



NATIONAL SCIENCE FOUNDATION  
OFFICE OF INSPECTOR GENERAL  
OFFICE OF INVESTIGATIONS

## CLOSEOUT MEMORANDUM

Case Number: I01070015

Page 1 of 1

The OIG received a call from NSF's Animal Care representative referencing the application for a Single Project Assurance (SPA) from a university for a pending proposal. The NSF representative noted that the university had an active award with animal experimentation but that NSF had not approved an SPA.

After conducting a site visit, interviewing university officials and the principal investigator for the grant and touring the facility housing the animals being used at the University, OIG wrote its report of investigation which did not reach a misconduct in research finding. However, our report made several recommendations to both the University and NSF.

The University and the agency accepted most of the recommendations from the OIG. On 24 January 2003, NSF sent a letter to the University outlining the remedial actions being taken to ensure that the University is complying with NSF regulations. These remedial actions are in effect for the two current grants until further notice.

Accordingly, this case is closed.

	Agent	Attorney	Supervisor	AIGI
Sign / date				

**National Science Foundation  
Office of Inspector General**



**Review of A Violation of Vertebrate Animal Research Requirements**

**01 April 2002**

A. Recommendations for Oversight of Vertebrate Animal Research at [redacted] University

Introduction

On October 10, 1999, [redacted] reviewed, approved and submitted to the National Science Foundation (NSF) a false certification<sup>1</sup> in connection with proposal [redacted].<sup>2</sup> The certification stated that [redacted] was in compliance with the applicable laws for use of animals in research (Animal Welfare Act [7 U.S.C. 2131] and the regulations promulgated thereunder by the US Secretary of Agriculture [9 C.F.R. 1.1-4.11]).

Specifically, [redacted] stated that it had a functioning Institutional Animal Care and Use Committee (IACUC) and that the IACUC reviewed and approved the proposed work of Principal Investigator (PI) Dr. [redacted] Associate Professor for [redacted]. Based on the evidence gathered during this investigation, we determined that [redacted] knowingly falsely certified to NSF that it was in compliance with the laws applicable to the use of animals in research.

Basis for Determination of False Certifications

OIG was contacted by Dr. [redacted], the NSF representative to the Interagency Research Animal Committee (IRAC) and the NSF Animal Welfare Officer, and informed that there was a pending proposal<sup>3</sup> from [redacted] that would require establishment of a special project assurance between the NSF and [redacted]. In the process of reviewing this proposal, which had been recommended for an award, Dr. [redacted] found there was a 1999 NSF grant<sup>4</sup> to [redacted] that proposed animal experimentation for which [redacted] apparently did not have the required approved special project assurance. In agreement with OIG, the NSF program officer,<sup>5</sup> and Dr. [redacted], NSF's Division of Grants and Agreements (DGA) suspended the conduct of any animal research under the 1999 award and did not approve the new award until [redacted] complied with the laws applicable to the use of animals in research and documented to NSF its compliance.<sup>6</sup>

NSF policy requires a special project assurance<sup>7</sup> for research using vertebrate animals when the grantee does not have a general assurance<sup>8</sup> on file with PHS. A special project assurance generally covers one project and is issued by the agency funding the project.

<sup>1</sup> Attachment 1 - Assurance submitted by [redacted]

<sup>2</sup> [redacted]

<sup>3</sup> [redacted] Principal Investigator, Dr. [redacted], co-Principal Investigators [redacted] entitled "[redacted]"

requests [redacted] in funding.

<sup>4</sup> [redacted] Principal Investigator, Dr. [redacted], co-Principal Investigators, [redacted] and [redacted] entitled "[redacted]"

Biology." It was funded for \$1 [redacted] December 2, 1999, with an effective date of July 1, 2000.

<sup>5</sup> Dr. [redacted] managing Program Director,

<sup>6</sup> Attachment 2 - Letter of suspension from [redacted] Branch Chief, Division of Grants and Agreements, NSF.

<sup>7</sup> Grant Policy Manual, Chapter VII § 713c "Before a grant involving the use of vertebrate animals in either field or laboratory activities can be made, NSF must receive a statement that the proposed activity has been reviewed and approved by the appropriate Institutional Animal Care and Use Committee (IACUC) at the grantee organization, and that the grantee has an approved Animal Welfare assurance with the Public Health Service (PHS) that assures

In addition to its failure to secure a special project assurance with the 1999 award and the false certification, \_\_\_\_\_ did not oversee the conduct of the 1999 grant and ensure adherence to the award conditions.<sup>9</sup> First, \_\_\_\_\_ permitted Dr. \_\_\_\_\_, the principal investigator on the 1999 grant, to also serve as the Chair of the Institutional Animal Care and Use Committee (IACUC) that authorized the submission of the certification on Dr. \_\_\_\_\_'s research proposal. Dr. \_\_\_\_\_'s position as PI and chair of the IACUC created an unacceptable conflict of interests when he provided oversight and approval for his own research with vertebrate animals.

Second, \_\_\_\_\_ certified<sup>10</sup> for \_\_\_\_\_ that "[t]his institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals." In fact, there was no IACUC or inspected animal care facility at the time it submitted the certification. \_\_\_\_\_ completed construction of the Animal Care Facility in September 2000, well after it filed the certification for \_\_\_\_\_ on October 25, 1999. Further, at the time of our review (two years after the submission of the 1999 grant), \_\_\_\_\_ still did not have a functioning IACUC. \_\_\_\_\_ violated GC-1, Article 29<sup>11</sup> by filing its false certification.

In consultation with NSF program management, grant officials, and NSF's Animal Welfare Officer, NSF decided that the best course of action would be to suspend any vertebrate animal research supported by the 1999 grant. Our office visited the University to gain an understanding of how best to resolve the issues outlined above. On July 10-11, 2001, OIG staff interviewed key \_\_\_\_\_ administration and faculty members, including the principal investigators on the 1999 grant. We confirmed that the certification was false, and that at the time the certification was submitted, there was no inspected facility to house animals or approved

---

NSF that it will comply with the PHS *Policy on Human Care and Use of Laboratory Animals*. . . . Applications from organizations not having a general assurance on file with the PHS will be reviewed first for scientific merit. If a decision to support the proposal is reached, NSF will make every effort to arrange for a special assurance to be negotiated." A special project assurance is given to a university that does not have a general assurance on file with PHS. This special project assurance is negotiated with NSF's Animal Welfare Officer and the grantee's Authorized Organizational Representative (AOR).

<sup>8</sup> A general assurance can be provided when an institution is carrying out two or more projects dealing with the same kind of research. The assurance covers all projects funded by the federal government while that assurance is current.

<sup>9</sup> Grant General Conditions, Article 1 states: "The awardee has full responsibility for the conduct of the project or activity supported under this award and for adherence to the award conditions. Although the awardee is encouraged to seek the advice and opinion of NSF on special problems that may arise, such advice does not diminish the awardees responsibility for making sound scientific and administrative judgments and should not imply that the responsibility for operating decisions has shifted to NSF." October 1998

<sup>10</sup> The certification was signed by Dr. \_\_\_\_\_, IACUC Chair, Dr. \_\_\_\_\_, IACUC member, and \_\_\_\_\_, IACUC member.

<sup>11</sup> Grant General Conditions, Article 29 (October 1998) states: "Any awardee performing research on vertebrate animals shall comply with the Animal Welfare Act [7 U.S.C. 2131 et seq.] and the regulations promulgated thereunder by the Secretary of Agriculture [9 CFR, 1.1-4.11] pertaining to the humane care, handling, and treatment of vertebrate animals held or used for research, teaching or other activities supported by Federal awards. The awardee is expected to ensure that the guidelines described in the National Academy of Science (NAS) Publication, "*Guide for the Care and Use of Laboratory Animals*" (1996) are followed and to comply with the Public Health Service Policy and Government Principles Regarding the Care and Use of Animal (included as Appendix D to the NAS Guide)."

protocols for care of the animals. Nevertheless, the PI, Dr. \_\_\_\_\_ purchased mice and was housing them in the newly constructed facility on campus. He explained that he intended to develop the necessary protocols to take care of vertebrate animals with these mice. He had placed himself in the untenable position of preparing to experiment with animals to develop protocols that he needed IACUC approval for before he could experiment. Approval of such protocols is a major part of the animal care and use certifications.

We also met with Dr. J \_\_\_\_\_ Executive Vice President and Provost at \_\_\_\_\_ who explained that in his previous position as Director of the Office of Grants, Contracts and Sponsored Research at \_\_\_\_\_ he was the Assurance Officer for the Institutional Animal Care and Use Committee.<sup>12</sup> Before becoming the Executive Vice President and Provost at \_\_\_\_\_, Dr. \_\_\_\_\_ was \_\_\_\_\_ Dean of the College of \_\_\_\_\_ and Acting Provost. As \_\_\_\_\_ Provost, \_\_\_\_\_ mentioned that he "continues to consistently encourage faculty to develop proposals to government sponsoring agencies to be in close contact with program directors from those agencies and to be in full compliance with relevant agency regulations and guidelines."<sup>13</sup>

If \_\_\_\_\_ had been in contact with NSF, it could have availed itself of any of several avenues to develop the necessary animal research procedures. First, \_\_\_\_\_ could have followed the guidance in NSF's Grant Policy Manual (GPM Chapter VII § 713c) and sought NSF's assistance in developing an approved Animal Care and Use program. Alternatively, if \_\_\_\_\_ did not want to establish its own IACUC, it could have sought assistance of a nearby institution. Although \_\_\_\_\_ claims it had spoken with the managing NSF Program Director<sup>14</sup> in 1999 regarding the expected animal use in the research, we can neither find any evidence of nor have we been provided any evidence to support that claim.<sup>15</sup>

Finally, \_\_\_\_\_ could have submitted a completed special project assurance to the managing NSF program. NSF's approval of this special project assurance would have established a mechanism for handling the funded animal research on the campus. \_\_\_\_\_ did eventually submit a completed special project assurance to the NSF Animal Welfare Officer for approval.<sup>16</sup>

Since OIG's visit, \_\_\_\_\_ officials have sought to comply with NSF regulations. Throughout this period, the award remained suspended. The University had difficulty

<sup>12</sup> Attachment 3 - Dr. \_\_\_\_\_ also served as Director of the Office of Research and Academic Development at \_\_\_\_\_. In that position, he was responsible for the management of research and oversight and compliance review programs. The systemic failures of this oversight are described in OIG's previous investigation involving \_\_\_\_\_, OIG Case # \_\_\_\_\_. As a result of that investigation, NSF imposed remedial actions on the University to ensure that it receives proposals that had received appropriate oversight.

<sup>13</sup> Attachment 4 - Page 1 of August 3, 2001, affidavit from Dr. \_\_\_\_\_ Executive Vice President and Provost.

<sup>14</sup> Dr. \_\_\_\_\_, former managing Program Director, ( \_\_\_\_\_ Program.

<sup>15</sup> We note that in connection with the \_\_\_\_\_ proposal, LSSU did contact NSF about animal care issues but it failed to alert NSF to the 1999 grant that did not have approved animal care and use protocols.

<sup>16</sup> Attachment 5 - Assurance of Compliance with NSF Requirements on Humane Care and Use of Vertebrate Animals, approved October 15, 2001, by Dr. \_\_\_\_\_.

identifying a veterinarian that met the guidelines for IACUC membership.<sup>17</sup> It also had problems setting up an IACUC meeting to approve the proposed work and get the full assurance completed to meet NSF requirements. Nevertheless, the university has now succeeded in creating a functioning IACUC, had a facilities inspection, and submitted a special project assurance for approval by the NSF Animal Welfare Officer. NSF reinstated the 1999 award on October 18, 2001.

In the process of reviewing and resolving this matter, we worked closely with the Division of Grants and Agreements, the NSF Animal Welfare Officer, and NSF program management. With their concurrence, we recommend the following requirements be implemented in addition to those already in effect. We believe these additional requirements should be incorporated into relevant awards made to \_\_\_\_\_ for a period of 3 years.

### Recommendations

1. In conjunction with each proposal involving research with vertebrate animals, \_\_\_\_\_ should provide a statement that it has:
  - a. a formal mechanism for assuring compliance with relevant federal regulations, and
  - b. trained faculty and staff that are responsible for the administration and conduct of federal grants.
2. During the life of the two awards, \_\_\_\_\_ should provide annual follow-up reports to NSF as part of the annual project report required by Section VII.A. of the Animal Welfare Assurance:
  - a. detailing actions it has taken in connection with NSF supported vertebrate animal research,
  - b. describing its efforts to ensure that the requirements of Grant Policy Manual § 713 and Grant General Conditions § 28 (April 2001) have been fulfilled, and
  - c. describing the results of any state or federal agency inspection of its facilities and its responses to any recommendations made in connection with those inspections.

In response to our report for comments, the University agreed to abide by our recommendations,

---

<sup>17</sup> 9 CFR § 2.31(b) IACUC Membership "(1) The members of each Committee shall be appointed by the Chief Executive Officer of the research facility; (2) The Committee shall be composed of a Chairman and at least two additional members; (3) Of the members of the Committee: (i) At least one shall be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility; (ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals; (4) if the Committee consists of more than three members, not more than three members shall be from the same administrative unit of the facility."

but did not agree with the report findings.<sup>18</sup> We contacted the Executive Vice President and Provost who provided no further information about the University's position. We are therefore forwarding this report and recommendations for NSF review without revision.

---

<sup>18</sup> Attachment 6 - I

response to report.

**B. Recommendations on NSF's Process for the Review and Approval of Special Vertebrate Animal Research Project Assurances**

NSF's expectations regarding the review and approval of vertebrate animal research are found in the Grant Policy Manual, the terms and conditions accompanying each award, the Grant Proposal Guide, and the Proposal and Award Manual. Although these documents generally speak to different audiences, they reflect the same policy. NSF's policy relies on the Animal Welfare Act, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the National Academy of Sciences' *Guide for the Care and Use of Laboratory Animals*. Specifically, institutions are expected to review the applicable rules and obtain approval for vertebrate animal research through the institution's Institutional Animal Care and Use Committee (IACUC).

Institutions that conduct projects involving vertebrate animal research funded by the NIH are expected to have a general assurance on file with OLAW. Those that do not have a general assurance but wish to conduct such research are expected to work with the funding agency to execute a special project assurance, or to work with another institution to take responsibility for approval AND monitoring. The general or special project assurance must be approved and in place BEFORE any research using vertebrate animals can be conducted.

If an organization notifies an NSF program officer that they need a special project assurance, that program officer then:

For those awardee organizations that have no general assurance on file with the Office of Laboratory Animal Welfare (OLAW) (small colleges or small businesses, for example), the Program Officer must initiate procedures for the preparation of a special assurance acceptable to NSF before an award can be made. This should be initiated only after review for scientific merit has been performed and an award recommendation is likely. The arrangements for a special assurance should be undertaken in consultation with the NSF representative to the Interagency Research Animal Committee (IRAC) and will be handled on a case-by-case basis.<sup>19</sup>

The NSF Proposal and Award Manual and the Grant Policy Manual do not provide sufficient information to program officers, grants officials, and the NSF's Animal Welfare Officer (AWO)<sup>20</sup> to provide guidance on assessing special project assurances or the need for them. NSF policy does not require the AWO to consult with legal, policy or ethics officials within the agency nor does it identify those individuals. We are aware that NSF officials are available to consult with the AWO, if the AWO determines it's necessary. However informally consultations may lead to misunderstanding as staffing for these positions changes occur.

NSF currently has such a structure and guidance for the review and approval of human subject research assurances. When a grantee organization proposes to conduct nonexempt

<sup>19</sup> PAM Chapter VII.B.2.b(3).

<sup>20</sup> The AWO is the NSF representative to IRAC, currently Dr. Directorate

, Program Officer, Division of



human subject research, NSF expects that it will have an Institutional Review Board (IRB) in conformance with the Common Rule for the protection of human subjects. Generally, institutions that conduct human subject research will have a Multiple Project Assurance (MPA) on file with DHHS' Office of Human Research Protections. If an institution does not have an MPA, NSF recommends that it contact a nearby organization with a valid MPA and arrange for that organization's IRB to review and approve proposals that contain human subject research. If an organization cannot make such arrangements, NSF explains that NSF:

may constitute an ad hoc panel to review the proposal and give a Single Project Assurance (SPA) for that project. This panel will be convened and chaired by the NSF Human Subjects Coordinator and will include the relevant Program Officer and at least three additional persons chosen from the following groups:

- A representative of the Office of the General Counsel (OGC);
- A representative of DGA;
- A representative of the Policy Office (BFA); or
- the NSF Program Officer for Ethics and Value Studies.<sup>21</sup>

This staffing structure provides legal, technical, and policy support for the review and approval of SPAs. Unlike the SPA process for research on human subjects, where NSF serves as the IRB for a specific human subjects project, the process for establishing an SPA for vertebrate animal research does not require review and approval of the research by NSF's AWO. The AWO ensures only that a properly convened IACUC committee is in place at an institution. Although the institutional IACUC decides whether to approve the project, NSF's AWO should have the same legal, technical, and policy support in approving specific project assurances as does NSF's Human Subjects Coordinator.

### Recommendations

We recommend that NSF:

1. Revise its procedures and staffing structure for reviewing special assurances for vertebrate animal research to ensure that the special assurances comply with technical, legal, and policy requirements.
2. Provide more extensive vertebrate animal research-training program for new program officers as well as provide regular updates or protocol refreshers for permanent staff.
3. Ensure that NSF programs have instituted mechanisms to protect the interests of NSF (we note in this context that the first award to \_\_\_\_\_ was awarded without the necessary SPA). For example, every six months management should review programs that support vertebrate animal research to ensure that each award is accompanied by the appropriate documentation.

---

<sup>21</sup> PAM Chapter VII.A.4.c.(3)

NATIONAL SCIENCE FOUNDATION  
4201 WILSON BOULEVARD  
ARLINGTON, VIRGINIA 22230

January 24, 2003

Dr. \_\_\_\_\_  
Executive Vice President and Provost

Re: NSF Grants \_\_\_\_\_ and \_\_\_\_\_

Dear Dr. \_\_\_\_\_

While the NSF Office of the Inspector General's Report dated April 1, 2002, does not contain a finding of misconduct in science against the University, NSF has decided to take the following remedial actions concerning the University (Part I) and the two current grants referenced above that involve vertebrate animals research (Part II).

- I. In conjunction with each proposal involving research with vertebrate animals, \_\_\_\_\_ is required to provide a statement that it has:
  - a. A formal mechanism for assuring compliance with relevant federal regulations, and
  - b. Trained faculty and staff that are responsible for the administration and conduct of federal grants.
  
- II. During the life of the two awards referenced above, \_\_\_\_\_ is required to provide annual follow-up reports to NSF based on the annual report required by Section VII.A of the Animal Welfare Assurance:
  - a. Detailing actions it has taken in connection with NSF supported vertebrate animals research,
  - b. Describing its efforts to ensure that the requirements of Grant Policy Manual, Section 713, and Grant General Conditions, Article 29 (July 2002), have been fulfilled, and
  - c. Describing the results of any state or federal agency inspection of its facilities and its responses to any recommendations made in connection with those inspections.

In addition, \_\_\_\_\_ must be in compliance with the NSF Grants Policy Manual, Section 713 "Animal Welfare Requirements". In accordance with Section 713, the grantee is responsible for having a project, involving the use of vertebrate animals, approved by an IACUC established through a multi-project assurance with the Office of Laboratory Animal Welfare of the NIH, or through a single-project assurance approved by the NSF. Any future awards to \_\_\_\_\_ will require new assurances, and the approvals must be in place before the issuance of the awards.

All of the documents described above, that need to be submitted to the NSF, should be sent to the attention of Dr. \_\_\_\_\_ the NSF Animal Welfare Officer.

The remedial actions in Part I will be in effect until further notice. The actions required in Part II would be in effect as long as the grants have not expired. Please advise the appropriate University departments and officials affected by this action. Thank you for your continued cooperation.

Sincerely,

Grants Officer  
Division of Grants and Agreements

Cc: \_\_\_\_\_, NSF Animal Welfare Officer