

**CLOSEOUT FOR M92010005**

This case was brought to OIG on October 9, 1991, when Dr. [REDACTED], Associate Provost for Research at [REDACTED] University, informed us that the university was initiating an investigation of alleged misconduct by [REDACTED]. Attached are the OIG investigation report, including its appendices and the letter of reprimand from NSF to the subject, which explains NSF's adjudicative decision. These documents explain the actions subsequently taken by OIG and NSF in this case.

cc: Deputy AIG-O, IG

NATIONAL SCIENCE FOUNDATION  
4201 WILSON BOULEVARD  
ARLINGTON, VIRGINIA 22230



OFFICE OF THE  
ASSISTANT DIRECTOR  
BIOLOGICAL SCIENCES

CERTIFIED MAIL -- RETURN RECEIPT REQUESTED

[REDACTED]  
[REDACTED]  
[REDACTED]

Re: Notice of Misconduct Determination

Dear Dr. [REDACTED]

The National Science Foundation's Office of Inspector General (OIG) issued an Investigation Report on June 28, 1995, in which it found that you committed misconduct in science. Based upon investigations conducted by the Special Review Board and the Institutional Review Board (IRB) of the [REDACTED] University, and its own independent investigation, the OIG found that you committed serious violations of the requirements for the protection of human subjects. We have reviewed the report and conclude that you have committed misconduct in science.

Misconduct and Proposed Action

Under NSF's misconduct in science and engineering regulations, "misconduct" is defined to include "fabrication, falsification, plagiarism, or other serious deviations from accepted practices in proposing, carrying out or reporting results from activities funded by NSF." 45 CFR §689.1(a).

The Agency's administrative record establishes that you failed to comply with the IRB guidelines by failing to respond to the IRB's requests for consent and assent forms, failing to pay research participants as promised, and failing to obtain consent from a school system to perform research on their students. You violated the usual and customary practices for treating human subjects. This constitutes a serious deviation from accepted practices for the treatment of human subjects, and, therefore, scientific misconduct.

NSF's regulations establish three categories of actions (Group I, II and III) that can be taken in response to a finding of misconduct. 45 CFR §689.2(a). Group I actions include issuing a letter of reprimand; conditioning awards on prior approval of particular activities from NSF; and requiring certification on the accuracy of reports or assurances of compliance with particular requirements. 45 CFR §689.2(a)(1). Group II actions include

Dr. [REDACTED]  
Page 2

restrictions on designated activities or expenditures and special reviews of requests for funding. 45 CFR §689.2(a)(2). Group III actions include suspension or termination of awards; debarment or suspension from participation in NSF programs, and prohibitions on participation as NSF reviewers, advisors, or consultants. 45 CFR §689.2(a)(3).

In deciding what response is appropriate, NSF considered the seriousness of the misconduct; whether it was deliberate or careless; whether it was an isolated event or part of a pattern; and whether the misconduct affects only certain funding requests or has implications for any application for funding involving the subject of the misconduct finding. See 45 CFR §689.2(b).

In this case, we do not believe that your failure to pay research participants was a pattern of non-payment. However, the record demonstrates that your failure to comply with the IRB requirements for protection of human subjects was part of a pattern of non-compliance with NSF grant conditions. You violated NSF grant conditions by using NSF funds to perform research other than that proposed to NSF, misusing funds that were allocated for payment of research participants, failing to secure the safekeeping or return of University owned equipment purchased under the NSF grant, and failing to cooperate with [REDACTED] Special Review Board and IRB inquiries and investigations concerning your activities.

Based upon the above facts, I conclude that as a condition to your receipt of future NSF funds, special grant conditions must be implemented to protect NSF's interests as well as those of human subjects. Accordingly, I will require, until January 1, 1998, that NSF, before making an award in which you are named as the principal investigator, shall require the grantee institution to establish and enforce special procedures to monitor your compliance with NSF's grant conditions. These procedures shall, at a minimum, provide for monitoring of your compliance with human subjects research requirements and proper distribution of any federal funds under your direct control. Such procedures must be approved in advance by NSF.

#### Procedures Governing Appeals

Under NSF's regulations, you have 30 days after receipt of this letter to submit an appeal of this decision, in writing, to the Director of the Foundation. 45 CFR §689.9(a). Any appeal should be addressed to the Director of the National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230. For your information we are attaching a copy of the applicable regulations

Dr. [REDACTED]  
Page Three

and of OIG's investigative report. If you have any questions about the foregoing, please call Lawrence Rudolph, General Counsel, at (703) 306-1060.

Sincerely,

*Mary E. Clutter*

Mary E. Clutter  
Assistant Director

Attachments (2)  
Misconduct in Science Regulations  
Investigation Report

## **NSF OIG REPORT**

**OIG Case Number M92010005**

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# REPORT OF INVESTIGATION INTO AN ALLEGATION OF MISCONDUCT IN SCIENCE AND ENGINEERING

## SUMMARY

The Office of Inspector General (OIG) has determined that [REDACTED] (the subject) committed serious violations of human subjects regulations; mishandled funds and equipment that were part of an NSF award; did not, during the time she was receiving NSF support, conduct the research she proposed to NSF; and did not cooperate with inquiries and investigations concerning her activities. These conclusions are based on investigations performed by the subject's former university and by OIG. OIG recommends that NSF find that the subject's violations of human subjects regulations are misconduct and take the following actions as a final disposition in this case. The subject should be told that NSF has made a finding of misconduct and should receive a letter of reprimand from the NSF Office of the Director. Until January, 1998, before making an award in which the subject is named principal investigator, NSF's Office of the Director, in consultation with scientists knowledgeable about research involving human subjects, should require that the grantee institution establish and enforce special procedures to monitor the subject's compliance with NSF's grant conditions, including, but not necessarily limited to, procedures for monitoring her compliance with human subjects regulations at the grantee institution.

## THE UNIVERSITY'S INQUIRY AND INVESTIGATION

Early in 1990, members of at least three families complained to [REDACTED] (the University) that they had been promised payments for their participation in experiments run by Dr. [REDACTED] (the subject) and had not been paid. The subject's experiments were performed under NSF award [REDACTED], entitled [REDACTED]. At the time the complaints were made, the subject was on leave at [REDACTED] (the current institution), where she subsequently accepted a permanent position. After repeated, unsuccessful efforts by officials at the University to verify and settle the participants' claims for payment, the chair of the subject's department referred the matter to the University's Research Integrity Committee, which conducted an inquiry. The committee, in turn, referred the case to a Special Review Board, which conducted an investigation.

A copy of the Board's investigation report appears in Appendix 1. The Board's report contains sixteen appendices, each identified by a letter (A-P). References to numbered appendices

indicate appendices to OIG's investigation report; where appendices are identified by a letter, this indicates that they are appendices to the Special Review Board (the Board) report and can be found in Appendix 1. Quotations in OIG's report, unless otherwise indicated, are from the Special Review Board report or its appendices, and page references refer to that report as well.

The Board report concluded (pages 22-23) that the subject had committed "scientific misconduct"<sup>1</sup> in the following respects:

1. She had "misused funds advanced to her for the purpose of paying human research subjects" and "repeatedly and significantly" violated procedures she and the University had established governing her use of her research checking account.
2. Using grant funds, the subject made an unjustified purchase of video equipment and failed "to secure the safekeeping of the equipment." Although the equipment was University property, the Board could not locate it.
3. The subject "violated the usual and customary requirements for the treatment of human subjects." The Board referred allegations of human subjects violations to the University Institutional Review Board for the Protection of Human Subjects (IRB). The IRB found seven instances in which the subject violated its guidelines. A copy of the IRB report appears in Appendix 2.
4. There was "no evidence" that the subject had performed the research she had proposed to NSF.
5. The subject did not cooperate with the Special Review Board investigation or with other related inquiries, including the IRB inquiry.

The Board's report describes the subject's research and the basis for the Board's findings. It is essential reading for making decisions concerning this case.

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<sup>1</sup>The University's "Policy and Procedures for Review of Alleged Misconduct in Research and/or Scholarship" define "scholarly misconduct" as "fabrication, falsification, plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research [footnote omitted] or (b) material failure to comply with federal, state or other requirements that uniquely relate to the conduct of research or (c) misconduct in science." The university does not define "misconduct in science" or "scientific misconduct" as such.

Because the subject was no longer employed by the University at the time the Special Review Board report was completed, the Board recommended no University action against the subject except that "the General Counsel . . . take the necessary legal action to recover" inappropriately spent funds from the subject. For the same reason, the IRB report recommended no actions against the subject.

The Board also recommended that NSF conduct its own investigation and suggested that NSF might be able to elicit or compel the subject's cooperation. The Board recognized that its own investigation was hampered by the subject's repeated failure to cooperate and noted that, if the subject cooperated with NSF, a more complete description of the facts might be obtained. The Board made the following recommendation (pages 24-25) to NSF:

On the basis of the evidence summarized in this report, the Board suggests imposing two of the sanctions listed in Group I of NSF's misconduct regulations. . . . NSF should (a) send a letter of reprimand to [the subject]; and (b) for some specified period, require as a condition of future awards that an institutional official certify the accuracy of reports generated under the award and provide assurance of [the subject's] compliance with institutional, federal, and professional standards, policies, guidelines, regulations, or special terms and conditions relating to treatment of human subjects (including recruitment, obtaining informed consent, and payment), disbursement of funds, accounting, and maintenance of pertinent records and documents. In addition, on the basis of additional information that may be obtained upon completion of its own investigation, NSF may wish to consider possible sanctions listed in Group III, including debarment of [the subject] from participation in NSF programs for some specified period.

#### OIG'S INVESTIGATION

Two OIG staff members, one of them a Ph.D. behavioral scientist, questioned the subject concerning the findings in the Special Review Board and IRB reports. The subject provided OIG with a sworn statement concerning her activities under her NSF award. A copy of this statement appears in Appendix 3. OIG's scientist also accompanied the subject to her office at her current institution, where the two of them searched for records bearing on



her activities under her NSF award.<sup>2</sup> OIG also audited the university's expenditures under the subject's NSF award. A copy of the audit report appears in Appendix 4.

In order to understand the evidence bearing on the university's conclusions in this case, it is important to understand the subject's research activities in 1989 (when she was at her former university) and early 1990 (after she had moved, in early January, to her new institution). During this period, the subject either was or claims to have been engaged in data collection for the following studies:

1. [REDACTED] study. This is the study design that the subject proposed to NSF. It is the only study design that NSF agreed to fund. It involved interviewing members of one hundred families with two parents and two adolescent children.
2. [REDACTED]. This study involved interviews with secondary school students.
3. [REDACTED]. This study involved interviews with "three-member family groups composed of a female college student, [REDACTED], and [REDACTED]." (Board report, page 14)
4. [REDACTED]. This study involved interviews with high school and college students.
5. [REDACTED]. This study involved interviews with young people about their expected [REDACTED].
6. [REDACTED]. This study involved videotaped interviews with family groups. It was designed in collaboration with another faculty member at the

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<sup>2</sup>The subject supplied copies of all relevant records that they could locate in her office or in storage rooms at her current institution. The subject had not prepared a collection of research records that she considered relevant in advance of OIG's visit, and, to facilitate the search for relevant files, generally permitted OIG's scientist to examine her files without herself screening them in advance. There is no reason to believe that the subject either deliberately withheld relevant records or carefully selected only certain records in order to document her own account of her activities. Indeed, she supplied many records that undermine her account, and she seemed imperfectly aware of the contents of what appeared to be long unopened boxes of files that she had brought with her from her former university.

subject's former university. This study was discontinued when the other faculty member left the subject's former institution.

For a more detailed description of these studies, see the Board report (pp.14-20). OIG believes that data for studies #2 and #4 were collected in 1989, as were a large part of the data for study #3. OIG believes that, despite the subject's statements to the contrary, the data for studies #1 and #5 were collected well after the subject arrived at her new institution and without the aid of her NSF award. The basis for these conclusions is discussed below.

### **Evidence Bearing on the University's Conclusions**

A summary of the evidence that relates to the five conclusions of the Special Review Board follows:

#### **1. Misuse of funds set aside for human subjects reimbursement.**

Shortly after the subject was notified that NSF would make an award, she sought to establish a checking account from which she could draw funds to pay participants in her experiments. Appendix J contains a copy of the subject's explanation to the University Purchasing Office of why she needed this account. The subject states:

A critical aspect of meeting this NSF grant obligation involves the prompt reimbursement of research participants. Because obtaining the full sample for this study depends largely on referral of new families received from previous participants, it is critical that individual reimbursements be paid at the conclusion of completed interviews rather than after a lengthy delay. Delays in payment of participant reimbursement would have the effect of diminishing the necessary referrals and undermine our ability to successfully complete this grant.

The subject's justification for establishing the checking account specifically restricts the use of account funds to interviewer travel (\$300) and human subject reimbursement (\$6000). The account required special justification in part because the subject, in furtherance of her research objectives, was asking the university, in the words of OIG's audit report (page 8), to depart from "prudent business practices and good internal controls" and thereby to increase "the risk of loss or misuse of funds" (see audit report in Appendix 4).

At the Special Review Board's request, the university's internal audit staff analyzed expenditures from the subject's checking account (see Appendix P). During 1989, when the subject was at the university and, at various times, employing three different research assistants under the grant and receiving additional research assistance from two other graduate students and several undergraduates, only four checks, totalling \$20, were written directly to research subjects. An additional six checks, totalling \$844, were written to the subject's research assistants, who told the review board that they had used this money to pay research subjects. The subject wrote two checks to cash, endorsed by herself, totalling \$800, with memo lines indicating that they were used for subject reimbursement.

When an OIG scientist visited the subject's office, the subject produced copies of consent and assent forms signed by persons who participated in her research in 1989 and receipts for payments to those persons. These forms and receipts relate to three "ancillary studies" that are thematically similar to the project the subject proposed to NSF but are not included in her NSF proposal (These studies are referred to above [page 4] as studies #2, #3, and #4). OIG believes that the preponderance of the evidence indicates that most or all of the money withdrawn from the checking account in 1989 was used for paying research participants in these ancillary studies and reimbursing interviewers for travel connected with these studies.<sup>3</sup>

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<sup>3</sup>The consent and assent forms and receipts that the subject supplied corroborate the testimony of the subject's research assistants (Appendix C) concerning her data collection activities.

The amount of money charged to the checking account for participant reimbursement in 1989 is roughly consistent with the amount that would have been necessary to pay the participants from whom the subject obtained data and for whom she produced consent or assent forms or receipts for payment. OIG did not tally the receipts against the withdrawals from the bank account because we believe that a discrepancy would be as likely to indicate that some receipts were missing as it would that money was misappropriated.

In her affidavit, the subject maintains that her 1989 withdrawals from her checking account were made for the purpose of reimbursing some or all of 91 families from her former university's state who were interviewed for the NSF study design. She acknowledges that "the amounts I withdrew for . . . reimbursement from the checking account are less than those which would have been necessary to pay 91 families \$10 or more per person. At this time I cannot recall where the money came from to pay the remainder of  
(continued...)

<sup>3</sup>(...continued)

the subjects participating in the study." This claim contradicts the evidence on at least two counts. First, there is no evidence that the subject collected any significant amount of data under the NSF study design while she was at her former university. Second, both the subject's former research assistants and the check records indicate that much of the money in the account was used to reimburse participants in the ancillary studies. On page 4 of the subject's affidavit (Appendix 3), she characterizes the testimony of the research assistant who collected data for [REDACTED] (study #3) as "substantially accurate." That research assistant said that she reimbursed participants in [REDACTED] research with money derived from the subject's checking account.

The subject's written reports of her research are further evidence that she interviewed human subjects for the three ancillary studies and are consistent with the idea that she did so in 1989 and reimbursed subjects for their participation with monies drawn from her NSF checking account. See, for example, [REDACTED] and [REDACTED], "[REDACTED]" in

[REDACTED] " in [REDACTED], pp. [REDACTED]; This paper is based on one of the subject's ancillary studies ([REDACTED], referred to as study #2 on page 4 above) and involved 72 adolescent participants. The subject's co-author was one of her research assistants in 1989, and the subject supplied assent forms and receipts for subject reimbursement for this study. There is, in short, overwhelming evidence that data for this one study was collected in 1989 at the subject's former university and with the aid of funds from her NSF grant.

The subject supplied OIG with a manuscript entitled [REDACTED] and written by [REDACTED] and [REDACTED], which is described on the title page as "an expanded version of a paper presented at the annual meeting of the [REDACTED] Association" in 1992. This manuscript is based on the data from [REDACTED] (study #3), another of the ancillary studies. A manuscript with a very similar title and list of authors is listed on page 11 of the curriculum vitae that the subject supplied to us in March, 1994 as submitted for publication.

The subject supplied reimbursement receipts and assent forms for a study on [REDACTED] (study #4) that indicate that data collection took place in 1989. Her  
(continued...)

In January, 1990, the subject assumed a visiting faculty position at her current institution. At that point, she had only one research assistant working for her, and both the subject and her assistant state that the assistant was not engaged in data collection (See her Affidavit in Appendix 3 and her research assistant's statement in Appendix C). Both also state that the assistant left the subject's employ by the end of the month.

Between February 13, 1990 and April 9, 1990, the subject withdrew \$3250 from her checking account in five checks made out to herself and one made out to cash. Memo lines on three of the six checks refer to [REDACTED] "one of the subject's ancillary studies. One memo line refers to [REDACTED] "the subject's label for the study supported by NSF, and another to an unspecified "Research study" (See Appendix P).

The subject could supply no documentation that these expenditures were made to reimburse research participants. In her affidavit (page 2), she stated that "these monies went to subject reimbursement for participants in the [REDACTED] Study, to the best of my recollection." She produced nothing of substance to support this claim. She supplied OIG with an undated log with the names and addresses of 40 potential research subjects who lived near her new institution. Information in the log indicates that the persons listed were potential participants in [REDACTED] " Other evidence, however, indicates that this log refers to persons who, if they participated in the study, did so long after the subject made her withdrawals from her checking account in early 1990. The subject supplied reimbursement receipts and consent forms from participants in the study who were interviewed after the subject moved to her new institution. All 16 such receipts were signed by people listed in the subject log. With one exception (a receipt dated May, 1990), these receipts are dated between November 1990 and May 1991. The subject supplied OIG with extensive records of data collection for two of her other ancillary studies, and partial records for [REDACTED]. The research assistant who worked on [REDACTED] stated that she herself kept some of the records for that study. The absence of any documentation to support the subject's claim that she collected data for [REDACTED] in the period between February and April, 1990, contrasts strikingly with the wealth of documentation she was able to supply concerning her other

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<sup>3</sup>(...continued)  
curriculum vitae lists a manuscript by [REDACTED], and [REDACTED] on this topic; the third author is presumably the research assistant of the same name who collected data for this project in 1989. OIG did not request a copy of this manuscript.

ancillary studies and her other activities with regard to [REDACTED] itself.

The research assistant who did most of the data collection for [REDACTED] reported to the Special Review Board that the subject interviewed "about 20" persons for the study after moving to her new institution (Appendix C; see also Appendix L).<sup>4</sup> Neither the subject nor the research assistant has ever claimed that the bulk of the data for this study were collected by the subject once she arrived at her new institution; the research assistant originally estimated that eighty percent of the data collection was done by the research assistant. This claim is consistent with the numbers of consent and assent forms and payment receipts from participants who lived near the subject's new institution that the subject produced during the visit by OIG investigators.

OIG believes that the preponderance of the evidence indicates that the subject's data collection activities for [REDACTED] after she moved to her new institution were restricted to a small number of the total of 168 participants in the study. Insofar as there is evidence of data collection for this study, that evidence shows that data collection occurred either far from the subject's new institution or well after April, 1990. Data collection activities for this study cannot account for the withdrawals from the subject's bank account in early 1990. The subject's claims to the contrary are not credible.

OIG further believes that it is wholly implausible that the subject could have spent this amount of money on participant reimbursement in this amount of time. The subject had recently arrived at a new institution. She had no paid research assistants engaged in data collection. She was thus working alone or with volunteers whom she had only recently met.<sup>5</sup> Even assuming a

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<sup>4</sup>Appendix L contains a letter from the same research assistant in which she discusses her activities. In that letter, the research assistant says that she cannot recall the number of participants that the subject interviewed after moving to her new institution. She also reports that she had records of at least 42 interviews conducted before the subject's move. In the subject's own records of data collection for this study, OIG discovered consent forms and payment receipts from the research assistant dated after the move, indicating that the research assistant continued to collect data for this study after the subject relocated.

<sup>5</sup>The subject provided no evidence that she had recruited and trained the large corps of volunteers that would have been needed to do this work.

generous rate of \$20 per research participant<sup>6</sup> and \$250 for interviewer travel, the subject would have to have interviewed 150 persons in two months to generate \$3250 in expenses. In the previous calendar year, working with three paid assistants (see breakdown of research assistant expenditures, Appendix 5) and several student volunteers (see Affidavit, Appendix 3, page 3), the subject collected data from approximately 250 secondary school students and a handful of adults.<sup>7</sup> She reports that her paid assistants were responsible for the bulk of this data collection (Affidavit, Appendix 3, page 2). The study designs that her assistants and she executed while she was still at her former university had much less stringent participant selection criteria than either [REDACTED] or the study design that was proposed to NSF. The latter two studies required participants in specified family configurations, whereas the former did not. To believe the subject's account would be to believe that, in contrast to her performance under more favorable conditions the preceding year, she carried out an enormous amount of data collection in a short period of time under a demanding research design without the aid of research assistants working under the grant. Although the subject was able to produce extensive documentation of her research and expenditures for the studies performed while she was still in residence at her former university, she could not produce comparable documentation-- or, indeed, any documentation at all-- of the activities that generated her expenditures in the early

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<sup>6</sup>This is much higher than in her studies at her former university, but using adult subjects rather than high school students would have necessitated a higher reimbursement rate. In her affidavit (appendix 3), she says that she increased the subject reimbursement rate from the \$10 that she proposed to NSF to \$20.

<sup>7</sup>This estimate is based on the assumption that data from two ancillary studies, one with 72 secondary school student participants and the other with 160 secondary school or college student participants, were collected entirely during 1989 at the subject's former university. An indeterminate number of [REDACTED] subjects were also interviewed during this year; a plausible estimate is 100, although the number might be as low as 50. A study of adolescents' [REDACTED] was also conducted at some point, but there is no documentary evidence that this was in 1989. Data collection for this study appears to have been done after the subject arrived at her new institution. The subject maintains that she collected data from 91 four person families while she was still at her former institution, but OIG believes that this claim is false (see above, page 6, and below, page 17). There is evidence that she collected data from up to nine such families in 1989, however (see below, page 18).

months of 1990. OIG believes that the subject's story is simply not credible.

OIG concludes that the subject misused funds set aside for human subject reimbursement. She departed from the procedures for using her bank account that she described in the special justification she submitted to her former university (see Appendix J) in that she typically wrote checks to herself or her research assistants and not directly to research participants. In addition, although the subject states that these funds were used for research related purposes, we were unable to locate any documentary evidence to establish how the funds were actually used.

## 2. Failure to account for video equipment

The Special Review Board report (Appendix 1, pp. 20-21) contends that the subject misspent grant funds for unnecessary video equipment:

. . . \$869.39 was used to purchase a stereo television monitor, a video cassette recorder, a TV/VCR stand, and associated cables (the expenditure summary and purchase orders are reprinted in Appendix P). The Board could not establish a need for this equipment. . . . According to [a faculty collaborator]'s statement (Appendix C), video equipment was used with a few pilot subjects in the study entitled [REDACTED]. It is not clear whether the video equipment purchased by [the subject] was used with these subjects; suitable video equipment was already available for use by members of [the subject's department] at the time of the research. According to [name], Chair of the Department, the equipment purchased by [the subject] is missing from the Department.

This equipment, because it was purchased with grant funds, is the property of the subject's former university. Even if it had been necessary for the subject's research, the subject would have had no right to take it from the university without permission.

On page 5 of her affidavit (Appendix 4), the subject offers the following account of this matter:

The equipment I purchased (I believe with NSF funds) for the [REDACTED] Study [referred to on page 4 of this report as study #6], which included an RCA VCR, a VCR cart, an RCA television monitor, and two cables, were left by me in my lab when I came to [her new state] in January 1990. I do not know what happened to this equipment; when I went back to [the University] in June 1991 to pack up my lab and office, the equipment was missing. I informed [a



faculty colleague] of this when we met in June 1991 to review which equipment belonged to me and which to [the University]. I felt it necessary to purchase this equipment for the [REDACTED] Study because I could not perform the study without this equipment, as three sets of TVs, VCRs, and cables were needed, and only two were available in [the faculty collaborator]'s lab.

The subject further explained that other video equipment in her former department would not have been readily available for her research, as it was housed in other laboratories and under the control of other researchers. From the subject's description of the research design in which the video equipment was to be used, OIG believes it is probable that the equipment was originally purchased for a legitimate research purpose, but not for purposes of executing the study design originally proposed to NSF.<sup>8</sup>

OIG believes that the evidence from our investigation tends to confirm the university's conclusion that the subject failed "to secure the safekeeping" of equipment belonging to the university.

### 3. Treatment of human subjects

The IRB at the subject's former university issued a report (Appendix 2) concerning the subject's violations of IRB guidelines. **This report is essential reading for making decisions concerning this case.** The sections of the Special Review Board report relating to human subjects violations (Appendix 1, chiefly pages 7-11, page 15, and page 19 and the report appendices referred to therein) also provide supporting documentation for the IRB findings.

Of the seven violations of IRB guidelines listed in the IRB report, five, in OIG's opinion, might reasonably be seen as serious deviations from accepted practice in the scientific community and hence as misconduct in science under NSF's definition. Because two of the IRB findings concern the same kind of violation (#3 and #4), we have grouped them together. The serious violations are:

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<sup>8</sup>When OIG interviewed the subject at her home, OIG staff noticed in plain view video equipment that appeared to be identical to that purchased with grant funds. The subject states in her affidavit (Appendix 3, page 5) that "though I have an RCA VCR in my home which matches the description of the VCR purchased for the Study, I will not give [the OIG staff member] my consent to inspect it to determine if it is the same as that purchased under the grant."

1. Failure to respond to IRB request for consent and assent forms. (1)
2. Failure to pay research participants as promised. (2)
3. Failure to obtain written consent from two school systems to perform research using their students. (3) and (4)
4. Failure to obtain IRB approval for data collection protocol. (7)

(Numbers in parentheses refer to the numbered IRB findings in Appendix 2). The remaining two violations, even considering that human subjects regulation is generally extremely rule and detail oriented, cannot reasonably be construed as serious enough to warrant a finding of misconduct in science and will not be discussed further. In her affidavit, the subject discusses her response to the findings in the report (Appendix 3, pp. 3-4).

Regarding the first finding, the subject admits she was unresponsive to her former university's IRB. She explained that a hostile environment and a poorly handled tenure review process had left her "depressed" so that she "reacted stupidly" (Affidavit, Appendix 3).

OIG notes that there is ample documentation that the subject repeatedly failed to cooperate in IRB and IRB related investigations concerning her treatment of human subjects (see Special Review Board Report, pp. 1-8, and Appendices D, E, and F). The evidence clearly indicates that the subject knowingly failed to respond to legitimate information requests from her former university's IRB. The subject admits that she received these requests and did not respond to them.

Regarding the second finding, the subject says it was "possible" that research participants who claimed not to have been paid as promised were "overlooked." She claimed that, on one of the several occasions on which her department chair contacted her about this matter in October and November of 1990, she offered to pay these participants (Appendices A and G bear on this claim, but do not corroborate it).

OIG's examination of the subject's payment records revealed that all three complainants participated in an abortive study that combined the study design the subject proposed to NSF with the collection and analysis of videotaped family interactions. The subject initiated this latter project in conjunction with a faculty collaborator who left the subject's former university for another

institution. For the other studies that OIG believes the subject conducted using funds from her NSF award,<sup>9</sup> the subject has ample records of participant payment.

OIG believes the preponderance of the evidence indicates that the payment problem was restricted to one abortive study. We do not believe there is strong evidence to relate this problem to the subsequent misuse of funds from the bank account the subject established to reimburse research participants, except insofar as her failure to pay the complainants meant that there was additional money available for misuse that remained in the account.

The preponderance of the evidence indicates that the subject was at least grossly negligent in not paying research participants in her study. The subject was an experienced researcher and a former IRB member. She was well acquainted with the rules for proper treatment of human subjects. Even for an aborted study, she should have had a system in place for maintaining records of research participation and sending promised payments. She had a convenient source of funds in her university authorized checking account, but failed to use these funds for their intended purpose. When alerted to her failure to pay her research subjects, she did not act affirmatively to remedy this failure, although she may have made general statements of her intention to pay. Her pattern of action in failing to pay her research subjects shows a gross lack of care that OIG believes is sufficiently blameworthy to justify a finding of misconduct.

Regarding the issue of school system approval, the preponderance of the evidence indicates that the subject failed to obtain approval from one school system whose students she solicited as research participants.<sup>10</sup> Although the subject claims to have a

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<sup>9</sup>This includes the three completed ancillary studies: [REDACTED], [REDACTED], and [REDACTED]. The subject contends that in 1989 with the support of her NSF grant she executed both the original study design she proposed to NSF and a study of adolescents' [REDACTED]. She lacks documentation of participant reimbursement for these studies, but that, in our view, is because she did not do them when she says she did. It is not because she failed to pay the persons who in fact participated. The evidence to support OIG's conclusions about what research the subject conducted in 1989, while receiving NSF support, is discussed below (pp.14-17).

<sup>10</sup>Regarding the other alleged instance of failure to obtain school system approval, the situation is as follows: the IRB found that the subject failed to get school system approval for (continued...)

copy of an approval from the public school system near her former university, she was unable to supply a copy of this approval. She did supply two forms containing requests "for approval of research study to be conducted in the [name] County schools." The subject herself had signed these forms, but they had not been signed by an official of the school system. She also supplied a letter, written on the stationery of her former department and dated January 20, 1989, addressed to an administrator at the school system in question. This letter thanks the administrator for meeting with the subject and expresses the subject's hope "to work with you on the research which we discussed." The letter describes two projects that were discussed in the meeting: one of the ancillary studies and the study that was proposed to NSF. While this letter is evidence that the subject attempted to obtain school system approval for conducting her research in the schools, it does not show that she actually obtained such approval.

OIG believes that the absence of a signed approval form in the records of either the subject or the IRB at her former university indicates that the subject did not obtain written approval and so could not have filed an approval form as required by the IRB.

The subject was at least grossly negligent in not obtaining school system approval for data collection involving students and not filing notification of approval with her university's IRB. Researchers who collect data in schools have a responsibility to know the importance of maintaining good relations with them and the importance of treating them properly. Because obtaining documented school approval for data collection is so important, neglecting to obtain it should not be considered merely careless.

The finding of data collection without an approved protocol concerns the subject's study of [REDACTED] (referred to on page 4 as study #5). OIG concludes that data collection for the study in question did not take place with the aid of the subject's NSF award and did not take place when the subject was at her former university, despite the subject's testimony to the contrary. The subject has no documentary record

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<sup>10</sup>(...continued)

soliciting research participants at the schools near her current institution. The subject contends that she "got subjects through advertisements in the newspaper and in flyers, not through schools." Neither OIG nor the Special Review Board has any substantial evidence to contradict the subject's claim on this point; the contrary impression seems to have developed from remarks the subject made to university officials concerning data collection that took place after she moved to her new institution (see Special Review Board Report, p.11; see also Appendix G).

of consent forms or subject reimbursement for 1989 concerning this study, nor did any of her research assistants testify to their involvement in it. The subject does have published reports of data from this study, however. These are co-authored by graduate students at her current institution and appeared long after she ceased spending money under her NSF award.<sup>11</sup> Although the subject acknowledges NSF support for this study, we believe that, at most, NSF supported planning for the study and not actual data collection. Because we conclude that the data collection in question was not aided by the NSF award, we have no reason to consider possible noncompliance with human subjects guidelines in this study.

#### 4. Non-performance of research

The Special Review Board concluded that in 1989 the subject did not perform the research she proposed to NSF. The evidence that the subject supplied to OIG during our interview tends to confirm this conclusion. We believe that the preponderance of the evidence indicates that the subject began collecting data for this study in the late summer or fall of 1989, but that she collected data from only a small number of subjects.

The earliest written record that the subject could supply for a data set matching the data set she proposed to collect under the study design described to NSF was a codebook dated November 25, 1991.<sup>12</sup> OIG believes this codebook supports the subject's claim

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<sup>11</sup>The subject supplied reprints of two published reports that are based on this study. [REDACTED]

[REDACTED], " in [REDACTED], pp. [REDACTED]; and "[REDACTED]

[REDACTED], " in [REDACTED], pp. [REDACTED]. Both are co-authored with students at her current institution. In one, she describes subject recruitment as having taken place through newspaper and radio advertisements, which is consistent with how she elsewhere described subject recruitment as taking place when she arrived at her new institution.

<sup>12</sup>It was prepared in SPSS-PC (Statistical Package for the Social Sciences) format. The codebook contains a list of all the variables for which the subject collected data, and the variables listed match those that would have been collected under the study design proposed to NSF. The subject also supplied OIG with a conference paper entitled "[REDACTED]"

(continued...)

that she performed the research, while at the same time contradicting her claim about when she did it. We do not, in other words, believe there is reason to think that she has fabricated data. We believe it is extraordinarily unlikely the subject would have fabricated a 1991 codebook to substantiate her claim that she collected these data in 1989, when she did not fabricate more direct evidence of 1989 data collection.

The Special Review Board found that none of the subject's research assistants reported collecting data under the study design proposed to NSF. The subject supplied OIG with an article from a local newspaper in which she describes her research and presents herself as seeking suitable participants for further research. The subject emphasized to OIG that she had checked the article for accuracy before it was published. The article is dated [REDACTED], 1989. It represents the subject as having "recently finished" two of the ancillary studies (#2 and #4) and as having a third one (#3) under way.<sup>13</sup> It presents her as "currently looking for additional volunteers for her studies" and says that "she needs approximately 100 families for the current round of testing." This description is consistent with the idea that in late [REDACTED], 1989, the subject had not yet begun collecting data under the study design she proposed to NSF.<sup>14</sup> The subject also provided OIG a copy of a letter

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<sup>12</sup>(...continued)

[REDACTED], " by [REDACTED], and [REDACTED]. This paper is identified on the title page as "a revised version of a poster presented at the biannual meeting of the [REDACTED], 1993." It contains data from "364 participants: 91 mothers and fathers, and two of their biologically related children." This description matches the subject's description of the data she collected under the study design she proposed to NSF.

<sup>13</sup>These descriptions are consistent with other evidence concerning the subject's data collection activities, including the subject's records of participant reimbursement and the signed consent and assent forms from these studies.

<sup>14</sup>If this inference is correct, it further undermines the subject's claim in her affidavit that in 1989 she used the money from her subject reimbursement account to pay families that participated in research under the study design proposed to NSF. From the beginning of July, 1989, to the end of the year the subject withdrew \$510 from that account. Of this amount, \$490 was paid in checks to the research assistant who ran the [REDACTED] project and \$20 was paid directly to subjects who participated in that (continued...)

to the same newspaper, dated [REDACTED] 1989, concerning an advertisement she wished to run to recruit research participants. This further supports the idea that she was early in the process of recruiting subjects for the NSF funded study.<sup>15</sup>

For the project that was funded by NSF, the subject supplied OIG with consent and assent forms signed by 27 members of nine families. These forms indicate that the subject planned to coordinate the research plan that she had developed with her faculty collaborator<sup>16</sup> with her research under the NSF study design. The forms describe a two step data collection procedure, the first step of which matches the study design for the study proposed to NSF and the second step of which matches the design for the study with the subject's faculty collaborator. The forms state that "each family member will be paid \$10.00 for completing Phase I, for a possible total of \$40.00 per family (i.e., both parents and up to two teenage children)." An equivalent amount was promised for completion of the second phase of the study.

Included among the consent and assent forms the subject supplied to OIG are the forms signed by all three of the complainant families. One complainant family claims that it is owed forty dollars, while another claims it is owed thirty dollars (see Appendix H). These amounts suggest that these families did not participate in both phases of the study. This is consistent with the collaborator's statement (Appendix C) that few if any subjects actually participated in the study that she and the subject designed.

The testimony of these participants as to the research process was, according to the Special Review Board report, "the only evidence of data collection activity on this project" (pp. 9-10).

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<sup>14</sup>(...continued)  
project. The research assistant, according to both the subject and the assistant herself, was not involved in executing the study design the subject proposed to NSF.

<sup>15</sup>The Special Review Board was unable to locate and interview one of the subject's research assistants. OIG was also unable to locate him. This assistant left the subject's employ before July. We therefore believe it is highly unlikely that he collected any significant amount of data under the research design proposed to NSF.

<sup>16</sup>This is the study of [REDACTED]. It is this study for which the video equipment was purchased. The newspaper article also describes this as a study on which the subject was currently working.

The signed consent and assent forms do not necessarily indicate that the signatories actually participated in the subject's research; the forms indicate only that the signatories agreed to participate.

OIG believes that the small number of consent and assent forms, the absence of research assistants who might have administered data collection or taken part in subject recruitment, and the absence of other evidence of data collection while the subject was in residence at her former university make it unlikely that in 1989, while receiving and spending NSF grant funds, the subject collected the data for the project that she proposed to NSF and that NSF funded.

#### **5. Non-Cooperation with Inquiries and Investigations.**

OIG's investigation did not uncover additional information relative to the subject's failure to cooperate with inquiries and investigations by her former university. The Board report discusses this issue on pages 8 and 21; further evidence can be found in Appendices D, E, and F.

#### **Evidence Bearing on an Additional Allegation**

The Special Review Board raised an additional allegation (p. 21) by one of the subject's graduate assistants that the subject "persuaded her to relocate to [the subject's new institution] under false pretenses: by promising her admission to the school and a full-time salary on the NSF-funded projects. Neither promise was fulfilled, and [the student] claims she is owed \$1400 for services rendered."

Because this allegation relies on the testimony of the parties, and cannot, for the most part, be verified by documentary evidence, it is a difficult allegation to substantiate and relies heavily for substantiation on the complainant's credibility.

In her affidavit (Appendix 3, page 4), the subject disputes the student's account of the events that took place after the student moved to the subject's new state and resumed working on the subject's research project. She states that the student "never had an intention of enrolling" at the subject's current institution" and "after the summer of 1989, she had decided to discontinue graduate studies in [REDACTED]" at the subject's former university. The subject told OIG's investigators that the student was planning to apply to medical school and had been taking pre-medical courses. OIG obtained a copy of the student's transcript and verified that the student was taking pre-medical courses and not [REDACTED] courses in her final semester at the subject's former university.



OIG believes that this evidence casts sufficient doubt on the credibility of the student's claims of non-payment to make it impossible to meet the burden of proof necessary to substantiate this allegation.<sup>17</sup>

#### **OIG's Conclusion Regarding Misconduct in Science**

NSF defines misconduct in part as "fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from activities funded by NSF" (§ 689.1(a)(1)).

OIG's investigation addressed those acts of the subject that fall within this definition, those acts that her former university considered to be "scientific misconduct," and one additional allegation noted by the Special Review Board. Following the university's recommendation, OIG interviewed the subject and examined her research records. The additional information generated by our investigation, while it has led us to revise or expand upon some of the university's factual findings, does not cause us to question their overall conclusions. Specifically, we agree with the university that the subject violated the usual and customary practices for treating human subjects, misused grant funds, failed to secure the safekeeping of university owned equipment purchased under the grant, failed to use her NSF award to conduct the study she proposed to NSF, and refused to cooperate with inquiries and investigations into the allegations directed at her.

We share the university's view that, taken together, the subject's failures to comply with human subjects regulations are a serious deviation from accepted practices for the treatment of human subjects (§ 689.1(a)(1)) and constitute misconduct as defined in NSF's regulation on misconduct in science and engineering.

OIG believes that the subject's failure to respond to IRB requests for information, failure to pay research participants as promised, and failure to obtain school system approval for research using the system's student population seriously deviate from accepted practice in the community of researchers that studies human beings. Condoning acts such as these would undermine the authority of the system of human subjects regulation that the federal government supports and oversees, erode the trust necessary

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<sup>17</sup>This is not to say that OIG accepts that the subject's account is therefore accurate. We clearly have ample reason to question the subject's credibility as well. We simply concluded that this allegation was unproven and unprovable.

for researchers to recruit subjects for their research, and ultimately threaten research subjects with significant harm. At the time when the subject's NSF supported research was conducted, NSF's definition of misconduct (45 CFR § 689.1(a)) specifically included "material failure to comply with Federal requirements for protection of researchers, human subjects, or the public."<sup>18</sup>

All institutions that receive federal funds to perform research involving human subjects are required to have IRBs that set guidelines for the proper conduct of such research and monitor compliance with those guidelines. The primary activity of IRBs is to educate researchers at their institutions about the proper treatment of human subjects and to work with them to develop research protocols that enable scientists to achieve their research objectives while protecting the interests of human subjects.

OIG believes that federally mandated IRBs are at the core of the effort to protect human subjects from abuse and that repeated failure to cooperate with a legitimate request from an IRB can be misconduct in science. We believe that the subject's failure to cooperate with her former university's IRB is her most serious violation of human subjects regulations. We note that the Office for the Protection from Research Risks (OPRR) at the U.S. Department of Health and Human Services (HHS), which oversees federally funded research involving human subjects, stresses that

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<sup>18</sup>This language was dropped in May, 1991, and was therefore no longer part of the definition when the Special Review Board and the IRB carried out their investigations. In the Federal Register, NSF explained that the language was omitted because it was deemed "unnecessary." It characterized the deleted types of misconduct as "either . . . subject to other enforcement procedures and penalties or . . . covered by the 'other serious deviation from accepted practices' language in the first clause of the definition of misconduct." (Vol. 56, No.30, February 13, 1991). Thus the history of NSF's definition of misconduct supports the idea that serious violations of rules protecting human subjects are included in the definition.

Sanctions against individual investigators have overwhelmingly been left to the IRBs, which have acted without direct federal government involvement. Where, as in the subject's case, an investigator moves to a new institution, however, the IRB of the former institution is powerless to take meaningful action. In such situations, only the granting agency can act to uphold the IRB's authority. The subject's actions clearly are not covered by "other enforcement procedures and penalties" that were referenced in the Federal Register when the wording of NSF's misconduct regulation was changed.

investigator noncompliance with legitimate IRB requests is a serious matter:

The most common lapses in investigator compliance include unreported changes in protocols, misuse or nonuse of the informed consent document, and failure to submit protocols to the IRB in a timely fashion. . . . Occasionally, an investigator will either avoid or ignore an IRB. Such cases present a more serious challenge to the IRB and to the institution. Regardless of investigator intent, unapproved research involving human subjects places those subjects at an unacceptable risk. When unapproved research is discovered, the IRB and the institution should act promptly to halt the research, assure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the question of the investigator's fitness to conduct human subject research. Beyond the obvious need to protect the rights and welfare of research subjects, the credibility of the IRB is clearly at stake. [emphasis added].<sup>19</sup>

OIG believes that keeping promises to research subjects and obtaining informed consent from institutions that control access to subjects are core IRB concerns and core aspects of respecting the dignity of research subjects. Failures in these areas can also be considered misconduct. The consequences of the subject's wrongdoing go beyond the sheer loss of money by a small number of research participants because the subject's acts challenge important and generally recognized principles for how human subjects ought to be treated.

OIG believes that the preponderance of the evidence supports the findings that the subject committed culpable acts and that she did so with a culpable state of mind. OIG concludes that the subject committed misconduct as defined in NSF's regulation on Misconduct in Science and Engineering and recommends that NSF make a finding to that effect.

#### OIG'S RECOMMENDED DISPOSITION

When NSF makes a finding of misconduct, it must consider the seriousness of the misconduct in determining what actions it should take (§ 689.2(b)). This includes considering the state of mind with which the subject committed misconduct and whether the misconduct "was an isolated event or part of a pattern." We have

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<sup>19</sup>OPRR, Protecting Human Research Subjects: Institutional Review Board Guidebook, I-15-16 (1993).

already explained that we conclude that the subject's human subjects violations are a serious deviation from accepted practice and hence are misconduct; this section explains OIG's recommended actions in light of our assessment of the seriousness of the subject's misconduct, i.e., of how serious this instance of misconduct is in relation to other instances.

We believe that the subject's failure to respond to her former university's IRB and to act affirmatively to rectify complaints from human subjects is serious. The subject's actions broke faith with both her research subjects who were not paid and with the community of researchers who study human subjects. It is not merely a bending of established rules, as when the subject's research assistant elicited consent orally rather than in writing or when the subject failed to obtain permission to do research from all relevant IRBs. The subject has clearly challenged key tenets of human subjects protection, even though the harm to individual subjects that resulted was relatively small.

We do not believe that the subject committed her misconduct out of deliberate contempt for either human subjects or human subjects regulation. This would be a far more serious offense if it were motivated by such contempt. Rather, we believe the offense was a by product of the subject's alienation from her former university and her desire to avoid confronting her own financial transgressions. We do not in any way believe that these motivations excuse the subject's actions.

We do not believe that the non-payment of research participants was part of a pattern of non-payment. When we read the Special Review Board report, we thought it likely that many subjects were not paid, but did not complain. The evidence we developed in our interview with the subject and our examination of her files leads us to conclude that the three complainant families were among a very small number of families interviewed for an aborted study and are not symptomatic of a pattern of non-payment of subjects. In the studies the subject executed in 1989 at her former university, she otherwise appears to have paid her subjects.

We also believe, however, that the subject manifests a pattern (§ 689.2(b)(3)) of non-compliance with NSF grant conditions that warrants special attention if and when the subject receives another grant. There are numerous indications of this non-compliance: her decision to use the NSF grant to perform her ancillary studies, rather than to follow the study design she proposed to NSF; her misuse of funds from a bank account that was specially designed to enable her to compensate research participants; and her failure to

secure the safekeeping or return of equipment that was the property of her former university are the outstanding examples.<sup>20</sup>

Because we believe that the subject's non-compliance with rules for the protection of human subjects is part of a pattern of non-compliance with NSF grant conditions, we recommend that NSF take special steps to ensure that the subject comply with NSF grant conditions in the event that she receives another award. We do not believe the subject's misconduct should prevent her from competing for future awards. However, we recommend that until January, 1998, before NSF makes an award in which the subject is named principal investigator, NSF management should require that the grantee institution establish special procedures to monitor the subject's compliance with NSF's grant conditions. These procedures should include, but should not necessarily be limited to, procedures for monitoring her compliance with human subjects regulations at the grantee institution.

We recommend a finding of misconduct under NSF's Regulation on Misconduct in Science and Engineering. We recommend two actions by NSF in response to the subject's misconduct. The subject should be sent a letter of reprimand, which is a Group I action (see § 689.2(a)(1)(i)). If the subject is named principal investigator on an NSF award, NSF should require that the grantee institution establish special procedures to monitor the subject's compliance with NSF's grant conditions (see preceding paragraph). This may involve a combination of Group I and Group II actions (see § 689.2(a)(1)(ii), § 689.2(a)(1)(iii), and § 689.2(a)(2)(ii)). We believe these actions adequately protect NSF's interests and are proportionate to the misconduct by the subject.

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<sup>20</sup>We note that the subject appears to have communicated her casual attitude to the rules of the scientific community to her research assistant, who responded by unilaterally altering IRB approved procedures for obtaining consent from research participants (see IRB finding #6, Appendix 2).