSC, to free up the SLO's time. The Director of ORAD said that he took on this responsibility despite knowing that "the radiation problem was going to just prevent me from doing anything with regard to biosafety. I was going to have no time."[33] The Director of ORAD said that the few responses he received "were put in a file on my desk and they just weren't, frankly were not paid attention to for quite a period of time."[34]

Thus, due to the "NRC Crisis," the BSC, which was ineffectual before February 1992, effectively ceased operations altogether and did not meet again for a full year. The BSC was reconvened to deal with the allegations against the subject, involving activities that to a great extent occurred during the BSC's self-imposed hiatus.[35]

In September 1993, the Director of ORAD, as Chair of the BSC, broadly circulated a memo to the University faculty and administrators requesting essentially the same information as the February 1992 memo. He received 16 responses from the faculty. We believe that this response, when compared to the 6 responses[36] he had received one year earlier, is indicative

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precautions." However, 10, 17, and 19 December 1991 memos from University officials clearly state its understanding that he was seeking "transformed but non-infected cells." The University's materials do not show that it was aware that he would eventually purchase SIV and HIV. *See* **The Subject's Acquisition and Use of Biohazardous Materials.**

[31] Dr. [redacted]

[32] 22 November 1993 testimony of the Director of ORAD to the HIV Investigation Committee, p. 30.

[33] *Id.* at 31. This inspection ultimately resulted in a civil financial penalty against the University. (Despite knowing he had "no time," he did not appoint a substitute for other oversight duties and no biosafety committee members took action to assure coverage of these duties—it is unclear how his replacement can or will distinguish himself from the past patterns and practices at this University. *See* Appendix 6 for a description of the "NRC Crisis" and its effect on the ability of the SLO and Director of ORAD to address biosafety issues. The term "NRC Crisis" first appeared in the 29 November 1993 Testimony of EH&S Director [redacted] to the HIV Investigation Committee, p. 60. *See also* 3 December 1993 Interview of the SLO, p. 32 (comment by the HIV Investigation Committee Chairman [redacted] about "radioactivity crisis"); 12 January 1996 HIV Investigation Committee response (p. 10) to question 51 of our 3 November 1995 letter.

[34] 22 November 1993 testimony of the Director of ORAD to the HIV Investigation Committee at 24.

[35] From 30 June 1990 until May 1, 1991, there was no Director of ORAD (the incumbent had resigned, and the current Director assumed the position on 1 May 1991). Investigation report p. 62-63 and 12 January 1996 response by HIV Investigation Committee, p. 6 (response 34).

[36] The University's response to our 3 November 1995 letter shows that he received at least 6 responses. This does not include the subject's 4 March 1992 response (which the Director of ORAD claimed he had not received).

of the faculty's increased awareness of their responsibilities with regard to biosafety—which, ironically, apparently came about as a result of the University's handling of the allegations against the subject.

We determined that while some administrators and some BSC members may have considered nonrecombinant DNA biohazard issues as part of the BSC's purview, others, including the faculty, were unaware of this as late as 1993 because such an expanded purview for the BSC had never been formalized or announced. When we visited the campus in 1996, we found little had changed.[37]

The BSC and the Subject's Applications

As far as we are able to determine, for all of the 12 proposals the subject submitted to external sponsors (including 5 to NSF) between 1989 and 1993, the subject unequivocally indicated on the *Form* that the projects involved rDNA.[38] On all but two of the *Forms,* an ORAD grants administrator typed or wrote dates indicating BSC approval for the rDNA projects—incomprehensibly, *all* of the dates for BSC approval of the subject's proposed research efforts *precede the subject's employment at the University.*[39] The ORAD grants administrator told us she believed this date was the "date the university got approval from somewhere" but did not know "how the approval is obtained."[40] The University explained that apparently

> clerks in the grants office made it a practice to list dates on approval forms as those when approval had been provided by regulatory agencies. These dates were on a clerical reference sheet in the grants office, which is no longer available.[41]

Two of the *Forms* and their proposals were approved by the AOR (the Director of ORAD) without any dates for the BSC approval. According to the HIV Investigation Committee, the Director of ORAD "stated that the signature on the face sheet is his; however, he does not recall seeing the application, and on July 7, 1992, because of [the "NRC crisis"] he would not have had time to read it."[42] None of these applications or the subsequent research was reviewed or approved by the BSC.[43]

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[37] *See* Appendix 7.

[38] Neither the subject nor the University was able to locate the approval form for one of the 12 proposals the subject submitted in that period.

[39] The subject also indicated that these projects involved radioactivity. The approval dates for each of these declarations also preceded his employment at the University.

[40] Tab 16, 18 October 1996 affidavit of [redacted], p. 1.

[41] 26 March 1996 letter to the University General Counsel from the Director of ORAD, p. 12.

[42] Despite the volume of material exchanged with the University about these matters, it did not respond to our question about how these proposals could have been submitted without the required approval dates. *See* the 31 March 1997 University response to OIG.

[43] *See* Appendix 8.

As indicated above, the BSC was improperly constituted, unclear as to its purpose, and uninformed about the very issues the University had delegated to it to review. Unsurprisingly, nobody else at the University was better informed about the responsibilities of the BSC than was the BSC itself.

The University's Inquiry Report recognized that failures in the University's procedures and oversight and the subject's style of communication created the environment in which the subject could carry out research in a multi-user facility using deadly pathogens without adequate University oversight and approval. As a result, we find all the more troubling the University's efforts, in its HIV Investigation Report, to place all the responsibility for these problems on the subject—while failing to ensure the future responsible behavior of University administrators then, and currently, assigned oversight and safety duties. This attitude of inattention, in a primarily undergraduate institution, was reflected in the responses we received personally from University administrators when we visited the campus in 1996, as well as in written responses we have received since then, causes us to doubt that these University administrators will address these problems without emphatic action by NSF.[44]

Implementation of the University's Exposure Control Plan

In December 1991, OSHA issued the *Standard for Occupational Exposure to Bloodborne Pathogens* (the *Standard*).[45] It required the University to implement a variety of safety practices. Among those were the need for the University to "establish a written Exposure Control Plan"[46] by 5 May 1992, and by 4 June 1992, to train and notify its employees of the *Standard*. By 6 July 1992, it was required to have the proper biohazard warning signs, storage, use, and disposal procedures in place, as well as protective gear available for its employees and a post-exposure follow-up procedure. With regard to "*HIV . . . Research Laboratories,*"[47] the *Standard* stated "when other potentially infectious materials . . . are present in the work area . . . a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors."[48] The *Standard* specifies the information required on it, including the name of the agent and of the laboratory director.[49] It also

[44] Our concerns were not alleviated by the University's response (Tab 32). It described much of its effort as plans and aspirations. For example, it appears that much of the revamping of the oversight process occurred after the resignation of the Director of ORAD and the appointment of his replacement during the 1998-1999 academic year. Because these plans have not yet been fully implemented, it is not known how effective they will be..

[45] Occupational Exposure to Bloodborne Pathogens, 56 Fed. Reg. 64,175 (1991) (codified at 29 CFR § 1910.1030).

[46] 29 C.F.R. § 1910.1030(c).

[47] The laboratories to which this portion of the regulation applies are "research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV." 29 CFR § 1910.1030(e)(1).

[48] 29 CFR § 1910.1030(e)(2)(ii)(D).

[49] *Id.* § 1910.1030(g)(1)(ii)(A).

specifies that a "biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually . . . ."[50]

The University's Coordinator of the Office of Environmental Health and Safety (the "EH&S Director"),[51] hired in February 1990, became responsible for implementing the OSHA regulation. According to the HIV Investigation Committee,

> [u]ntil attending a training session . . . on infectious agents and virology late in 1993, [the EH&S Director] had no expertise in this area. Until early 1992, [the EH&S Director] had no interaction with either the [BSC] or ORAD, and, in fact, was unaware in 1990 and 1991 that the [BSC] existed.[52]

In May 1992, the EH&S Director sent a survey to the Biological Sciences Department lab manager and others requesting the identity of any pathogenic organisms being used. Later that month she received a response completed by either the subject or his postdoctoral researcher[53] that identified the pathogens as "Entroviruses, Retroviruses (HIV, SIV), Poliovirus" to which employees might be exposed.[54] The EH&S Director told us that she "reviewed [the survey for] about 30 seconds" and then "called [the Director of ORAD] who said it was no problem, because [the subject] was not using live HIV and couldn't get it."[55] She did not contact the subject regarding his declared use of HIV, SIV, or poliovirus.[56]

University administrators claimed that since the subject did not use the adjectives *live*, *infectious*, or *viable* to modify HIV in the text of his proposals, it understood the subject to be using noninfectious, nonviable virus. From our review of the proposals we concluded that he had disclosed the use of infectious materials and that a more likely explanation is that the University was careless in its review of the survey responses and proposals, and did not react to the subject's clear references to the use of HIV and other pathogens in his research.[57] The assumption that the virus was not infective is difficult to understand. At the very least the responsible administrators should have sought clarification from the subject of his written

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[50] *Id.* § 1910.1030(e)(2)(ii)(M).

[51] [redacted]

[52] 29 November 1993 testimony of the EH&S Director to the HIV Investigation Committee, p. 7.

[53] Dr. [redacted]

[54] The survey and the response are at Tab 24.

[55] Tab 19, 15 October 1996 affidavit of the EH&S Director, p. 2. However, she said that she did not provide this information in her testimony to the HIV Investigation Committee or in her prior response to NSF because she did not want to "implicate" the Director of ORAD. *Id.* She claimed that the order of presentation of the information provided on the survey caused her to believe that the subject was not using "live HIV." 9 January 1996 memo to the General Counsel. This latter explanation is not credible.

[56] Similarly, the EH&S Director did not follow up on the subject's declared use of poliovirus despite her knowledge that it was covered by the *Standard* she was responsible for implementing. In her 22 February 1994 memo to the HIV Investigation Committee, the EH&S Director stated, "polio virus, as a bloodborne pathogen found in *human* blood/body fluids/tissues is undoubtedly covered by the standard . . . . [T]he Standard is absolute, without regard to immunization status."

[57] *See* Appendix 12 and Tabs 26-28.

notification, rather than crediting oral speculation by those who were not conducting the research.

In our view, the University's position is inconsistent with the plain text of the subject's proposals, which clearly indicate that he is attempting to identify and assess the survivability of HIV persisting in wastewater. The University's position is also inconsistent with the biological scientific community's understanding of the term "virus," which, by definition, is a synonym for "infectious agent."[58]

When we asked the HIV Investigation Committee why it took this contrary view it said that the subject

> himself has written terms such as *live HIV, authentic HIV* and *viable HIV* in order to make clear to the reader that this is not referring to *attenuated* or *inactivated* HIV. . . . [F]ollowing a review of the May, 1990 NSF application, it is the opinion of the investigation committee that all of the experiments described in the proposal could have been done without viable HIV. Thus, even though the word HIV was present in the title of this application, it was the opinion of the Committee that all of the experiments described in the application could have been done with inactivated HIV. The Committee concluded that regardless of what the general convention might be for the usage of the term HIV, in the context in which [the subject] used the term in the May 1990 NSF Application, it referred to samples which would be inactivated.[59]

The Committee's rationale (and that of the administrators it interviewed) requires that one accept the premise that if one can conjure up a way that this research *could* be done without using infectious material, that this should be accepted without clarification.[60] We believe that it was inappropriate, particularly for research with a fatal disease vector, for University administrators not to have determined the infectivity of the HIV or wastewater samples and taken the appropriate precautions. We do not find the University's efforts to explain the decisions by the EH&S Director and the Director of ORAD to be credible. Had University administrators or the oversight committee members acted responsibly, the University could

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[58] Davis, et. al., *Microbiology*, 3d Ed., Harper & Row, 1980, p. 7.

[59] 12 January 1996 response of the HIV Investigation Committee to OIG, p. 2.

[60] In its response, the university said, "The Committee's report pointed out that there was a general impression at the university that [the subject] was working with inactivated HIV. Although this impression was supported by the article on [the subject's] research which was written by [another author] and appeared in the [University newspaper], the committee did not intend to indicate their general impression was reasonable." (Tab 32, p. 6). We were concerned by this response because the committee report expresses information about this issue as its beliefs and therefore appears to be its opinion on the reasonableness of this impression. (Tab 2, p. 22.) We note that the "general impression" was partly based on misinformation and second-hand knowledge, and that the committee had received information that contradicted the "impression." The newspaper article used to support the "general impression," did not discuss whether or not the subject was using infective virus.

have reacted, in a timely manner, to the subject's proposed use of biohazardous materials and taken the appropriate safety precautions.[61]

The subject also had a responsibility to ensure that the University considered the safety implications of the potentially infectious samples he used for its employees and students, and to ensure that his use of the samples was consistent with the intent of the University's Exposure Control Plan.

In September 1992, the EH&S Director circulated a second set of forms which were to be "distributed to . . . supervisory personnel." The forms sought information about bloodborne pathogens but did not request the identity of the pathogens. These forms were completed by the biology stockroom technician,[62] who told us she recommended that the EH&S Director speak with the subject about his use of HIV.[63] The EH&S Director did not do so.[64, 65]

On 30 September 1992, the EH&S Director circulated the Bloodborne Pathogen Exposure Control Plan to the Biological Sciences Department, and on 6 October 1992, she conducted a training session in the Department attended by the subject. The subject and others had been specifically invited to the seminar because "your lab uses human biohazardous materials, [and] you are required to have training in this subject."[66]

Besides HIV, SIV, and poliovirus, the subject's research required the processing and extraction of possible viral contaminates from human sewage. There is no indication that the University considered the safety issues associated with the subject's collection and use of human sewage. His use of these materials is of particular concern because 1) the stated objective of the subject's external and internal wastewater proposals was to demonstrate the persistence, or survivability, of infectious pathogens in wastewater; and 2) some of these

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[61] The HIV Investigation Committee's lack of discussion of this issue is a clear example of its unwillingness to address systematic University deficiencies. The Committee wrote that "[We] wish to emphasize that this discussion should in no way be considered a criticism of [the EH&S Director]." HIV Investigation Committee Report, p. 12. However, in the same Report, it later acknowledged the inadequacy of her efforts, albeit apologetically: "It is clear that [in October 1992] the method of information-gathering used by EH&S was *evolving* and *undergoing improvements* with regard to *accurately* determining who was using which pathogens in the various research departments." *Id.* at 53 (emphasis added).

[62] [redacted] The EH&S Director indicated that the biology stockroom technician handled this matter because the Department Lab Manager, who normally would have handled the matter, was unresponsive.

[63] Tab 11, 18 October 1996 affidavit of the biology stockroom technician, p. 2.

[64] Tab 19, 15 October 1996 affidavit of the EH&S Director, p. 2.

[65] We note that in the University's response it said that one of the changes that had been implemented was that the Office of Environmental Health and Safety "modified and added to the Blood Borne Pathogens (BBP) record keeping forms to require more detailed information from researchers regarding the infectious agents being handled, and added a requirement for a signature certifying that the researchers obtained Biosafety Committee Approval." (Tab 32, p. 4). In 1992, the subject provided the EH&S Director with sufficient information to alert her to his use of lethal, infectious, blood borne pathogens and she chose to ignore the information and did not ask him what he was doing. It is unclear how revising EH&S forms will prevent such communications problems from reoccurring.

[66] 22 September 1992 memo from the biology stockroom technician.

samples were taken from a particular location because they were considered to be more likely to contain HIV than samples from other locations.[67] The OSHA *Standard* explains that the *Universal Precautions* described in it are an approach to infection control.[68] It instructs that "Universal Precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials."[69] Although these precautions reasonably apply to the subject's sewage samples, there is no evidence that the University considered whether these samples were infectious and should be handled according to the precautions described in the *Standard.*

Applications for Registration of rDNA Laboratories[70]

The systemic character of the University's inadequate oversight is further illustrated by its handling of its applications to register its laboratories conducting rDNA research with the [redacted] Department of Public Health. In the three *Application[s] for Registration of Laboratories for Recombinant DNA Research* we reviewed (submitted in 1987, 1989, and 1991),[71] the "responsible officer for the Institution" signed a statement "affirm[ing] that this Institution and the laboratories listed herein are complying with the current NIH Guidelines for recombinant DNA research."[72] However, the BSC was not involved in the review and preparation of the applications, or the projects listed on them, even though the BSC is the University entity expressly charged with the approval of projects that fall under the *Guidelines* (and for independently assessing the project containment levels, facilities, procedures, practices, and training).

This protracted failure by the University to comply with its own oversight policy is particularly noteworthy in light of the fact that the SLO and certain researchers involved in preparing the applications were also members of the BSC.[73]

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[67] *See* Tab 28, NSF proposal number [redacted]. 9.

[68] 29 CFR § 1910.1030(b) (1992).

[69] *Id.* at (d).

[70] Although many of the events described in this section are not directly associated with NSF funding, we believe they support the conclusion that the University's oversight process was disorganized and ineffectual and its PIs uninformed about their responsibilities with regard to oversight.

[71] *See* Tab 25.

[72] *See* Appendix 1. These officers were [redacted] (the AOR who preceded [redacted] or the Vice Provost.

[73] One applicant had been a BSC member since 1984 and two others were BSC members since 1989. One of these applicants, who was the BSC chair at the time of our visit, said he "submitted [the applications] to the State directly;" the "[f]orms didn't go to [the] BSC." (Tab 22, 18 October 1996 affidavit of the Chairman of the Biosafety Committee, p. 3) The University told us that its officials could "not recall the details of the process by which the applications were reviewed by [the University] or the BSC" and that "the PI's [sic] were requested to designate rooms and P levels for registrations." (31 March 1997 letter from the University to OIG).

The University's Poor Oversight of the Subject's Proposals

It is unsurprising that the University's absence of oversight included its handling of the subject's proposals. Including internal applications, subcontracts, external proposals, and requests for supplemental funding, prior to the 1993 inquiry into this matter, the subject submitted 31 requests for research funding either to University committees or to external sponsors—all with University approval.[74] And contrary to the surprise described by the University in its HIV Investigation Report, in fact the subject clearly stated his plans to use infectious human pathogens in his internal and external proposals, which were properly submitted to University administrators for their review and approval. These were not confidential documents: announcements about his submitted proposals and funded projects were placed by ORAD in its *Research Bulletin*; the subject posted articles about his research on a departmental bulletin board, across from the department office; and the subject indicated on each external proposal *Form* that the project involved rDNA. Despite these repeated declarations, no University administrator or BSC member acted to ensure that the subject's work was reviewed and approved.

Although we focus on the subject's internal applications and external submissions, we also discuss other researchers' applications and submissions that we believe demonstrate that the University's deficient oversight practices were not limited to the subject's proposals or applications.

The Subject's Internal Funding Requests

The subject submitted 14 applications for internal funding to three internal University committees: the University Research Committee (URC), the Biomedical Research Support Grant (BRSG) Committee, and the Research Excellence Fund (REF) Committee.

Although external proposals require a completed *Form* with explicit declaration of any use of rDNA, and administrative confirmation of BSC review, there was, at the time of the subject's submissions, no such declaration requirement for internal proposals to any of these committees. Although the committees referred a few proposals to the BSC, in general they reviewed and approved projects without regard for biosafety oversight.

The URC[75]

The URC reviews applications for intramural research funds from students and faculty. From 1990 to 1992, the subject submitted four applications to the URC, and received funding for one.[76] None of his applications, including the funded project that specifically mentioned

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[74] *See* Appendix 9.

[75] *See* Appendix 10 for additional material regarding the URC and the REF Committee.

[76] The applications were entitled, [redacted] (1990), [redacted] (FY 1990, funded), [redacted]

genetic engineering, was referred to the BSC or another safety body for review and approval. Information provided by the University showed that its handling of the subject's applications was not unusual.

Among the 46 projects funded by the URC between 1988 and 1996, fourteen explicitly involved biohazardous research—nine of these were funded between 1989 and 1993 (the period from the subject's hire to the inception of the investigation).[77]

Four of the funded projects studied a parasite that causes "horrible disfiguration" in mammals, including humans.[78] One of these projects was referred to the Institutional Animal Care and Use Committee (IACUC). It concluded "there will be no hazard to other research animals or personnel from these studies."[79] None was referred to the BSC until December 1993. The BSC gave that project conditional biosafety approval contingent on the BSC Chair reviewing specific rooms used in the research "for suitability for BSL2 activity" and a "[c]larification" of the assertion in the proposal that "this organism does not multiply in mammals . . . ."

The URC records show that although the University began careful radiation reviews after the "NRC Crisis," it did not extend its concern for safety oversight to ensuring reviews in other safety areas.[80] The URC's lack of attention to obvious biosafety concerns is particularly disturbing in light of the fact that the Director of ORAD, who was an *ex officio* member of the URC since 1991, had overall responsibility for safety issues at the University, was intimately involved in the "NRC Crisis" response, and understood that the BSC had been charged with expanding its authority to include oversight over all biosafety issues.[81]

The BRSG Committee

The BRSG Committee obtained funds from NIH to support biomedical and behavioral research. The proposal cover pages accompanying the University's annual BRSG competition announcements require no information about the potential hazards of the research, nor do the announcements require approvals from University safety committees.

[redacted] (1991), and [redacted] (1992).

[77] The details of these 14 awards are provided in Appendix 11. The University provided us with BSC reviews for two other projects that did not match their descriptions.

[78] According to the PI's materials, this parasite, [redacted] is transmitted by infected mosquito bites into humans where it blocks lymphatic ducts.

[79] 11 February 1991 IACUC approval by the faculty member who was subsequently appointed Chairman of the HIV Investigation Committee.

[80] For example, although this is not related to the URC, we noted in the University's response that "[i]n 1996, the university had been cited [by the USDA] for lack of review of [an] investigator's proposed projects. The 1997 inspection contains an indication that the University had corrected this concern." (Tab 32, p. 7.)

[81] The Director of ORAD stated that the BSC expanded its authority shortly after its inception to provide approval for experiments using infectious agents and for its review in 1989 of the subject's research. *See* Appendix 3 and 20 December 1995 memorandum from the Director or ORAD to the General Counsel, p. 2.

Between 1989 and 1993, the BRSG funded 22 projects but referred only one to the BSC for review.[82] Among the funded projects not referred were two by the subject,[83] which described experiments clearly involving rDNA and/or biohazardous materials, and those by another faculty member to study the parasite described above. In 1994, following the highly-publicized controversy over the subject's research, the BRSG referred at least four proposals to the Director of ORAD for biosafety review. Clearly—like the rest of the University—the BRSG had been unsure of the BSC's function and only the events surrounding the review of the subject's 1993 proposals heightened its awareness of the need to obtain such biosafety oversight.

The REF Executive Committee

The REF Committee Chairman, who was also a member of the BSC from 1989-1993, explained the committee's charge as the "allocation of REF funding for biotechnology research" at the University. He also said that "[r]equests for REF funding have not been formally coordinated with the BSC, IRB,[84] IACUC, Radiation safety, etc. Applicants for REF support are responsible for independent approval for projects that pose potential hazards."[85] To the contrary, between 1989 and 1993, the annually issued instructions for REF applications did not require applicants to obtain relevant safety committee approvals.

Between 1989 and 1993, the subject submitted six applications to the REF Committee and received a total of $13,000 in funding for three of them.[86] Even though the applications that described projects involving the use of rDNA or biohazardous materials clearly described that use, none was reviewed by a safety committee. During the review[87] of the subject's 1993 REF application, the second such application to involve the use of HIV, the REF Chairman

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[82] In December 1989, the committee was concerned about the use of "clinically dangerous organisms; e.g. [redacted] etc." in a faculty member's proposal entitled [redacted] The BSC approved a revised proposal.

[83] The subject submitted four BRSG proposals. They were, [redacted] (11/13/89, funded), [redacted] (1990), [redacted] (1990, funded), and [redacted] (1991).

[84] Institutional Review Boards are convened to review and approve research with human subjects.

[85] 21 December 1995 memo from the REF Committee Chairman to General Counsel, p. 1.

[86] The proposals were: [redacted] (1990), [redacted] (1990, funded), [redacted] (1990), [redacted] (1991, funded), [redacted] (1992, funded), and [redacted] (1993).

[87] *See* Appendix 10 for descriptions of the review process employed by the REF Committee.

> raised the [biosafety] issue . . . . [W]ell the whole committee was aware immediately and was concerned. And since I also served on the [BSC], I assured the committee that this was the first I had heard [of] live HIV.[88]

The subject's 1991 and 1992 REF applications outlined the subject's plans to work with human bloodborne pathogens, potentially contaminated materials, and rDNA in conducting his research. The REF committee did not refer any of these projects to the BSC or express concern about its use with any administrative official or the subject.

Regarding the subject's 1992 application, [redacted] the REF Chairman later said, "I wonder how it got past us."[89] Another Committee member said:

> "in retrospect" [I] realize[] that "tissue culture" means HIV[; the] same sentence that caused alarm in 93 was in [the] 92 proposal and says the same thing; it didn't impact [my] awareness; "obviously [I] didn't read it real closely."[90]

With regard to the subject's 1991 application, which explicitly stated that the project involved HIV, the REF Committee member said

> "persistence" [of HIV] means whether it's alive; it was assumed [the subject] was doing tests without live virus, . . . but [I] now see [] references to "tissue culture" which [I] understand [] means live, infective virus; looking at this proposal now, I see something totally different. [I] agree [] that this should have been the first time the REF committee realized what [the subject] was doing. [The r]eason for REF committee's not realizing [his] activities [was that the University] was "naïve" and did not have the expertise to understand these issues . . . .[91]

We would have expected a strong, natural linkage between the BSC and the REF Committee because of the nature of the projects funded by the REF Committee—and the fact that the REF Committee chairman was a longstanding member of the BSC. However, there was little or no communication between these two committees, and none of the subject's applications described above was referred to the BSC before 1993.

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[88] 6 December 1993 testimony of the REF Committee Chairman to the HIV Investigation Committee, p. 26. Subsequent concern by the REF Committee and the BSC gave rise to this case.

[89] Tab 7, 16 October 1996 affidavit of the REF Committee Chairman, p. 2.

[90] Tab 10, 15 October 1995 affidavit of Department of Biology Faculty Member 1, p. 2.

[91] *Id.*

Subcontract Support for the Subject's Research

Unlike proposals submitted to external sponsors for research grants, the University did not require safety committee approval of research supported by external contract. In late 1989, two of the subject's ongoing research projects supported by his former institution were transferred from his former institution to the University by means of subcontracts.[92] In early 1992, the University also completed a subcontract supporting the subject's efforts on a collaborative project with a PI at another university funded by an NSF award to the other university.[93]

The three subcontracts that supported the subject's research efforts were completed by the Office of Risk Management [redacted], a function separate from ORAD. According to the Risk Management Director,[94] contracts came to Risk Management through ORAD, but were processed separately, and Risk Management's role was limited to liability issues.[95] There were no forms or established procedures for review of any subcontracts by any oversight committee. We were told that review occurred on an *ad hoc* basis if the Director of Risk Management requested it from the Director of ORAD.[96]

At least one of the subcontracts issued in 1989 for the subject's research involved rDNA and, therefore, if it had been submitted as an external proposal it would have been required, by University policy, to receive BSC approval.[97] The 1992 subcontract, funded by the NSF grant to the other university, supported the subject's work on the feasibility of a probe for the detection of HIV. The BSC was not informed of this project (it was, however, reviewed by the University's general counsel's office for liability issues). It was executed 4 months after the deadline for the establishment of the University's Exposure Control Plan had passed and 7 months after the BSC had been charged with expanding its review of hazardous organisms.

The handling of these subcontracts, particularly for the NSF grant, demonstrates an extraordinary lack of coordination between the University's offices and inconsistent application of safety reviews to externally supported research efforts. Our conclusion is supported by the observations of the Director of ORAD, the Vice Provost, and Risk Management[98] who told us that the connection between Risk Management and the Biosafety Committee was informal and there were no established procedures to ensure the hazard review of research described in contracts.

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[92] The project titles were: [redacted] and [redacted]

[93] NSF award [redacted] entitled [redacted] named Dr. [redacted] as the PI. It was awarded to the University [redacted]

[94] The Director is Ms. [redacted]

[95] Tab 12, 17 October 1996 affidavit of the Director of Risk Management, p. 2.

[96] Tab 18, 15 October 1996 affidavit of the Vice Provost, p. 4.

[97] *See* Tab 26.

[98] See Tab 9, p. 4; Tab 12, p. 2, and Tab 14, p. 2.

The Subject's External Submissions

The University's procedures require that proposals submitted to external sponsors be approved by the AOR; this approval is to be preceded by approvals by the appropriate safety committees.[99] From 1989 through 1993, when the University's investigation began, the subject submitted ten proposals to four federal agencies, including NSF. He also submitted two requests for supplemental funding to NSF and two proposals to private foundations seeking support for his research.[100] Although each of his proposals described the use of rDNA and/or other biohazardous materials, and the *Forms* indicated the need for BSC review, none received it.

We have included copies of subject's NSF award, [redacted] his NSF proposal [redacted] and the award to the PI at the other University.[101] We have highlighted those portions of them that clearly indicate the project's use of biohazardous materials or rDNA. For example, the subject's December 1991 supplemental funding request to NSF clearly states his intention to determine whether "the persistence of HIV-I-specific nucleic acid in some wastewater samples . . . are from the infective or noninfective virus." It states his intention to expose tissue cultured cells to virus concentrate developed from wastewater and "monitor for the cytopathic effects and compare[] with the simultaneously run positive controls."[102,103]

The one-page request was countersigned by the Director of ORAD, who told us that the subject presented it to him and said he needed it signed right away so that he could get funding. The Director of ORAD told us that he read it and signed it, but nothing stood out that concerned him. He noted that he had no training in viruses and was unaware that he had any responsibilities regarding biosafety.[104] He acknowledged that the letter did not reflect an attempt by the subject to hide what he was trying to do, and that he simply didn't pay enough attention to it.[105] The Director of ORAD told the HIV Investigation Committee:

> I must admit that the level of training that I had in molecular biology and in virology was virtually nonexistent and it was not possible for me to look critically at that supplemental request and the detail within it to ascertain whether there was any thing really potentially harmful or not.[106]

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[99] *See* Appendix 2.
[100] *See* Appendix 9.
[101] *See* Appendix 12 and Tabs 26-28.
[102] A positive control, in this case, would be created by exposing the same cell cultures to a known quantity of purified HIV.
[103] *See* Tab 28.
[104] Tab 14, Notes of 15 October 1996 OIG interview with the Director of ORAD, p. 2.
[105] *Id.*
[106] 22 November 1993 testimony of the Director of ORAD to the HIV Investigation Committee, p. 2. *See* similar assessment of the EH&S Director's virology knowledge, discussed above.

Thus, aware of his ignorance of the subject matter of the request, but without inquiring of the subject or anyone else knowledgeable in the field, the University official entrusted with responsibility for biosafety approved this request. This is fundamentally irresponsible. The signature of an approving officer is only meaningful insofar as it indicates that the matter has been considered and approved by an individual who is capable of understanding the details of the matter, and who is capable of determining whether any basis for disapproving the request exists. By serving as a "rubber stamp" for this supplemental request, this administrator placed form over substance in a way that endangered the safety of numerous individuals at the University.

Conclusion Regarding the University's Oversight of Biosafety

We believe the evidence demonstrates the University's failure, despite its professed concern, to establish either clear, well-defined, and appropriate oversight guidelines, and to disseminate those guidelines to the appropriate parties, or a functional, comprehensive oversight structure. These failures created a systemic, long-term atmosphere of inattention regarding biosafety issues. We believe that our recommendations as to the University are necessary to protect NSF's interest that its funded research is carried out in ensuring a safe environment, for the public, faculty members, and students.

The Subject's Responsibilities and Commitments

As has been described above, the University's oversight structure and procedures were totally inadequate for the kind of research being conducted by the subject. However, such deficiencies do not liberate the subject from upholding his well-recognized responsibilities, and to comply with express commitments he made in order to obtain biohazardous materials to use in his research.[107]

The subject was an experienced researcher who was well aware of his responsibilities. In 1989, the University conducted a nationwide campaign seeking a scientist with "experience in molecular biology"—someone with "sufficient experience to merit immediate consideration for promotion to associate professor with tenure."[108] The University hired and promoted the subject because he was considered to be a leader in molecular biology for the University.[109] The subject acknowledged to us that he is, and was, well aware of relevant safety and oversight standards.[110] For example, the Public Health Service publishes *Biosafety in Microbiological and Biomedical Laboratories*[111] (the *Biosafety* book), which is generally

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[107] *See* Tabs 29 and 30 for copies of the certifications discussed in this section.

[108] [redacted]

[109] *See* Appendix 13 for a more detailed discussion of the subject's application and credentials.

[110] Tab 5, 17 October 1996 of the subject, pp. 2-3.

[111] The *Biosafety* book was revised in 1988 (HHS Pub. No. (NIH) 88-8395) and 1993 (HHS Pub. No. (CDC) 93-8395), but the basic instructions in the book have not changed in these revisions. Both versions of the *Biosafety* book include as an appendix *The 1988 Agent Summary Statement for Human Immunodeficiency Virus*

recognized to establish the minimal standard—and in the laboratory where his biohazardous research was conducted, the subject posted a notice instructing users to read the *Biosafety* book.[112]

The laboratory director has the fundamental burden of ensuring the safe conduct of the research.[113] For example, the laboratory director is required to prepare and have readily available a biosafety manual; and either to supervise directly or have a trained scientist supervise the research personnel.[114] In addition, implementation of a biosafety regimen consistent with the *Biosafety* book requires the involvement of administrators in the institution. For example, a laboratory conducting research with HIV should have in place:

1) a medical surveillance program that is consistent with "institution policy and applicable local, state, and Federal regulations;"[115]
2) written institution policies "regarding the management of laboratory exposure to HIV, such policies should deal with confidentiality, counseling, and other related issues;"[116] and
3) institution policies to ensure "safe and healthful working conditions to protect employees against occupation infection with HIV."[117]

None of these objectives can be accomplished without the assistance of university administrators knowledgeable about the applicable policies and laws. However, neither the indifference of those administrators nor the existence of inadequate oversight mechanisms relieves the laboratory director of those responsibilities that require active institutional involvement. In this case, when the subject was faced with what he knew to be inadequate oversight processes and practices at the University, he chose to continue his research project in disregard of his commitments to ensure safety and oversight.

The Subject's Acquisition and Use of Biohazardous Materials

As part of his approved research activities at the University, the subject requested and received, between December 1990 and February 1993, potentially pathogenic materials,[118]

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and Report of Laboratory-Acquired Infection with Human Immunodeficiency Virus, first published in Morbidity and Mortality Weekly Report, April 1, 1988, vol. 37, no. S-4 (referred to herein as the "*MMWR*").

[112] The first line of the undated *Users of P-2 facility for infectious materials* memo the subject posted stated: "Please read the HHS publication No. (N[I]H)88-8395 and HHS Publication No. (CDC) 88-8395." Both citations refer to the *Biosafety* book.

[113] *See, e.g.*, the *Biosafety* book p. 4, 8-9 and MMWR at 111.

[114] *See Biosafety* book , p. 4, 8-9.

[115] MMWR at 111.

[116] *Id.*

[117] *Id.*

[118] The laboratory notebooks show that some of these agents were simply received and stored for subsequent use in freezers. The remainder were used in numerous experiments (see Appendix 14) conducted by two successive postdoctoral researchers. Some were received in the July to September 1992 period when the subject was out of

including reagents, cells, HIV, SIV, poliovirus, and raw human sewage from five different sources.[119]

The subject submitted his first request to the [redacted] (the AIDS Program) in December 1990. Prior to placing this order, the subject and the Director of ORAD signed the *Annual Repository Registration Form*,[120] and the subject initialed a *Certification of Compliance with Safety Standards* within the *Registration Form*:[121]

> I understand that the requested substance(s) may pose health risks to persons handling or in the vicinity of the material, the environment, and the community. In that regard, I certify that I am cognizant of and will employ the appropriate biosafety standards including special practices, equipment, and facilities as specified in the Material Data Sheet. I will comply with all applicable Government health and safety regulations and the Guidelines detailed in [the MMWR[122]]. I will directly supervise all users of the reagents and I will assume responsibility for assuring that those users are cognizant of and comply with safety standards and good laboratory practices.[123,124]

The AIDS Program informed him that it could not provide him with a biohazardous item he requested without an indemnification form endorsed by the University, which the University decided to provide only after much deliberation,[125] including a tour of his laboratory.[126]

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the country. It is unclear whom, during his absence, was appointed to provide the supervision recommended by the *Biosafety* book and *MMWR*.

[119] The materials were acquired from the AIDS Research and Reference Reagent Program, Dr. [redacted] (the other researcher) at [redacted] Dr. [redacted] and other scientists, and The [redacted]

[120] The *Registration Form* required, and the subject provided, a written description of his use of the reagents. The subject stated that "the cell lines will also be useful for determining the viable counts of the virus in the samples."

[121] *See* Tab 29. The *Registration Form* identified NSF grants [redacted] and [redacted] as support for this research.

[122] *See* note 111.

[123] [redacted] p. 2.

[124] We note in this connection that the subject was out of the country for approximately one month when some of these experiments were conducted. He testified that, because of his absence, he had not reviewed his postdoctoral researcher's work and was unaware of his use of HIV in a particular experiment. *See* 7 February 1994 transcript of the subject's interview with the HIV Investigation Committee, pp: 123-128.

[125] *See* 17 December memo from the staff attorney (now General Counsel) to the Senior Vice President for Academic Affairs and Provost and the Vice President for Finance and Administration. The staff attorney told senior officials "once the Compliance Agreement is in the hands of [the AIDS Program, it] may then use it for any substance which [the University] purchases from [it], until . . . the Compliance Agreement expires." *See also* the 10 December memo from the Director of ORAD.

[126] The Director of ORAD, Dean, and the Vice Provost "thoroughly investigated" the subject's laboratories on 19 December 1991. Their conclusions that (1) "the containment equipment [the subject] plans to use in his next research project . . . have a safety rating significantly above that which would be required if the cell line which he intends to pursue had any potential hazard associated with it" and (2) "there is no danger, either present or future in the organism requested nor in the experiments proposed," were documented in a 19 December memo from the

Between October 1991 and February 1993, the subject placed six orders with the AIDS Program. Among the items he received were nine that were identified as biohazardous and the accompanying data sheets specified that BSL-2 practices were required to handle the materials.[127]

Some of the research conducted in the subject's laboratory used SIV engineered for reduced pathogenicity, obtained from either another researcher or the AIDS program. To receive this virus from the other researcher, the subject signed a document provided by the researcher stating that he accepted the conditions that the

> materials are to be used with caution and prudence in any experimental work since all of their characteristics are not known. Cells and supernate containing virus must be handled with caution and with appropriate biosafety procedures and equipment.[128]

After a conversation with the other researcher, the subject provided a written assurance that "the virus will not be released into the environment in any circumstances."[129] The other researcher concern about the use of SIV became formal in September 1992, the CDC and NIH began circulating information about the possibility of humans contracting SIV. Subsequently, in May 1992 and January 1993, the subject received shipments of this virus from the AIDS Program. The data sheet accompanying these shipments stated, "STRICT ADHERENCE TO BIOSAFETY LEVEL-2 PRACTICES IS REQUIRED."[130]

The subject permitted the use of this virus in experiments and took no action to ensure institutional involvement, as would have been appropriate according to the *Biosafety* book, the new CDC/NIH warning, the institution's Exposure Control Plan, or as necessitated by the BSL-2 warnings on the materials safety data sheet and certification he signed to obtain this virus.

In December 1990, to obtain cell lines from the Human Genetic Mutant Cell Repository, the subject signed an *Agreement* to "adhere to the procedures and recommendations outlined in

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Vice Provost. *See* Appendix 5 for a discussion of the qualifications of these individuals to review the subject's laboratory. The *State Institutional Compliance Agreement,* was dated 20 December 1991 and was endorsed by the University's Director of Risk Management [redacted] and countersigned by the subject.

[127] *See* Appendix 15.

[128] 18 June 1991 letter from the researcher to the postdoctoral researcher. On 10 June 1991, the subject endorsed the letter as an official of the "Research University or Nonprofit Institution" and the postdoctoral researcher as the "Research Investigator."

[129] The researcher sought this assurance because he was concerned about "whether appropriate safety conditions were available at [the University], which he described as a small university with little research activity." 7 December 1993 notes by [redacted] of conversation with the researcher, p. 1. In its response, the University expressed concern about the researcher's characterization of it as "small." However, we note that the Director of ORAD described it similarly to us (Tab 4, p. 3). We believe this characterization serves to provide context to our concerns (Tab 32, p. 7).

[130] Emphasis in original.

. . . the attached *Minimum Safety Guidelines Recommended for Working with Lymphoid and Virus-Transformed Human Cell Lines.*"[131] The *Minimum Safety Guidelines* stated that it was the University management's responsibility to

> establish a biohazards committee to institute and enforce a health and safety policy which includes a specific safety program for work involving human cell lines. The program should meet applicable federal, state, and local regulations and include safety training, maintenance of accident records, and provision for emergency treatment.[132]

The *Minimum Safety Guidelines* also specified that the PI was responsible for

> the preparation of safety protocols for the research program under his direction. The protocols should include appropriate procedures for use, storage, decontamination, disposal, and emergency treatment. The protocols should be approved by the biohazards committee and discussed with the research staff before starting the research program.[133]

The subject signed this *Agreement* knowing that there was no such biohazards committee[134] and no protocols approved by a biohazards committee for his research. He obligated himself by the *Agreement* not to conduct any biohazardous research until a biohazards committee had been created and had approved his activities. By proceeding with his research in the absence of such oversight, he violated his *Agreement* with the cell repository[135] and his broader responsibility to conduct research in a trustworthy matter.

Although the subject repeatedly committed to complying with standards he knew he could not be meeting, he did take some steps to ensure that the research was conducted in a safe manner. It appears that the subject posted a universal biohazard sign on the door of the multi-user facility (the sign did not specify the infectious agent and was removed by another faculty member), and he placed a P2 label on the biological hood used by his laboratory personnel.[136] He claims to have posted, some time in 1991, a *Laboratory Biosafety Level 2* notice on the room door, that itemized *Standard Practices* and *Special Practices*, and that instructed users to "[r]eport spills and accidents immediately to" him and another scientist.

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[131] *See* Tab 30.

[132] *Id.*

[133] *Id.*

[134] In a 9 December 1991 memo to the Director of ORAD he had called for its "activation." This memo was the subject of some debate within the HIV Investigation Committee, see Tab 2, pp. 24-25.

[135] This view is consistent with the University's findings on this issue. HIV Investigation Report, p. 14.

[136] The Multi-user Facility Director 2 removed the sign. He told us that he "didn't see P2 instructions, but saw (and took down) sign on door of 304D identifying 304D as a P2 facility; [the Multi-user Facility Director 2] took the sign down (this was after May 92) and threw it out, because he saw no reason to call it a P2 facility; doesn't recall sign on hood for P2." Tab 17, 16 October 1996 affidavit of the Multi-user Facility Director 2, p. 2. He did not inquire who had posted the sign or why.

And as part of the BSC's much-delayed effort to implement the Vice Provost's instructions for it to review biosafety matters, the subject provided it with a draft of a biosafety manual, which he subsequently revised and circulated to the committee.

Assessment of the Subject's Responsibility

Between December 1990 and February 1993, the subject permitted research to be conducted that violated the commitments he made in order to obtain biohazardous materials. His acquisition agreements with the AIDS Program and from the Cell Repository obligated him to take those steps necessary to ensure the safety of his colleagues and oversight by the University. He knew there was no credible oversight over his research and that no biosafety manual or institutional biosafety standards existed at the University. The MMWR—which he agreed to abide by to obtain materials from the AIDS Program—states that the "laboratory director . . . is responsible for carrying out the biosafety program in the laboratory"[137] and also specifies institutional responsibilities. The cell repository agreement he signed incorporated *Minimum Safety Guidelines* stating that there should be an institutional biohazards committee, and that his protocols should be approved by it before he began his research. By certifying on the AIDS Program and cell repository forms he committed himself, ethically and professionally, to University oversight with regard to his research. When he made these commitments with full knowledge that he would not—indeed, could not—comply with them, the subject violated his professional ethical responsibilities.

When asked why he had submitted his NSF proposals without a biosafety review, the subject said he felt that BSC review

> was unnecessary due to the nature of the activity . . . [I] felt [I] only had to declare rDNA [and] the university ha[d] the responsibility to apply those rules to the proposal.[138]

He said that he had asked the Director of ORAD and the Vice Provost about the BSC in 1991 and he "thought they had to set up the committee" to provide oversight, and that his proposal would be approved before the work was started.[139] He asserted that he

> did the best he could in that environment; since the [BSC] didn't exist, he went ahead without it, since otherwise he couldn't have gotten his research program started and could facilitate tenure because it's not REQUIRED at [the University] (as [the subject] understood). [He] was interested in science only. [He] looked out for safety . . . but he was only one person, and couldn't change things single handedly; if [he] had seen anything wrong in terms of risk, he

[137] MMWR, Vol. 37/Number S-4, p. 5.

[138] Tab 5, 17 October 1996 affidavit of the subject, p. 2.

[139] *Id.* He noted that this same proposal (ultimately [redacted] had been reviewed and considered exempt from the rDNA *Guidelines* by his former institution's BSC.

would have stopped. [He] underst[oo]d that it wasn't desirable for [the] PI to be responsible for oversight on his own grants; tried not to make too many waves being the new guy, and felt that even if he tried it wouldn't achieve anything.[140]

The commitments the subject made to conduct his research with University oversight and consistent with University policies required him to coordinate his work with University officials and ensure University involvement in oversight of the research. In our view, the difficulties he may have encountered in obtaining this oversight or determining if policies existed did not relieve him of these responsibilities.

Use of Research and Education for Undergraduates (REU) Funds

As described in Appendix 12, the subject received $5,000 to support an undergraduate student.[141] The University spent these funds. However, when we asked the University for financial documentation, it said no undergraduate had been employed. The University was unable to provide further detail about how these funds were spent. We believe the expenditure of these funds on efforts other than an REU student is unacceptable and the University should reimburse NSF for that amount.

OIG Findings

We believe this case involves a serious, long-term, systemic breakdown in the administration of the University's oversight responsibilities and an abrogation of the subject's ethical responsibilities and commitments for the safe conduct of his research. We believe a preponderance of the evidence supports the conclusions that 1) the University did not provide responsible oversight over NSF-funded research and 2) the subject did not uphold the commitments he made to obtain the biohazardous materials used in his research.

The University

The evidence shows that for years the University maintained an improperly convened, inexperienced BSC that reviewed research projects on an inconsistent basis. The committee members were unevenly aware of its responsibilities and the faculty was unevenly aware of its existence or its charge. The University's efforts, as exhibited by the actions of the administrators and committees with regard to radiation safety, rDNA review, and infectious agents, can be described as casual, at best.[142] We concluded that the University has provided little credible guidance to its researchers about its requirements and expectations in the area of biosafety generally, as well as with regard to the subject's research under his NSF award.

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[140] *Id.* at 2-3.

[141] Ms. [redacted]

[142] Appendix 16 provides a summary of the instances of problematic oversight described in this report.

This finding is supported by the Inquiry Report, which reflected the failure of both the subject and the University to act responsibly. In its HIV Investigation Report, the University, however, ultimately decided to take strong action regarding the subject only, while ignoring its own administrators' failings. The arbitrator reversed the subject's penalty partly in recognition of the University's share of responsibility.

Although many of the events of this case occurred some years ago, we continue to be concerned about the University's understanding and administration of its primary responsibility as the grantee for oversight issues and about the persistence of the attitudes that led to the desultory approach to biosafety review. It has revised some manuals and the *Form* and reconstituted the BSC,[143] but these actions fail to address the sources of the administrative breakdown. The final approval of the *Form* and responsibilities for the oversight committee rest with the Director of ORAD, and for biohazards with the Director of EH&S. No changes in management or supervision were made to correct the significant failures of these individuals to execute their responsibilities.[144]

The University's unbalanced approach to this case—that is, its emphasis on the subject's failings to the exclusion of its own—also concerns us.[145] When we asked about this, the Vice President[146] told us that the Vice Provost and the Director of ORAD had been reprimanded.[147] However, when we asked for the supporting documentation from the University's files, we were told that their personnel files did not contain any "records of any disciplinary action against either individual because of facts revealed in the case . . . ."[148] At the arbitration hearing, the Director of ORAD denied ever being disciplined as a result of this matter.[149]

NSF has no assurance that the individuals who are in these positions appreciate their responsibilities, or that they can and intend to execute the University's oversight duties. It also has no assurance that the University's training system ensures that its scientists understand their and the University's responsibilities.

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[143] Despite these changes, the BSC was incorrectly constituted at the time of our visit, and continued, in 1997, to have member attendance problems.

[144] In its response, the University said that after the departure of the Director of ORAD in 1998, his replacement, an "internal candidate," began making changes in the procedures and manuals. (Tab 32, p. 2.) It is unclear if these changes will effectively alter the institutional culture.

[145] *See* Appendix 17.

[146] Dr. [redacted] the current University president.

[147] He told us that the Director of ORAD and the Vice Provost "were disciplined ([the Director of ORAD's] compensation was affected i.e. lower rating resulting in lower pay eligibility, [the Vice Provost] has received no pay increase and has resigned (negotiation; his performance as a factor in his resignation) effective 1-1-97); their performance reviews reflect statements re: their management of process and the policies, but not this case specifically; it was [the Vice Provost's and the Director of ORAD's] responsibility to oversee the oversight committees; discipline reflected their performance in this regard." Tab 18, 18 October 1996 affidavit of the University Vice President, p. 2.

[148] 21 March 1997 memo from the Acting Associate Vice President for Academic Affairs.

[149] [redacted]

The Subject

The subject justified his actions on the basis of expedience: he did what he had to do, so he could obtain sufficient results to obtain tenure. It is unacceptable to place one's career ambitions ahead of the safety of others. Such motivations cannot justify conducting biohazardous research in the absence of proper oversight.

Actions that have the real potential of jeopardizing the physical safety of others are undoubtedly among the most serious. Despite promises to the contrary, the subject proceeded with biohazardous research despite what he knew to be inadequate oversight. His belief that his interest in conducting the research outweighed these safety concerns and that he could provide oversight of his own research is of equal concern.

While we believe the subject's actions are not consistent with accepted practices in the scientific community, we also believe that the University's lack of administrative structure and support for biohazardous research cannot be ignored when considering the severity of his actions. This case would simply not have arisen at a university that carefully managed its safety issues and provided the necessary oversight. In such circumstances the subject's actions and failures to fulfill his express commitments would be a serious deviation from accepted practices. Here, there was no accepted practice, and while the evidence supports the conclusion that the subject continued his biohazardous research despite his knowledge that there was no administrative oversight, he was not completely remiss. He did take some actions to ensure the safe conduct of the research in the extant environment. We therefore concluded that the subject's and University's actions do not rise to the level of misconduct in science.

OIG's Recommended Disposition

As a final disposition of this case, although we do not recommend a misconduct finding, we recommend that NSF take the following remedial actions to ensure that biohazardous research is conducted at the University in a way that protects public safety, educates the University community about its responsibilities, and builds public confidence that that biohazardous research at the University is administered effectively:

1. Send the University a letter describing its expectations for the safe conduct of biohazardous research and the need for effective oversight of potentially dangerous research by competent university administrators.

2. Require the University to ensure that its review and oversight procedures are consistent with those of other institutions. To accomplish this, the University should consult with and seek the advice of other institutions' committees or administrations that have successful safety processes and review and approval procedures. The University should submit a report on its efforts to NSF, and provide a copy to NSF's Office of Inspector

General. The report should include descriptions of its processes for ensuring and providing oversight and review. It should describe the qualifications of the administrators and committee members appointed to manage these processes. NSF should determine whether the report adequately addressed the problems described in this report and whether the University's plan and personnel can adequately protect public safety.[150]

Until the report is approved by NSF, NSF should require the University to submit documentation with any proposal submitted to NSF that describes whether the project was required to be reviewed by a safety committee, and, if required, shows that the project has been approved by that committee. Copies of the documentation and approvals (and the rationale for the approvals) are to be submitted to NSF with copies to NSF's Office of Inspector General.[151]

Alternatively, if the University determines that the magnitude of the required remedial effort is disproportionate to the funding the University receives for biohazardous research, the University may decide that it is not cost effective to comply with the requirements specified above to conform with federal expectations for safely conducting biohazardous research . If the University decides that it is unable or unwilling to comply with these requirements, the University should immediately: (a) inform NSF of its decision; (b) cease conducting biohazardous research; and (c) no longer apply for further federal funding in this area.

3. Require the University to reimburse NSF for $5,000 in REU funds that were not spent as intended.

We also concluded that the subject violated the commitments he made in order to obtain biohazardous materials. We recommend that NSF take the following actions with regard to the subject to ensure that his biohazardous research is conducted in a manner that protects public safety and ensures University oversight:

1. Send the subject a letter describing NSF's expectations for the safe conduct of biohazardous research and the need for coordinating potentially dangerous research with university administrators. NSF should explain that, had the subject committed the same acts at a university with responsible oversight, it would consider his actions to be misconduct in science.

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[150] We noted that the University received funding from several federal agencies including, the National Institutes of Health, the Department of Agriculture, and NSF, for potentially biohazardous research.

[151] The University requested that this documentation contain particular wording and it be limited to a paragraph that does not indicate it is prompted by this report. (Tab 32, p. 7.) We believe that this paragraph should contain sufficient information for a program officer to assess whether the review sufficiently considered the relevant issues and the Committee arrived at a reasonable judgment given the facilities, capabilities of the investigator, and the planned oversight program.

2. Require that, in connection with any NSF-supported activity, the subject submit copies of any representations or promises he has made in order to obtain biohazardous materials. He should accompany those documents with a written description of his plan for complying with them. These materials should be sent to the NSF program supporting the subject's research, with copies provided to NSF's Office of Inspector General.[152]

3. Require as part of the conditions of any NSF-supported activity, that the subject describe, in every progress report, the steps he has taken, and will continue to take, to ensure that proper notification of his research and its hazard potential is posted, and that his research has received the proper oversight. This requirement should be in effect for 3 years from the final disposition of this case.

The University's and the Subject's Responses to the Draft Report

In April 1999, we received the University's response to our draft report (Tab 32). We have modified the final report to address the University's comments. These modifications are found in footnotes 13, 15, 16, 22, 33, 44, 60, 65, 80, 98, 129, 144, 151, and 152. We have modified the text of the report to emphasize our focus on describing systemic breakdowns at the University and its need to provide NSF with documentation to show not just that forms, manuals, and procedures have changed but that these have prompted the necessary cultural changes in the administration and faculty to ensure that such problems will not arise in the future.

Our modifications have not changed the substance of the report. We are concerned that the University's response shows a remarkable lack of progress in the 5 years that have passed since this case began. It reinforced our view that NSF must take action to ensure that biohazardous research conducted at this institution with NSF funds is routinely reviewed carefully and monitored.

In March 1999, we received the subject's first response to our draft report. (Tab 33.) We did not find his response to be supported by the evidence he provided or the case materials. We therefore asked him to provide supporting documentation supporting his assertions that:

1) University officials approved room 304D as a P2/BSL2 facility;
2) appropriate University officials approved his HIS/SIV, polio, and/or sewage sample research; and

[152] In its response the University requested that the subject be required to provide the documentation described in points 2 and 3 to it. We believe that such communication should be part of a healthy institutional biohazard oversight and review process.. The University's request is reasonable, but it should be uniformly applied by the University to all researchers conducting similar research and not applied exclusively to the subject. Therefore, we have not modified our recommendations, but encourage the University to consider instituting processes it believes will provide it with sufficient information to construct and maintain a credible review and oversight process.

3) his projects received contemporaneous active oversight from qualified University officials. (Tab 34.)

We received his second response in May 1999. (Tab 35.) We have attached copies of the documents and included in Appendix 18 our evaluation of these documents. The documents he supplied did not support his assertions, and many of them were dated and described events occurring after the February 1993 allegations surfaced. We concluded that the documents he provided did not demonstrate the existence of the continuing, active institutional oversight of his biohazardous research that was required by the certifications and promises he made.

In support of his first assertion, the subject said the department chairman's assignment of laboratory space, resolution of space disputes, and management of the Multiuser Facility were indicative of the department chairman's approval of the use of the room for his biohazardous research. (Tab 34, p. 2.) However, none of these management activities by the department chairman can reasonably be construed as constituting the review, approval, and oversight that the subject knew to be required.

The subject also said his first assertion was supported by the University's review that preceding its authorization of his purchases from the AIDS Research and Reference Reagent Program, and that the review demonstrated an awareness of the biohazard issues associated with the subject's HIV/SIV research. (Tab 35, p. 3.) In fact, they reflect only an awareness of the hazards associated with the transformed but non-infected cell lines. The University did not review his subsequent purchases of HIV and SIV, or their use in the Multiuser facility.

Finally, in support of his first assertion, he said the biosafety committee reviewed his HIV/SIV research and the facility. (Tab 35, p. 3.) However, none of the documents provided by the subject show any review or approval of his intended use of the Multiuser Facility.

In support of his second assertion, the subject said the department chairperson knew of his research and allowed him and others to use the Multiuser facility for BSL2 research. (Tab 35, p. 3.) Again, he did not provide *any* documentation to show that University officials responsible for providing the review, approval, and oversight of his HIS/SIV, polio, and/or sewage sample research had done so. The department chairman's authority does not extend to superseding or substituting for that review, approval, and oversight.

In support of his third assertion, he said the department chairman, the Multiuser Facility Directors, the Biology Stockroom manager and his technician, the SLO, the Director of ORAD, the EH&S Director, and the Director of Risk Management were involved in the oversight of his research. (Tab 35, p. 4) This is not credible. The Multiuser Facility Director who removed the biohazard sign said he did not know why it was on the door, the

stockroom employees are not qualified to provide oversight, and the Directors of ORAD, EH&S and Risk Management, uniformly dispute his assertion. Notably absent from this list are the members of the biosafety committee whose involvement he guaranteed by his certifications and promises. We note that he included the SLO as a member of the Biosafety Committee. The SLO denied providing such oversight and had asked to be removed from the chairmanship position because he believed he was unqualified. Again, the subject was unable to provide any document or testimony that demonstrated that his projects received contemporaneous active oversight by qualified University officials.

The subject noted in his response the roles of Director of ORAD in reviewing of his proposals and participating in biosafety committee meetings and the EH&S Director in assuring compliance with OSHA regulation. The materials provided by the subject and his remarks only reinforce our view that this University has systemic problems associated with oversight and that NSF needs to take action to ensure that research it funds is responsibly administered and that its PIs fulfill their promises and commitments.