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SPECIAL ISSUE

Vol. 18, No. 30, September 1, 1989

SPECIAL ISSUE

RESPONSIBILITIES OF AWARDEE AND APPLICANT INSTITUTIONS FOR DEALING WITH AND REPORTING POSSIBLE MISCONDUCT IN SCIENCE

P.T. 22, 34, 44; K.W. 1014004, 1014006

Public Health Service

SUMMARY: To implement section 493 of the Public Health Service (PHS) Act (and also section 501(f) of the PHS Act as amended by section 2058(a)(2)(C) of the Anti-Drug Abuse Act of 1988), this Final Rule adds a new Subpart A to 42 CFR Part 50. The new Subpart A sets forth the responsibilities of PHS awardee and applicant institutions for dealing with and reporting alleged or suspected misconduct in science involving research, research training, applications for support of research or research training, or related activities for which PHS funds have been provided or requested.

EFFECTIVE DATE: November 8, 1989

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Reported instances of scientific misconduct appear to represent only a small fraction of the total number of research and research training awards funded by the PHS. Nevertheless, even a small number of instances of scientific misconduct is unacceptable and could threaten the continued public confidence in the integrity of the scientific process and in the stewardship of Federal funds. The PHS has adopted interim policies to provide guidance for dealing with allegations and investigations, based on experience with a number of cases. These interim policies were published for the information of the public in the July 18, 1986, issue of the "NIH GUIDE FOR GRANTS AND CONTRACTS" and became part of the PHS Grants Administration Manual on September 1, 1988.

The PHS also recently established two new offices for dealing with scientific misconduct (see 54 FR 11080, March 16, 1989). The Office of Scientific Integrity Review (OSIR), established in the Office of the Assistant Secretary for Health, is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where scientific misconduct has been established. When necessary, OSIR may conduct independent investigations.

In addition, the Office of Scientific Integrity (OSI), established in the Office of the Director, National Institutes of Health (NIH), oversees the implementation of all PHS policies and procedures related to scientific misconduct; monitors the individual investigations into alleged or suspected scientific misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary.

The PHS Grants Administration Manual will be revised to accommodate the establishment of these offices.

The PHS Act directs the Secretary to establish procedures requiring that entities receiving funds from the PHS for the conduct of biomedical and behavioral research submit assurances on an annual basis that: (1) These entities have established (based upon regulations prescribed by the Secretary) an administrative process to review reports of scientific misconduct in biomedical or behavioral research, and (2) they will report to the Secretary any investigation of alleged scientific misconduct that appears substantial. The Secretary also has authority to respond to information received with respect to possible scientific misconduct involving projects under the PHS Act and to take appropriate action in response to such misconduct.

The provisions of section 493 of the PHS Act contemplate that there will be a close working relationship between the awardee institutions and the Department in resolving allegations of scientific misconduct. Section 493 envisions that

the awardee institutions will have the primary responsibility for preventing, detecting, investigating, reporting and resolving allegations of scientific misconduct. The Department, however, retains the ultimate responsibility and authority for monitoring such investigations and becoming involved in those investigations if appropriate or necessary.

In order to carry out his formal responsibilities under section 493, the Secretary published a Notice of Proposed Rule making on September 19, 1988 (53 FR 36347). That document set forth for public comment proposed responsibilities of applicant and awardee institutions, including requirements that they establish policies and procedures for investigating and reporting allegations of scientific misconduct involving research, research training, or related activities for which PHS funds have been awarded or requested. Proposed Section 50.104 specified an appropriate time and method for notifying the PHS of instances of possible misconduct. Proposed section 103 specified that, if there is a reasonable indication of a criminal violation, the Department's Office of Inspector General would be notified within 24 hours.

This final rule applies only to institutions applying for or receiving financial assistance from the PHS. A separate proposed rule amending 48 CFR part 3 will be published in the Federal Register to cover entities applying for contracts. Institutions are urged to develop, as soon as possible, policies and procedures for dealing with and reporting possible misconduct in science within their institution. After the effective date of this rule, each institution must have in place an assurance for dealing with scientific misconduct, as outlined by this rule. Updated information with respect to assurances will be due each year, on a date to be specified by OSI. Assurances should be submitted for approval to the Director, Office of Scientific Integrity, at the above-cited address.

As stated, this final rule implements section 493 requiring the Department to issue regulations concerning investigation and reporting of "scientific fraud". [See subsequent text in this preamble regarding use of the terms "fraud" and "misconduct" in this context.] Consequently, the rule does not contain specific measures to foster scientific integrity. Other issues remain to be addressed, including: retention of laboratory data, authorship practices, the role of grantee institutions and funding agencies in the performance of audits or studies to prevent the occurrence of scientific misconduct, and the consistency of such policies across federal agencies. HHS will continue to monitor institutions' responses and propose policies as may be necessary in the future. Such action may be based in part on the advance notice of proposed rulemaking published in the Federal Register on September 19, 1988 (53 FR 36344). In addition, consistency of policies in this area across Federal agencies will be monitored by the Office of Management and Budget in cooperation with the Office of Science and Technology Policy.

SUMMARY OF COMMENTS

As noted, the Secretary published a proposed rule in the Federal Register on September 19, 1988 (53 FR 36347) for public comment. The comment period was open through November 18, 1988. One hundred thirty-nine responses were received that addressed a wide spectrum of issues concerning the proposed rule and scientific misconduct in general. The respondents included 60 institutional representatives, 37 individual staff or faculty members, 20 representatives of professional associations, 16 representatives of research institutes or faculty groups, three individuals from Federal offices, two private citizens, and one representative of a scientific journal. The responses were generally supportive of the PHS's efforts and of the proposed rule. Most respondents emphasized that the main responsibility for investigating or preventing cases of scientific misconduct should remain with the institution.

The following is a summary of other main points contained in the comments on the proposed rule, and the Departmental responses.

Applicability and Definition of "Misconduct in Science." The proposed rule defined "misconduct in science" to mean (1) 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; or (2) material failure to comply with federal requirements that uniquely relate to the conduct of research. The comments and suggestions received were particularly helpful in refining this proposed definition. A number of respondents pointed out that, to the extent the second clause in the definition was largely intended to deal with violations of human and animal experimentation requirements, these areas are already covered by existing regulations and policies. Other commenters requested that honest error be excluded from the definition. Still others urged omission of the word "deception" inasmuch as deception can be an

acceptable component of specific types of research. Some commenters disagreed with the section of the definition that addressed "other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research" and proposed that this portion of the definition be deleted. On the other hand, some commenters suggested expanding the definition to include duplicate publication and intellectual piracy. Some commenters preferred the term "fraud" rather than "misconduct."

Response. The definition has been modified considerably in light of the comments. The term "deception" has been deleted. The second clause, referring to material failure to comply with federal requirements that uniquely relate to the conduct of research, has also been deleted in order to avoid duplicative reporting of violations of human and animal experimentation requirements. Further, a sentence has been added to make it clear that the definition does not include "honest error or honest differences in interpretations or judgments of data." At the same time, the language "other practices that seriously deviate" has been retained to assure coverage of any serious misconduct that might not technically be considered "fabrication, falsification, or plagiarism." With regard to the comments preferring "fraud" over "misconduct", the word "misconduct" is coming into increasing use because it avoids confusion with common law fraud, which contains certain unique characteristics that have no applicability to what has commonly come to be known as scientific misconduct. For this reason, the term "misconduct" is being retained.

Assurances. The notice of proposed rulemaking stated that an institution applying for or receiving PHS support must have an assurance satisfactory to the Secretary regarding procedures for dealing with misconduct in science. Most respondents agreed with the assurance mechanism. This final rule, in section 50.103, specifies that the assurance, on a form prescribed by the Secretary, must be submitted to the OSI as soon as possible after November 8, 1989, and no later than January 1, 1990, and be updated thereafter on an annual basis. This will enable PHS to ensure that institutions are establishing procedures that are consistent with the requirements of 42 CFR part 50. The assurance will consist of a series of affirmative statements, to be provided on the form prescribed by the Secretary. The OSI will also review annually a sample of institutions' policies and procedures.

Investigations and Reporting. Most of the respondents agreed with the overall proposed timing for completion of the inquiry and investigation phases. However, the need for flexibi-lity was stressed in recognition of the complex and heterogeneous nature of individual cases. Five respondents said the proposed time schedule was too short, and three others suggested following the National Science Foundation's timetable. The need to request formally an extension was questioned, and there were two suggestions to include "Inquiries" in the title of this section.

Response. After considering all the comments, the PHS believes the proposed timetable for conducting inquiries and investigations is reasonable. The PHS agrees that a certain degree of flexibility also is appropriate but disagrees with the contention that institutions should not be required to request an extension if the investigation cannot be completed within the specified time period. Therefore, the proposed language for this purpose in section 50.104(a) is retained.

PHS expects that as institutions refine and enhance their policies and procedures and gain collective experience in conducting investigations, the quality and timeliness of such investigations will improve. Where institutions fail to carry out their responsibilities as specified in the rule, the Department will use whatever remedies may be available under the circumstances. If problems persist, PHS will consider rulemaking to establish additional sanctions, such as restrictions on or reductions in indirect-cost funding going to an institution, or charges for the costs of investigations that have to be performed by the OSI.

The term "Inquiries" has been added to the title of this section, since the rule includes a specified time period for this activity. This section also has been expanded to give more specific guidance regarding the scope of inquiries, investigations, and reports.

Reporting Requirements. Most of the concerns expressed by respondents with respect to the reporting requirements were related to the issue of confidentiality and to possible damage to the reputations of innocent individuals. They were concerned about the treatment of both the accused and accuser, although eight respondents specifically called for the identification of the accuser. Twenty-one respondents were concerned about the due process rights of the accused during an institutional inquiry and/or investigation, as

well as the responsibilities of the PHS to protect individuals' privacy and the need to maintain information confidential. Many respondents stated that a report should be made to the PHS only if substantial evidence is found, and some respondents stated that only essential information should be reported.

Response. After considering the comments received regarding the reporting requirements, the PHS has concluded that these requirements should be retained as originally proposed, with the addition that the reports be made part of the assurance review process. The PHS understands, and agrees with, the need for the confidential handling of information relevant to investigations. The PHS accepts and pursues anonymous allegations, so long as sufficient information is provided to be able to initiate an inquiry. No information, other than that which ordinarily is available, for example under the Freedom of Information Act, is released by the Department while an investigation is under way, except to Department personnel on a need-to-know basis.

The reporting requirements also have been changed to reflect the establishment of the OSI, which now is the focal point for all of the PHS for dealing with allegations of scientific misconduct involving research, research training, or related activities supported under the PHS Act. All reports shall be sent to the OSI, rather than to PHS as was stated in the Proposed Rule.

The PHS strongly encourages institutions to adopt procedures that will provide due process to the accused. Section 50.104 sets forth basic due process procedures to be followed during the investigation, such as assuring that the accused is interviewed and has an opportunity to comment on the findings of the investigation.

The PHS believes the reporting requirements are not unduly burdensome and that they are necessary in order for the Department to carry out its responsibility under the statute for the stewardship of Federal funds. As recipient institutions gain experience in the conduct of investigations and the preparation of the reports of those investigations, the PHS will continue to evaluate its monitoring function. However, at this initial stage of implementation, the PHS believes that an active monitoring role is important and that the reports required under the regulation are essential to that role.

Impact Analyses

Executive Order 12291 requires that a regulatory impact analysis be prepared for "major" rules which are defined in the Order as any rule that has an annual effect on the national economy of $100 million or more, or certain other specified effects.

The PHS does not believe that this regulation will have an annual economic impact of $100 million or more or the other effects listed in the Order. For this reason, the PHS has determined that this regulation is not a major rule within the meaning of the Order.

The Regulatory Flexibility Act (5 U.S.C. 605(b)) requires that, for each rule with a "significant economic impact on a substantial number of small entities," an analysis be prepared describing the rule's impact on small entities and identifying any significant alternatives to the rule that would minimize the economic impact on small entities.

The Secretary certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and record-keeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

TITLE: Responsibilities of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science.

DESCRIPTION: As required by the PHS Act, the Secretary shall require that applicant and awardee institutions receiving PHS funding investigate and report any allegations of misconduct in science.

DESCRIPTION OF RESPONDENTS: Non-profit institutions, small businesses or organizations, for-profit organizations.

ESTIMATED ANNUAL REPORTING AND RECORD-KEEPING BURDEN:

Applicable Section of Policy	No. of Respondents	Hours per Response	Total hours
REPORTING:			
103(b)(1)	2,500	7	17,500
103(b)(2)	(2,500)	3.5	8,750
103(c)(4)/(d)(4)	(20)	0.2	4
103(d)(5)	(2)	0.5	1
103(d)(12)	(20)	0.5	10
103(d)(15)	(20)	0.5	10
104(a)(3)	(5)	0.5	2.5
104(a)(4)	(20)	0.2	4
104(a)(5)	(4)	1	4
104(b)	(2)	0.5	1
TOTAL			17,534
RECORD-KEEPING:			
103(d)(1)	(40)	4	160
103(d)(6)	(40)	0.5	20
103(d)(7)	(20)	40	800
103(d)(10)	(20)	0.2	4
TOTAL			984
DISCLOSURE:			
103(c)(2)	2,500	1.0	2,500
103(d)(1)	(40)	0.5	20
103(d)(7)	(20)	0.5	10
TOTAL			2,530
TOTAL BURDEN			21,048

As required by section 3504(h) of the Paperwork Reduction Act of 1980, the Department will submit for review by the OMB the above-cited information collection requirements. As OMB control numbers are assigned, we will publish a Notice in the Federal Register announcing them. Organizations and individuals desiring to submit comments on the information-collection requirements should direct such comments to the above-cited information address, and to:

Office of Information and Regulatory Affairs, OMB
New Executive Office Building, Room 3208
Washington, D.C. 20503
ATTN: Richard A. Eisinger

Catalog of Federal Domestic Assistance

This rule affects a great many PHS research programs. It would be wasteful and cumbersome to include a multi-page listing of them all here. Questions about this rule should be directed to the information address above where individual programs listed in the Catalog of Federal Domestic Assistance are affected.

List of Subjects in 42 CFR Part 50

Administration practice and procedure, American Samoa, Drugs, Family Planning, Grant programs in health, Guam, Northern Mariana Island, Pacific Islands Territory, Virgin Islands.
Dated: March 22, 1989

Ralph R. Reed,
Acting Assistant Secretary for Health
Approved: April 3, 1989

Louis W. Sullivan,
Secretary

For the reasons set out in the preamble, Title 42, Subchapter D, of the Code of Federal Regulations is amended to add Subpart A to Part 50, consisting of sections 50.101 through 50.105 to read as set forth below.

PART 50 - POLICIES OF GENERAL APPLICABILITY

Subpart A - Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science

Subpart A - Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science

Authority: Sec. 493, Public Health Service Act, as amended, 99 Stat. 874-875 (42 U.S.C. 289b); Sec. 501(f), Public Health Service Act, as amended, 102 Stat. 4213 (42 U.S.C. 290 aa(f)).

Section 50.101 Applicability.

This subpart applies to each entity which applies for a research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act. It requires each such entity to establish uniform policies and procedures for investigating and reporting instances of alleged or apparent misconduct involving research or research training, applications for support of research or research-training, or related research activities that are supported with funds made available under the PHS Act. This Subpart does not supersede and is not intended to set up an alternative to established procedures for resolving fiscal improprieties, issues concerning the ethical treatment of human or animal subjects, or criminal matters.

Section 50.102 Definitions.

As used in this Subpart:

"Act" means the Public Health Service Act, as amended, (42 U.S.C. 201, et seq.)

"Inquiry" means information gathering and initial factfinding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

"Institution" means the public or private entity or organization (including federal, state, and other agencies) that is applying for financial assistance from the PHS, e.g., grant or cooperative agreements, including continuation awards, whether competing or noncompeting. The organization assumes legal and financial accountability for the awarded funds and for the performance of the supported activities.

"Investigation" means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

"Misconduct" or "Misconduct in Science" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

"OSI" means the Office of Scientific Integrity, a component of the Office of the Director of the National Institutes for Health (NIH), which overseas the implementation of all PHS policies and procedures related to scientific misconduct; monitors the individual investigations into alleged or suspected scientific misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary.

"OSIR" means the Office of Scientific Integrity Review, a component of the Office of the Assistant Secretary for Health, which is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where scientific misconduct has been established.

"PHS" means the Public Health Service, an operating division of the Department of Health and Human Services (HHS). References to PHS include organizational units within the PHS that have delegated authority to award financial

assistance to support scientific activities, e.g., Bureaus, Institutes, Divisions, Centers or Offices.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

Section 50.103 Assurance - Responsibilities of PHS awardee and applicant institutions.

(a) Assurances. Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant:

(1) Has established an administrative process, that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and

(2) Will comply with its own administrative process and the requirements of this Subpart.

(b) Annual Submission. An applicant or recipient institution shall make an annual submission to the OSI as follows:

(1) The institution's assurance shall be submitted to the OSI, on a form prescribed by the Secretary, as soon as possible after November 8, 1989, but no later than January 1, 1990, and updated annually thereafter on a date specified by OSI. Copies of the form may be requested through the Director, OSI.
(2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe.

(c) General Criteria. In general, an applicant institution will be considered to be in compliance with its assurance if it:

(1) Establishes, keeps current, and upon request provides the OSIR, the OSI, and other authorized Departmental officials the policies and procedures required by this Subpart.

(2) Informs its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures.

(3) Takes immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged.

(4) Informs, in accordance with this Subpart, and cooperates with the OSI with regard to each investigation of possible misconduct.

(d) Inquiries, Investigations, and Reporting - Specific Requirements. Each applicant's policies and procedures must provide for:

(1) Inquiring immediately into an allegation or other evidence of possible misconduct. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry. If they comment on that report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

(2) Protecting, to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.

(3) Affording the affected individual(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

(4) Notifying the Director, OSI, in accordance with section 50.104(a) when, on the basis of the initial inquiry, the institution determines that an investigation is warranted, or prior to the decision to initiate an investigation if the conditions listed in section 50.104(b) exist.

(5) Notifying the OSI within 24 hours of obtaining any reasonable indication of possible criminal violations, so that the OSI may then immediately notify the Department's Office of Inspector General.

(6) Maintaining sufficiently detailed documentation of inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry, and shall, upon request, be provided to authorized HHS personnel.

(7) Undertaking an investigation within 30 days of the completion of the inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation. The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

(8) Securing necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation.

(9) Taking precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

(10) Preparing and maintaining the documentation to substantiate the investigation's findings. This documentation is to be made available to the Director, OSI, who will decide whether that Office will either proceed with its own investigation or will act on the institution's findings.

(11) Taking interim administrative actions, as appropriate, to protect Federal funds and insure that the purposes of the Federal financial assistance are carried out.

(12) Keeping the OSI apprised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

(13) Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

(14) Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated.

(15) Notifying the OSI of the final outcome of the investigation.

Section 50.104 Reporting to the OSI.

(a) (1) An institution's decision to initiate an investigation must be reported in writing to the Director, OSI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the PHS application or grant number(s) involved. Information provided through the notification will be held in confidence to the extent permitted by law, will not be disclosed as part of the peer review and Advisory Committee review processes, but may be used by the

Secretary in making decisions about the award or continuation of funding.

(2) An investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, and submitting the report to the OSI. If they can be identified, the person(s) who raised the allegation should be provided with those portions of the report that address their role and opinions in the investigation.

(3) Institutions are expected to carry their investigations through to completion, and to pursue diligently all significant issues. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under section 50.103(d), a report of such planned termination, including a description of the reasons for such termination, shall be made to OSI, which will then decide whether further investigation should be undertaken.

(4) The final report submitted to the OSI must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution.

(5) If the institution determines that it will not be able to complete the investigation in 120 days, it must submit to the OSI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the OSI. If satisfactory progress is not made in the institution's investigation, the OSI may undertake an investigation of its own.

(6) Upon receipt of the final report of investigation and supporting materials, the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The OSI may then request clarification or additional information and, if necessary, perform its own investigation. While primary responsibility for the conduct of investigations and inquiries lies with the institution, the Department reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation.

(7) In addition to sanctions that the institution may decide to impose, the Department also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seems appropriate.

(b) The institution is responsible for notifying the OSI if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exist:

(1) There is an immediate health hazard involved;

(2) There is an immediate need to protect Federal funds or equipment;

(3) There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

(4) It is probable that the alleged incident is going to be reported publicly.

(5) There is a reasonable indication of possible criminal violation. In that instance, the institution must inform OSI within 24 hours of obtaining that information. OSI will immediately notify the Office of the Inspector General.

Section 50.105 Institutional compliance.

Institutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested. An institution's failure to comply with its assurance and the requirements of this subpart may result in enforcement action against the institution, including loss of funding, and may lead to the OSI's conducting its own investigation.

NOTE: This Final Rule was published in the Federal Register on August 8, 1989, Vol. 54, No. 151, pp 32446-32451.

*U.S.GOVERNMENT PRINTING OFFICE:1990-261-138:00048