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The NIH Guide announces scientific
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SPECIAL ISSUE--POLICIES AND PROCEDURES FOR
DEALING WITH POSSIBLE MISCONDUCT IN SCIENCE

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MISCONDUCT IN SCIENCE

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FOREWORD

POLICIES AND PROCEDURES FOR DEALING WITH POSSIBLE MISCONDUCT IN SCIENCE

In recent years the issue of misconduct in science has become a matter of concern to research institutions, individual scientists, sponsors of research, and the general public. Examples of such misconduct are fabrication of research results, plagiarism, and misrepresentation of findings. Although instances of verified misconduct are rare, virtually every instance raises serious questions about the integrity of research and, since most biomedical and behavioral research is Federally funded, about the stewardship of Federal funds.

Prior to 1982, the National Institutes of Health (NIH) and other agencies of the Public Health Service (PHS) did not have established policies and procedures for responding to allegations or evidence of misconduct in research or related activities funded or conducted by PHS, unless those activities were also subject to regulation by the Food and Drug Administration (FDA). The occasional instances of misconduct were thought to be unique and therefore best treated on a case-by-case basis. More recent experience suggests that, at the very least, the incidence of reported misconduct has increased, and that certain fundamental issues obtain across the spectrum of cases. Therefore, recognizing that a formal conceptual framework could do much to ensure efficiency and equity, the Assistant Secretary for Health (ASH), DHHS, in 1982 directed NIH to coordinate the development of policies and procedures for dealing with misconduct in research and related activities funded, conducted, or regulated by PHS, and to develop a system for sharing information among agencies on matters of common concern.

The policies and procedures in this special edition of the Guide are the product of that effort and include the following documents:

- 1) "General Policies and Principles"--a brief statement intended to underscore the commitment of PHS to integrity in all research funded, conducted, or regulated by any PHS component.
- 2) "Policies and Procedures for Agencies and Programs Authorized to Make Awards for Research and Research Training"--a guide for agency staff responsible for grants, cooperative agreements, and contracts. Included is guidance for evaluating the significance of allegations, conducting an investigation, taking interim administrative actions when appropriate, and taking appropriate actions based on the findings of the investigation. It emphasizes the importance of protecting the rights of accused persons and informants and spells out the obligations of organizations that accept PHS funds for research and related activities.
- 3) "Summary of Procedures Affecting Regulated Research"--a compendium of FDA authorities affecting research funded or conducted by PHS. This document does not set forth new policies but explains how existing regulatory authorities affect PHS research programs.

- 4) "Policies and Procedures for Agencies Authorized to Conduct Research"--a guide for agency managers responsible for intramural research. It embodies the same general principles as the document described in (2) above modified to comply with civil service procedures.

Scope of Policies and Procedures

These documents define "misconduct" as: (1) serious deviation, such as fabrication, falsification, or plagiarism, from accepted practices in carrying out research or in reporting the results of research; or (2) material failure to comply with Federal requirements affecting specific aspects of the conduct of research--e.g., the protection of human subjects and the welfare of laboratory animals. Excluded are deviations from grant or contract management policies that may result from a weakness in institutional controls or disagreements between an awardee institution and a PHS component. Also excluded are matters that involve possible criminal violations. Most importantly, perhaps, this definition does not include certain types of possibly inappropriate practices that should be of concern to scientists everywhere but do not necessarily call for Federal action. These include, for example, coauthorship practices, recognition of collaborators, and multiple publication. Although PHS encourages institutions, professional societies and individual scientists to address broad questions of proper scientific conduct, the scope of these policies is limited to issues affecting funding or other direct transactions with PHS.

Status and Implementation

The policies and procedures described above were approved by the Acting Assistant Secretary for Health, on April 8, 1986. They are currently in effect for PHS. They have been designated as "interim" policies pending the completion of certain actions, such as their incorporation into standard guidance documents for staff. Portions of the policies requiring additional implementation steps are discussed below.

"Policies and Procedures for Agencies and Programs Authorized to Make Awards for Research and Research Training" includes a section entitled "Awardee Responsibilities" setting forth the obligations of organizations that accept PHS funds. In brief, awardee institutions are required to (1) develop their own policies and procedures for dealing with possible misconduct and (2) inform PHS of the initiation of a formal investigation of possible misconduct. Essentially the same requirements were enacted as a provision of P.L. 99-158, the "Health Research Extension Act of 1985." The scope of the legislation is broader, as it requires the filing of an assurance from each applicant organization covering the two points above.

The PHS is developing a regulation to implement the recent legislation and expects to issue a notice of proposed rulemaking within the next few months. Associated with this is a review by the Office of Management and Budget of the reporting and record-keeping requirements imposed by the policy and regulations.

Also in preparation is a Federal Register notice announcing the proposed expansion of the NIH ALERT system to all PHS research and related activities. The ALERT is a system for providing responsible agency officials, on a need-to-know basis, with information that an individual or institution is currently under

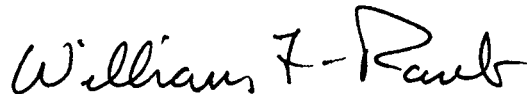
investigation or is subject to some restriction, for a specified period of time, as a result of adjudged misconduct. Inclusion in the ALERT does not necessarily preclude receiving an award or otherwise participating in PHS programs, e.g., as a review committee member. It enables the agency to make informed decisions about individual circumstances. Access to records in the ALERT is strictly controlled.

The NIH ALERT is a system of records under the Privacy Act. The current Privacy Act notice was published in the Federal Register on November 29, 1983 (Vol. 48, No. 230, pp 53851-2). PHS expects to publish a notice of a proposed major alteration to this system in the near future.

Agency Contacts

Finally, it should be noted that the policies require each PHS agency to designate a "Misconduct Policy Officer" (MPO) to oversee the implementation of the policies and to coordinate agency investigations. I will serve as the PHS MPO. Agency MPOs are listed on the following page.

We hope these documents will be helpful to the research community. We welcome your comments on these documents as well as the formal Federal Register notices. Please direct your comments to Ms. Mary L. Miers, the NIH MPO, at the address on the following page.



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PUBLIC HEALTH SERVICE

POLICIES AND PROCEDURES FOR DEALING WITH POSSIBLE MISCONDUCT IN SCIENCE

General Policies and Principles

BACKGROUND AND PURPOSE

- A. Instances of misconduct in scientific activities conducted, funded, or regulated by the Public Health Service (PHS) are rare. However, when such instances occur, they present a serious threat to continued public confidence in the integrity of the scientific process and the stewardship of federal funds.
- B. This policy provides the basis for uniform procedures for dealing with instances of alleged or apparent misconduct, as the term is defined herein, and the responsibilities for such actions.

APPLICABILITY

The policies and procedures articulated in this document apply to all instances of alleged or apparent misconduct involving research, research training, and related activities conducted, funded or regulated by the PHS. Issues that are not primarily scientific are outside the scope of these procedures.

DEFINITION

"Misconduct" is defined as (1) serious deviation, such as fabrication, falsification, or plagiarism, from accepted practices in carrying out research or in reporting the results of research; or (2) material failure to comply with Federal requirements affecting specific aspects of the conduct of research--e.g., the protection of human subjects and the welfare of laboratory animals.

POLICY

- A. It is the policy of the PHS to maintain high ethical standards in research and to investigate and resolve promptly and fairly all instances of alleged or apparent misconduct.
- B. The scientific community is expected to make every effort to prevent misconduct. Also, for every incident of alleged or apparent misconduct that is judged to warrant investigation by an awardee institution, that institution is expected to report promptly on the matter to the head of the appropriate PHS agency/office or his/her designee in accordance with PHS reporting requirements. Issues involving potential criminal violations, such as misappropriation of Federal funds, must be promptly reported to the HHS Office of Inspector General prior to any investigation under these procedures.

SANCTIONS

If it is determined that misconduct has occurred, the head of the PHS agency/ office has a number of options available, depending on the severity of the misconduct and the mission of the agency/office:

1. In the case of research funded by the agency/office, there will be action with respect to present or future grant and/or contract awards (e.g., imposition of special conditions, suspension, termination, or recommendation for debarment of an individual or institution), or other transactions such as committee appointments.
2. In the case of research regulated by the agency/office, there will be special restrictions on individuals or institutions, (e.g., disqualification from eligibility to use investigational drugs).
3. In the case of research conducted by the agency/office, there could be termination of employment or other disciplinary action against an individual.

RESPONSIBILITIES

- A. Officials and scientific staff of organizations receiving funds from the Public Health Service (PHS) are responsible for:
 1. Taking steps to prevent misconduct in PHS-funded research.
 2. Taking immediate and appropriate action when misconduct is known, suggested, or alleged.
 3. Informing research staff of the importance placed on this subject matter by the institution and the PHS.
- B. The Deputy Director for Extramural Research and Training (DDERT), Office of the Director, NIH, is the PHS designated official for the development and assessment of policies and procedures for preventing, detecting, reporting, and handling instances of alleged or apparent misconduct in science and for oversight and coordination of PHS activities related to misconduct.
- C. The head of each PHS agency/office will:
 1. Provide leadership to ensure appropriate agency implementation of policies and procedures for the fair and prompt handling of instances of alleged or apparent misconduct in science.
 2. Make decisions regarding sanctions that should be applied in a given case of confirmed misconduct.
 3. Designate an official for implementing PHS policies and procedures; coordinating its activities with the PHS designated official and other departmental officials, including the Inspector General and the General Counsel, as appropriate; and ensuring that each bureau, institute, and equivalent organizational unit designate an official for handling matters relating to misconduct in science.

D. Alleged or apparent violations of Federal regulations governing the protection of human subjects or PHS animal welfare policy in cases involving DHHS funded research are the responsibility of the Office for Protection from Research Risks (OPRR), NIH.

INTERIM PUBLIC HEALTH SERVICE
POLICIES AND PROCEDURES FOR DEALING WITH
POSSIBLE MISCONDUCT IN SCIENCE

Policies and Procedures
For
Agencies and Programs Authorized to Make Awards
for Research and Research Training

APPLICABILITY

The policies and procedures described in this document apply to all instances of possible misconduct involving research, research training, or related activities for which Public Health Service (PHS) funds have been provided or requested. This guidance is an extension of the PHS General Policies and Principles for dealing with alleged or apparent misconduct in scientific activities conducted, funded, or regulated by the PHS. Issues that are not primarily scientific are outside the scope of these procedures.

DEFINITIONS

"Misconduct" is defined as (1) serious deviation, such as fabrication, falsification, or plagiarism, from accepted practices in carrying out research or in reporting the results of research; or (2) material failure to comply with Federal requirements affecting specific aspects of the conduct of research, e.g., the protection of human subjects and the welfare of laboratory animals.

"Funded by," means the provision of monetary support for grants, cooperative agreements, fellowships, contracts, or interagency agreements, and includes subgrantees, subcontractors and individuals who work on the funded research project even though they do not receive compensation from the Federal funds.

"Investigator" means the principal investigator, the co-investigator(s), the program director or trainee on a training grant, the recipient of a career award or fellowship, or other individual who conducts or is responsible for research or research training funded by the PHS.

An "Inquiry" consists of information-gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

An "Investigation" is a formal examination and evaluation of all relevant facts to determine if an instance of misconduct has taken place. If misconduct has already been confirmed, an investigation may, nevertheless, be conducted to determine the extent of any adverse effects resulting from the misconduct.

The PHS ALERT for Misconduct in Science is a system for collecting, controlling, and disseminating to PHS officials on a need-to-know basis information that an institution, organization, or individual currently receiving PHS funds or likely to submit a grant or cooperative agreement application or a contract proposal: (1) is under investigation for possible misconduct, or a decision has been made to undertake such an investigation; or (2) has been subjected to a sanction at the conclusion of an investigation for misconduct (e.g., debarment by the Secretary, Department of Health and Human Services (DHHS) from eligibility for research funding, disqualification by the Food and Drug Administration (FDA) from use of investigational drugs, or in the case of scientists employed by the PHS, termination of employment). The information about an organization or individual is used to aid the PHS official in making an informed decision regarding the funds or other PHS benefits to that organization or individual, but such information does not automatically result in a withholding of funds or other benefits.

"Agency" or "funding agency" means each of the PHS agencies as well as the awarding units within the Office of the Assistant Secretary for Health (OASH).

"Component" refers to (1) the organizational units within an agency that have the delegated authority to conduct and/or make awards for scientific activities, e.g., Bureaus, Institutes, Divisions, or Offices, or (2) in the case of the FDA, National Centers or Bureaus.

"Program" is a set of plans and activities for a specific area of scientific or technical subject matter within the mission of a component.

"MPO" means Misconduct Policy Officer, i.e., the official designated to oversee and coordinate PHS, agency, or component implementation of policies related to misconduct in science. Such designation need not entail creation or change in title of a position provided the functions described in this issuance can be appropriately discharged.

RESPONSIBILITIES

1. Awardee institutions have primary responsibility for preventing, detecting, and dealing with possible misconduct in research programs funded by the PHS. These responsibilities include conducting, supporting, or commissioning investigations as appropriate, as well as informing and cooperating with the awarding agency.
2. The Deputy Director for Extramural Research and Training (DDERT), Office of the Director, NIH, is the PHS MPO. He is responsible for the development, implementation, and assessment of PHS policies related to misconduct in science.
3. The head of each PHS agency will (a) provide leadership to ensure appropriate implementation of policies and procedures for fair and prompt handling of alleged or apparent instances of misconduct in scientific activities currently or previously funded by the agency; (b) decide whether or not interim administrative actions should be taken to protect Federal interests during

investigation of possible misconduct; (c) within the scope of his/her authority, make decisions regarding sanctions that should be applied in cases of confirmed misconduct; and (d) identify an agency MPO.

4. Agency-level MPOs will, in consultation with the responsible offices: (a) coordinate activities with the PHS MPO as appropriate; (b) provide guidance to agency staff regarding these policies and procedures; (c) ensure that inquiries and investigations are conducted in an appropriate and timely manner; (d) coordinate intra- and interagency activities as necessary; (e) determine when a record of individuals and/or institutions under investigation should be established in or removed from the PHS ALERT System, (f) recommend to the agency head interim administrative actions, where appropriate; (g) coordinate follow-up actions to an investigation, and (h) provide guidance to awardee institutions regarding their responsibilities for promoting adherence to high ethical standards in science and otherwise for dealing with instances of possible misconduct.
5. The director of each awarding component will (a) provide the leadership to ensure implementation of these policies and procedures, (b) make recommendations, as appropriate, to the agency head on specific cases, and (c) identify an individual to be the MPO for the component.
6. Component-level MPOs will (a) make available to staff within the component information on policies and procedures related to misconduct; (b) notify, when appropriate, other offices within the agency that need to be informed of possible misconduct; (c) coordinate and/or assist in conducting investigations at the component level, if appropriate; and (d) coordinate follow-up actions to those investigations that are undertaken.
7. Instances of possible misconduct which become known to agency staff must be reported promptly to the MPO of the involved component, who, in turn, will be responsible for informing his/her Component Director and agency-level counterpart.
8. Agency-level MPOs shall decide how instances of possible misconduct will be handled and shall coordinate the necessary activities with the MPO and other relevant staff of the appropriate component.
9. Cases involving possible misuse of federal funds, DHHS internal audits, and investigations by the General Accounting Office or the Office of the Inspector General will be handled by the agency's unit that has jurisdiction over such matters.
10. Investigation of alleged or apparent violations by recipients of PHS research funds of either (a) federal regulations governing the protection of human subjects or (b) PHS animal welfare policy is the responsibility of the Office for Protection from Research Risks (OPRR), NIH. In the case of research that is both funded by the Food and Drug Administration (FDA) and subject to FDA regulation, responsibility for the conduct of individual investigations will be assigned according to mutual agreement between OPRR and the FDA MPO.

11. Matters arising during an inquiry or investigation that (a) involve current or potential litigation or (b) require legal interpretation will be handled by or in consultation with the Office of General Counsel (OGC). OGC should be consulted throughout the inquiry/investigation process to ensure that all potential legal issues have been considered.
12. Matters arising during an inquiry or investigation that involve a potential criminal violation shall be promptly referred to the OIG. Where the OIG or another law enforcement agency is conducting a related investigation into potential criminal violations, that agency must be consulted during the inquiry/investigation into scientific misconduct to ensure proper coordination.
13. After the initial referral to the OIG, the agency-level MPO shall insure that the OIG is consulted in advance in all appropriate instances.
14. The agency-level MPOs will meet bimonthly as a standing committee (the "PHS Committee on Misconduct in Science") under the chairmanship of the PHS MPO. This committee is to ensure (a) mutual consultation on, and review of, policy issues of common interest, (b) sharing of information relevant to more than one agency, and (c) collaboration on joint investigations, when warranted. The Committee will refine PHS-wide policies and procedures, as necessary, and promptly apprise relevant agency staff and awardees of changes once they have been approved by the Assistant Secretary for Health (ASH).
15. Inquiries from the communications media will be coordinated by a designated office in each agency and referred to the agency-level MPO, as appropriate. Press releases related to misconduct in science must be cleared by the agency's public affairs office, the Office of Assistant Secretary for Health and the Office of the Secretary.

POLICY

1. The MPOs throughout the PHS will make a continuing effort to inform agency staff, scientific review groups, national advisory councils/boards (or equivalents) and the scientific community of the policies and procedures defined in this document and to emphasize the importance placed on this matter by PHS.
2. All agency actions taken in response to instances of alleged or apparent misconduct will take into consideration (a) safeguards for the affected parties--e.g., confidential treatment, prompt and thorough inquiry and/or investigation, and opportunity to comment on all allegations and/or findings; (b) the rights of informants--e.g., protection of their privacy and (c) the need to ensure that the interests of the Government are protected.
3. As a general rule the awardee and/or employer institution should initiate its own inquiry into an instance of possible misconduct and conduct a subsequent investigation, if warranted, unless the possibility of a criminal violation suggests that early notification of the OIG is warranted. Such notification may be made through the funding agency.

4. When a PHS agency decides to initiate an investigation, the individuals and/or institutions that are to be the subjects shall be notified of that fact before the investigation commences, unless a law enforcement agency conducting a related investigation requests otherwise. This notification should include information on the nature of the allegations or concerns and the focus of the investigation. The recipients of the notification will also be informed of the opportunity to provide comments and other relevant information to the funding agency, and if criminal charges are involved, the OIG, or other law enforcement agencies.
5. Interim administrative actions may be necessary prior to completion of an investigation to safeguard the integrity of the project involved, prevent inappropriate use of Federal funds, or otherwise protect the interests of the funding agency and the public.
6. As a general rule, allegations or information developed in the course of an ongoing investigation will be made available only to the PHS MPO, the appropriate agency-level MPO, agencies conducting related investigations, and individuals who (a) are involved in or associated with the actual conduct of an investigation; or (b) have direct responsibility for an ongoing or pending award. The agency-level MPO will immediately inform his/her counterparts in the other agencies if: (a) it appears that they have an active or pending award that might be affected; (b) it might have a bearing on a decision to appoint an individual as an advisor, consultant, or reviewer; or (c) the information is relevant to the regulatory responsibilities of another agency. As provided in the PHS ALERT for Misconduct in Science, the bimonthly meetings of the PHS Committee on Misconduct in Science will include a brief review of pending investigations to ensure that all relevant agency concerns are addressed.
7. Review of grant/cooperative agreement applications and contract proposals for scientific merit will not ordinarily be delayed by concerns about possible misconduct or by a pending or ongoing investigation. To avoid influencing the review process, PHS awarding units generally will not inform members of scientific review groups about instances of possible misconduct or the status of ongoing investigations. However, if certain instances have received such extensive publicity that the review may be compromised, the agency-level MPO may recommend that officials responsible for review defer the review or inform the reviewers of the status of the agency's activities with regard to the possible misconduct. By contrast, findings from completed investigations should be shared with scientific review groups whenever the information bears directly upon the investigator's scientific or fiscal integrity or disclosure is necessary to provide an accurate account of the facts in the case.
8. Directors of awarding components are to consult with and seek the advice of their national advisory councils/boards (or equivalents) on a potential competing grant or cooperative agreement award to an individual or institution under investigation by the awardee institution, the funding agency, or another entity (when such disclosure is otherwise permissible). When a non-competing award is involved, the agency-level MPO should be consulted.

9. The agency-level MPO, in consultation with the appropriate offices, will determine if a record of the subject(s) of investigation is to be created in the ALERT system and, if so, will implement such a decision through the Director, Division of Management Survey and Review (DMSR), NIH. (See PHS ALERT for Misconduct in Science for further details.)
10. The agency-level MPO shall ensure that every reasonable effort is made to allow the subject(s) of an ongoing or completed investigation to provide comments, rebuttals and other related information for consideration by the investigating agency.
11. In responding to any request(s) from a non-DHHS source for information about ongoing investigations, agency staff shall maintain the confidentiality of such information to the greatest extent possible under the provisions of the Freedom of Information Act, the Privacy Act, and other applicable law. To the extent permitted by law, agency personnel will protect the identity, if desired by the subject, of any person who is the subject of an inquiry that is terminated without triggering an investigation, or any person on whom an investigation fails to confirm misconduct. To the extent permitted by law, it is PHS policy to protect the identities, if desired by the persons affected, of those who in good faith report apparent misconduct or furnish information about such apparent misconduct.
12. If the investigation does not establish misconduct, the funding agency responsible for the investigation shall promptly notify all concerned parties in writing.
13. Upon completion of an investigation that confirms misconduct, the funding agency shall take steps to initiate or impose appropriate sanctions.
14. When sanctions are imposed upon recipients of PHS financial assistance or contracts, the head of the PHS awarding component shall ensure that the notification is provided as required under the HHS Alert System. (See PHS Grants Administration Manual Chapter i:1-06.)

PROCEDURES

Reporting of Possible Misconduct

1. The PHS MPO shall maintain and update, as necessary, a list of the names of individuals who have been appointed as agency-level MPOs.
2. Each agency-level MPO shall maintain and update periodically a list of the names of individuals who have been appointed as MPOs at each level within the agency.
3. Staff who receive a report or suspect an instance of possible misconduct shall promptly and discreetly inform the MPO at the awarding component level who will then notify the agency-level MPO and the director of the awarding component.

4. To the extent possible, the identity of informants who do not wish to be generally known will be kept confidential.
5. The awarding component's MPO should document whatever information he/she receives regarding an instance of possible misconduct. If appropriate, he/she should request additional information from the awardee institution.
6. The agency MPO, in consultation with other offices as appropriate, shall review the allegation for the purpose of determining if there is a possibility of criminal misconduct. If the possibility exists, the agency MPO shall ensure that the matter is referred through appropriate channels to the OIG and shall coordinate efforts if a related investigation is initiated.

INQUIRIES

1. The unit in whose jurisdiction the case falls—e.g., OPRR, DMSR, or the awarding component—shall promptly initiate an inquiry to determine whether an investigation is warranted. As a general rule, no more than 60 days should elapse between the reporting of an instance of possible misconduct and the completion of an inquiry.
2. The agency-level MPO shall direct that a search of its record system(s) be made to identify other ongoing or pending awards so that (a) if appropriate, other awarding components within the agency, including review staff, may be informed and (b) the potential effects of any misconduct on the institution's or investigator's eligibility for current or future awards are duly considered.
3. The agency-level MPO, in consultation with (a) the director of the agency's unit that has authority for investigating the type of possible misconduct reported, (b) the MPO in the awarding component, and (c) the director of the awarding component shall decide whether a formal investigation is warranted. These determinations, to be made on a case-by-case basis, require an assessment of the following factors:
 - a. the accuracy and reliability of the source of information about the possible misconduct;
 - b. the seriousness of the possible misconduct;
 - c. the scope of the incident(s) and the context in which it (they) became known;
 - d. explanations, if any, that are provided by the subject(s) of the inquiry; and
 - e. other information developed during the inquiry.

INVESTIGATIONS

1. When an awardee institution has promptly initiated an investigation, the funding agency may defer its own fact-finding activities until it has received the results of the institutional investigation. If at the end of 120 days the institutional

investigation is not making satisfactory progress and if it offers little prospect of an expeditious conclusion, then the agency should proceed with its own investigation. In an instance in which the funding agency decides to defer its own fact-finding activities, such decision should be documented by the agency-level MPO.

2. If the matter involves a concurrent investigation of scientific and criminal allegations conducted by the Department of Justice, the Federal Bureau of Investigation or the Office of the Inspector General without the knowledge of the individual or institution, OGC or the agency's unit in whose jurisdiction the case falls will notify both the awarding component's MPO and its director as to what information, if any, may be disclosed to the subject(s) of the investigation. Disclosure should be made only after consultation with the OIG and other appropriate law enforcement offices.
3. When the agency decides to initiate an investigation, individuals and/or institutions that are to be investigated must be notified immediately in writing by the agency-level MPO or his/her designee.
4. The agency-level MPO shall take appropriate steps to establish a record of individuals and organizations under investigation in the PHS ALERT as provided in "Public Health Service ALERT for Misconduct in Science."
5. The methods and procedures for conducting an investigation will necessarily vary depending on a number of factors, including: (a) the nature of the allegation/evidence; (b) the source(s) of information; (c) the extent to which a current award(s) may be involved; (d) whether an awardee institution has already conducted and documented its own investigation, and the extent to which documentation is available; and (e) the degree of publicity associated with the case; and (f) the involvement of law enforcement agencies.
6. An investigation may consist of a combination of activities such as, but not limited to:
 - a. review of readily available documents that the agency has already received from the individual and/or institution, e.g., grant or contract files, reports and other documents;
 - b. review of documents at the awardee institution or elsewhere;
 - c. review of administrative procedures and/or methods at the awardee institution, including whatever investigative process the institution followed in dealing with the instance at hand;
 - d. inspection of laboratory or clinical facilities and/or materials at the awardee institution; and/or
 - e. interviewing of parties with an involvement in or knowledge about the case.

7. In any given case, the agency-level MPO shall be responsible for ensuring that appropriate consultation takes place among representatives of the involved awarding component(s), OGC, the agency unit responsible for investigating the case, and review staff. Investigations falling clearly within the jurisdiction of a particular office (e.g., OPRR, DMSR) may be coordinated by that office provided the agency-level MPO is informed of progress and any problems that may arise.
8. If outside consultants are to be invited to participate in an investigation, either as site visitors to the awardee institution or in some other capacity, they must be appointed in a manner that ensures the official nature of their involvement and provides them with such legal protections as are available to federal employees.

INTERIM ADMINISTRATIVE ACTIONS

1. Prior to completion of an investigation by either the funding agency or the awardee institution, the agency-level MPO may recommend to the director of the awarding component that interim administrative actions be taken to protect the welfare of human or animal subjects of research, prevent inappropriate use of federal funds, or otherwise protect the public interest. This recommendation shall be made only after consultation with:
 - a. the MPO of the awarding component;
 - b. OGC;
 - c. the unit of the agency responsible for investigating the case; and
 - d. a senior grants or contract management official.

Interim actions affecting more than one awarding component should be brought to the attention of the agency head.

If an investigation is being conducted by a law enforcement agency or the OIG, the agency MPO should (1) consult with OGC before recommending any action that might disclose or otherwise compromise the investigation and (2) consult with the OIG prior to implementing any administrative actions.

2. The following principles should guide the selection of an interim administrative action:
 - a. Interim actions should be taken only after it has been determined that a formal investigation is warranted. The decision to undertake an investigation is a necessary, but not always sufficient, condition for taking an interim action.
 - b. Any interim restriction should be taken with a view toward protecting the rights of all involved parties and minimizing disruption to the project, the institution, and the activities of those involved in the project.

- c. Interim action should be taken promptly when (1) there is evidence of a serious failure to comply with the requirements for the protection of human or animal subjects, or (2) the welfare of such subjects of research is or has been jeopardized.
 - d. An interim action may be taken when additional information developed during the course of an investigation indicates the need for such action. Similarly, temporary restrictions that have been imposed should be reviewed periodically and modified, if warranted by additional facts or findings.
3. Interim administrative actions may include, but are not limited to, the following:
 - a. total or partial suspension of an award;
 - b. total or partial suspension of eligibility for financial assistance (grants or cooperative agreements) in accordance with DHHS debarment regulations (45 CFR 76) and for contracts in accordance with applicable regulations (48 CFR Subpart 9.4; 48 CFR 309.4; 50 Federal Register 7780, February 26, 1985).
 - c. proscription or restriction of certain research activities, e.g., restrictions to protect any human or animal subjects of research whose welfare may be in jeopardy;
 - d. requirement for special certification, assurances or other administrative arrangements to ensure that specific activities are carried out in compliance with applicable regulations or terms of the award;
 - e. more restrictive requirements for prior approval;
 - f. deferral of a noncompeting continuation grant or cooperative agreement;
 - g. deferral of a competing grant or cooperative agreement;
 - h. delaying a contract award; and
 - i. restriction or suspension of the use of individuals under investigation as advisors or consultants to the agency.
 4. All interim administrative actions that are taken, and the reasons for taking them, must be fully and promptly recorded in the investigative files. Information recorded in the grant or contract files shall be limited to the minimum necessary to implement the action(s).
 5. Certain interim administrative actions under 3.a. through h. above shall also be reported to the Director, DGC/OASH, for possible inclusion in the HHS Alert System. Interim actions that should be communicated to OASH include those having PHS-wide or DHHS-wide implications, e.g., suspension of an award or recommendation that an individual or institution be suspended from eligibility for funding. Such actions, while they may be taken prior to the conclusion of an investigation, include procedural safeguards for the protection of individual

rights and institutional interests. Actions whose scope is limited to a single agency's transactions, e.g., restrictions on appointments to advisory committees or imposition of special terms or conditions on an award, are ordinarily not appropriate for disclosure to PHS staff who do not have a clear need to know of them.

POST-INVESTIGATIONAL ACTIONS

1. Upon completion of an agency investigation, the investigative team shall prepare a written report summarizing its findings. This report shall be reviewed by the agency-level MPO and the director of the awarding component.
2. If there is an ongoing related law enforcement investigation, the agency-level MPO shall obtain the OIG concurrence prior to releasing the report to the subject.
3. As a general rule, every reasonable effort should be made to complete an investigation and the report of findings within 120 days of completion of the preceding inquiry. This time frame will, however, depend heavily on such factors as whether or not the instance of possible misconduct was an isolated event or part of a repeated pattern, whether the subject has already admitted culpability or disputes the allegations or other information suggesting his/her culpability, and other circumstances that may require time-consuming pursuit of facts. If an investigation and the attendant report of findings cannot be completed in 120 days, an interim report on progress to date and an estimated schedule for completion of the final report must be prepared and submitted to the agency-level MPO at the end of 90 days. Thereafter a status report must be submitted every 60 days until such time that the report of investigative findings is completed.

When investigative findings fail to confirm an instance of misconduct and the agency-level MPO concurs with such findings, the following procedures shall apply:

- A. The subject(s) of the investigation, his/her immediate supervisor and, if appropriate, the individual or institutional official who reported the possible misconduct, will be notified in writing. This notification, which may include the report of findings from the investigation, will be sent by:
 - (1) the unit of the agency responsible for conducting the investigation; or
 - (2) OPRR, if the case involved possible violations of either federal regulations governing the protection of human subjects or PHS animal welfare policy; or
 - (3) the agency-level MPO, if the case did not fall in the jurisdiction of the units identified in (1) or (2) above.
- B. A copy of the above notification should also be provided to:
 - (1) the agency-level MPO (if the latter is not the party responsible for sending the notification);

- (2) the director of the awarding component;
 - (3) the awarding component's MPO; and
 - (4) members of the investigative team, if any, who are drawn from outside the investigative unit.
- C. The agency-level MPO will assure the lifting of whatever interim administrative restrictions may have been imposed.
 - D. If a record of the subject(s) of investigation has been created in the ALERT system, the agency-level MPO will direct the removal of the names of the affected individual(s) or organizations(s).
 - E. If a competing application or proposal is pending or anticipated in the near future, the agency-level MPO will consult with officials responsible for review in order to identify and resolve any concerns that might affect the objectivity of the review, e.g., informing the Executive Secretary and reviewers of the outcome. Such action should only be taken if there is reason to believe that reviewers have received incomplete or misleading information about the case.

When investigative findings confirm misconduct and the agency-level MPO concurs with such findings, the following procedures shall apply:

- A. The agency MPO will, except in unusual circumstances, provide a copy of the report to the individual(s), his/her immediate supervisor, and/or institution(s) under investigation. As a general rule, the subject(s) of the investigation shall be allowed no more than 30 days to provide comments or rebuttal.
- B. All responses submitted by the subject(s) of the investigation shall receive full consideration and, where appropriate, may lead to revision or expansion of the report before it is forwarded for action to the agency head. Such comments will be appended to the report unless it is determined that such action would constitute an unwarranted invasion of an individual's privacy.
- C. In a case in which the report of investigative findings is prepared by the awardee institution, the funding agency must take certain actions to assess the accuracy, thoroughness and acceptability of the report. These actions may include (i) seeking the comments/rebuttal of the subject(s) of the investigation in instances in which the institution has failed to do so, and (ii) conducting a review of the institution's investigation in instances in which there is insufficient documentation of adequate procedures, scope or thoroughness in the investigation. Upon completion of this process, which generally may take up to 30 days, the agency shall either accept the institution's report or initiate its own investigation.
- D. When an investigative report is determined to be complete and accurate, the agency-level MPO will arrange for a systematic review of the investigative findings and all relevant documents, including comments and rebuttals, if any,

from the subject(s) of the investigation, to determine what sanctions should be recommended to the agency head. (A listing of possible sanctions is given below.) As a general rule, this process, including the preparation of the decision document for the agency head, shall be completed within 30 days.

- E. Participants in the effort to review the investigative report and recommend sanctions shall include at least the following:
 - (1) the agency-level MPO;
 - (2) the director(s) of the awarding component(s) currently funding an award or considering a pending award;
 - (3) the awarding component's MPO;
 - (4) the director(s) of the affected program(s) within the involved awarding component(s);
 - (5) senior agency-level grant or contract policy staff;
 - (6) a representative of OGC; and
 - (7) at least one senior agency official with no direct involvement in the case.

- F. Agency staff members who have conducted the investigation may be invited, as appropriate, to serve as resources to the group identified in E above.

- G. When the investigative report has been compiled by the OIG, that office may be invited to participate. If a related law enforcement investigation is underway, the OIG should be consulted prior to transmitting recommendations to the agency head.

- H. The following factors should be considered in deciding which sanctions are appropriate in a given case:
 - (1) need for reasonable consistency in the application of sanctions, i.e., violations of the same type or degree deserve the same kind of sanction(s);
 - (2) the nature of the misconduct, i.e., was the violation deliberate, the result of carelessness, or was it caused by factors that might not have been reasonably foreseen or controlled?
 - (3) whether the incident of misconduct was an isolated event or part of a pattern;
 - (4) the degree of seriousness or gravity of the violation (e.g., were data fabricated or falsified? was human life jeopardized? were animals abused?)

(5) whether the nature of the misconduct is relevant only to certain funding requests/awards or whether it is germane to all requests from or awards to the institution or individual(s) found culpable of misconduct.

- H. The agency head shall review the recommendations of the group identified in E above. If he/she elects to recommend debarment, he/she must apprise the appropriate higher level official promptly and in writing; subsequent communications with the affected individual(s) or institution(s) shall be in accord with the applicable regulations. Otherwise, the agency head within 30 days, as a general rule, shall communicate his/her decisions in writing to the affected investigator(s) and/or institution(s).
- I. Any sanctions imposed by the agency head shall be communicated in writing to the Director, DGC/OASH for inclusion in the HHS Alert System.
- J. The PHS ALERT may be used to implement post-investigational sanctions. Information retained in the official grant or contract file shall be limited to the minimum necessary to implement the action(s) in order to avoid unintended damage to individual reputations or prospects for funding.

SHARING OF AGENCY FINDINGS OF MISCONDUCT

The following options are available to the PHS MPO and the agency-level MPOs for application in appropriate circumstances. These options are reserved for cases of confirmed misconduct in which the seriousness of the misconduct-- e.g., widespread dissemination of fabricated research findings or the abuse of human research subjects or laboratory animals--necessitate sharing of information about the affected individual(s) and/or institution(s) with other federal or non-federal groups and/or organizations. These options should not be considered as mandatory actions but rather as potential actions that might be taken by a PHS agency.

1. The PHS MPO may share investigational findings - including associated commentaries/ rebuttals from the affected individual(s), department(s) and/or institution(s) - with other PHS agencies, federal agencies outside the PHS, and non-federal agencies or organizations.
2. The agency-level MPO may share, for a specified period of time, investigative findings - including associated commentaries/rebuttals from the affected individual(s), department(s) and/or institution(s) - with scientific review groups and national advisory councils/boards (or equivalents) when they consider requests for further funding from those individual(s), department(s), and/or institution(s).

SANCTIONS

The sanctions listed below, provided here for guidance, are classified by degree of severity, ranging from those which constitute minimal restrictions (Group I) to those that are the harshest and most extreme (Group III). They do not include possible criminal

sanctions which may be applicable in some cases. Any of these sanctions may also involve recovery of funds if such action is warranted by the investigative findings and is otherwise appropriate to the funding instrument.

GROUP I SANCTIONS

- o Send a letter of reprimand for improper action to the individual and/or institution.
- o Require, for a specified period of time, that an individual, department, and/or institution obtain from the funding agency special prior approval of particular activities as a condition of award.
- o Require, for a specified period of time, that an institutional official other than the individual found culpable of misconduct certify the accuracy of reports generated under an award and/or provide assurance of compliance with particular policies, regulations, guidelines, or special terms and conditions.

GROUP II SANCTIONS

- o Restrict, for a specified period of time, specific activities or expenditures under an active award(s).
- o Require, for a specified period of time, that the concerned national advisory council(s)/board(s) (or equivalents) conduct a special review of all awards to the affected individual, department, and/or institution to determine whether funding should be continued.
- o Require, for a specified period of time, special reviews of all requests for funding from the affected individual and/or institution to ensure that the every reasonable step has been taken to prevent repetition of the misconduct.
- o Prohibit participation of affected individuals on peer review committees, advisory groups or in other related PHS activities for a specified period of time.

GROUP III SANCTIONS

- o Immediately suspend/terminate an active award(s).
- o Withhold funding of specific future non-competing grants or contracts.
- o Debar or suspend the individual, department, and/or institution for a specified period of time, declaring them ineligible for any participation in PHS grants,

cooperative agreements or contracts. (This action may be taken only by the Deputy Assistant Secretary for Procurement, Assistance, and Logistics, OS.

PROTECTION OF RECORDS FROM RELEASE UNDER THE FOIA

1. An investigation will be considered to be pending and prospective, or active and ongoing, and therefore all records will be withheld to the extent allowed by the FOIA, until one of the following events occurs:
 - a. In the event the investigative findings fail to confirm misconduct: When the subject(s) of the investigation are notified in writing of that decision.
 - b. In the event the investigative findings confirm misconduct: When the agency head communicates his/her decision in writing to the affected investigator(s) and/or institution(s), or when the appropriate DHHS official makes a decision on a recommended debarment or suspension.
2. The records of a closed misconduct investigation are normally releasable unless the disclosure would constitute an unwarranted invasion of personal privacy or impede an on-going related investigation, or if it is otherwise decided to invoke one of the exemptions to the disclosure mandate of the FOIA.

AWARDEE RESPONSIBILITIES*

1. Efforts should be made by awardee institutions on an ongoing basis to inform their scientific staff of policies and procedures for dealing with instances of alleged or apparent misconduct in science and to emphasize the importance placed on this subject matter by both the institution and the PHS.
2. The primary responsibility for prevention of misconduct in association with PHS-funded research rests with the awardee institutions. The PHS supports institutional adherence to the principles and guidelines stated in the June 24, 1982 report of the Association of American Medical Colleges Ad Hoc Committee on the Maintenance of High Ethical Standards in the Conduct of Research and the report of the Committee on Integrity of Research of the Association of American Universities.
3. Officials and scientific staff of organizations applying for or receiving funds from the PHS have a responsibility to take immediate and appropriate action as soon as misconduct on the part of employees of their organization is known, suspected or alleged.

* This section will be published separately for comment as a notice of proposed rulemaking.

4. Awardee institutions should adopt policies and procedures that, at a minimum, provide for:
 - (a) conducting an inquiry immediately into any allegation or other evidence of misconduct;
 - (b) protecting the privacy of those who in good faith report apparent misconduct;
 - (c) affording the affected individual(s) confidential treatment, a prompt and thorough investigation (if warranted), and an opportunity to comment on allegations and/or findings;
 - (d) notifying the awarding component immediately if findings from the inquiry indicate that an investigation is indicated;
 - (e) in instances in which institutional officials determine, on the basis of their inquiry, that it is not necessary to undertake an investigation, documenting the reasons for the decision and the findings from their inquiry (if the funding agency subsequently becomes aware of the case and believes it to be sufficiently substantive, the agency will proceed with its own investigation);
 - (f) undertaking an investigation if findings from the inquiry provide sufficient basis for doing so; in carrying out investigations, awardee institutions should act promptly, ensure fairness to all, secure necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence, and take precautions against real or apparent conflicts of interest;
 - (g) taking interim administrative actions, as appropriate;
 - (h) keeping the funding agency apprised of any developments during the course of the investigation which disclose facts that may affect current or potential PHS funding for the individual(s) under investigation or that the funding agency needs to know to ensure appropriate use of federal funds and otherwise protect the public interest;
 - (i) if the possible misconduct is not substantiated, undertaking diligent efforts, where appropriate, to restore the reputation of those under investigation;
 - (j) if misconduct is confirmed, imposing appropriate sanctions (awardee institutions should recognize that the funding agency may impose sanctions of its own); and
 - (k) notifying the awarding component of the final outcome.
5. Allegations or other indications of misconduct in PHS-funded research must be reported to the director of the program in the awarding component except when an institution's inquiry indicates that there is no basis for an investigation.

Upon receipt of such reports of possible misconduct, the program director shall then notify the awarding component's MPO who will be responsible for informing his/her agency-level counterpart.

6. There may be instances where the awarding component should be notified by the awardee institution even prior to the latter's decision to initiate an investigation. The following factors should be considered in deciding when to notify the awarding component:
 - a. the seriousness of the possible misconduct;
 - b. whether a situation of immediate health hazards is involved;
 - c. the need to protect the interests of the funding agency;
 - d. the need to protect the interests of the individual who is the subject of the impending investigation as well as his/her co-investigators and associates, if any;
 - e. the institution's responsibility to the scientific community and the public at large;
 - f. whether there are allegations of criminal violation.
7. As a general rule, the institution is encouraged to take no more than 30 days to conduct its inquiry and determine whether an investigation is warranted. If the inquiry cannot be completed within 30 days, the institution must notify the agency immediately, provide the reasons for the delay and indicate when the inquiry would be completed. If an investigation is to be undertaken, the institution shall generally take no more than 120 days to complete the investigation, prepare the report of findings, obtain the comments of the subject(s) of the investigation, and make a decision on the disposition of the case. If the institution determines, at the end of 90 days, that it cannot complete its investigation and related activities within the 120-day period, it must submit to the agency an interim report on progress to date and an estimated timetable for completion of the necessary activities. Thereafter a report must be submitted every 60 days until such time that the investigation and all attendant actions are completed.

PUBLIC HEALTH SERVICE

POLICIES AND PROCEDURES FOR DEALING WITH POSSIBLE MISCONDUCT IN SCIENCE

Summary of Procedures

Affecting Regulated Research

APPLICABILITY

Regulated research is research conducted by Federal agencies, private industry, academic institutions, and individuals to generate safety and efficacy data required by law to support marketing applications for foods, drugs, cosmetics and medical devices. The authority and responsibility for the review of this research and the approval of the marketing applications lie with the Food and Drug Administration (FDA). Thus most of the investigations related to regulated research will be carried out by the FDA.

OBJECTIVE

FDA operates a Bioresearch Monitoring Program (BMP) to ensure the quality and integrity of research data submitted to FDA to support the approval of marketing and research applications. The program encompasses preclinical and clinical research and includes the protection of the rights of human subjects participating in regulated research. Allegations of "misconduct in science" are investigated under this program. The mechanism for achieving compliance is through on-site inspections carried out by FDA field investigators.

EDUCATION AND PREVENTION

FDA has carried out a number of industry, professional, and public education activities associated with the administration of the BMP. As each of the regulations associated with the BMP are finalized, regional conferences are held across the country to explain the requirements of the regulations and to answer questions from the affected parties regarding the agency's administration and enforcement of the program.

FDA employees participate in industry sponsored seminars and workshops which promote the concept of quality assurance in research. Thousands of requests for BMP information are responded to annually by the agency.

As part of routine surveillance inspection visits, the field investigators explain to the inspectee the purposes of the program and the general requirements of the applicable regulations.

The agency believes that these activities maintain a public awareness of the FDA Bioresearch Monitoring Program and that this awareness serves as a deterrent to misconduct in science as well as a system which promotes quality control and subject protection in the research area.

PROGRAM DESCRIPTION

The BMP is composed of four distinct regulatory programs under which routine surveillance-type inspections are conducted. When suspicions of misconduct exist, however, more intense, directed investigations are initiated which target on the suspicions or allegations.

Preclinical Laboratory - Compliance Program 7348.808. FDA has promulgated good laboratory practices (GLP) regulations (21 CFR 58) which must be complied with in order for safety studies on regulated products to be acceptable to the FDA as support for marketing approval and clinical trials. Under this program, FDA conducts biennial inspections of all toxicology laboratories which test FDA regulated products. When warranted, data audits are also performed on submitted safety studies to verify the validity of the data. FDA also performs inspections and data audits for other Federal agencies and shares inspectional findings with them (EPA, NIH, DoD). FDA also inspects its own laboratories and the laboratories of other Government agencies that conduct regulated safety studies on FDA regulated products.

Clinical Investigators - Compliance Program 7348.811. FDA audits the performance of 400-500 clinical investigators yearly to ensure that the clinical studies are being conducted and reported in accordance with the study protocol and FDA regulations (21 CFR 312). Since this number represents only approximately 4% of the total universe of clinical investigators, inspections are primarily limited to drugs which are important entities or are close to receiving marketing approval. The clinical investigators who are inspected include those physicians employed by Federal agencies as well as those employed in private industry and academia.

Sponsors/Monitors of Research - Compliance Program 7348-810. FDA inspects biennially all the sponsors and monitors of clinical research on FDA-regulated products to ensure that they meet their obligations for monitoring the conduct of that research (e.g., reviewing raw data, assuring adherence to protocols). FDA expects to issue guidelines which then will clarify the monitoring obligations which the agency expects sponsors of research to fulfill.

Institutional Review Boards - Compliance Program 7348.809. FDA inspects biennially the 1,000 or so IRBs which review and approve clinical studies associated with FDA regulated products. Under FDA regulations (21 CFR 50 and 56), all clinical research on drugs and devices which involve human subjects must be approved by an IRB before they may be started. The IRBs are also responsible for providing continuing review of these studies and ensuring that proper informed consent is obtained by the investigators. FDA regulations governing IRB review of regulated research are essentially identical to the IRB regulations promulgated by DHHS which apply to funded research.

AGENCY CONTACT

The Program Director for the Bioresearch Monitoring Program is the Associate Commissioner for Regulatory Affairs/FDA and the focal point within his office for information dealing with this program in general and "misconduct in science" specifically, is the Director of the Bioresearch Monitoring Staff, Office of Regulatory Affairs.

REPORTING AND INVESTIGATING ALLEGATIONS OF MISCONDUCT

FDA inspections under the BMP may be triggered by any one of the following:

Surveillance Inspections -

- a) Routine scheduling based on planned rate of coverage.

Directed or Compliance Inspections -

- a) reports of alleged misconduct received from sponsors or monitors of research,
- b) reports of alleged misconduct received from institutions engaged in research or from IRBs,
- c) reports of alleged misconduct received from informants, former employees, associates,
- d) suspicion of FDA reviewers that the data may not be accurate or factual.

All reports of alleged misconduct received by elements of the agency are directed to the Bioresearch Monitoring Program manager within the bureau which has jurisdiction over the product. An inspection assignment is prepared and issued to the appropriate FDA field district for an on-site investigation. Inspections are carried out by specially trained field investigators located throughout the U.S. When necessary, technical support is provided by headquarters' scientists from the respective bureaus. FDA investigators review procedures to establish whether standard operating procedures and protocols have been followed, whether certain specified tests have been made and results accurately recorded. Raw data is also compared to reports of results which have been submitted to the agency.

Upon completion of the investigation, a report is written and forwarded to the bureau having jurisdiction over the research for evaluation and determination of any need for regulatory action. When the conclusions of the inspection report are that the inspectee is essentially in compliance, the report is classified as "No Action Indicated" (NAI) and the file is closed. When minor violations are reported which can be corrected voluntarily, the report is classified as "Voluntary Action Indicated" (VAI). When serious deficiencies are reported the report is classified as "Official Action Indicated" (OAI), and

recommendations for corrective action and/or regulatory sanctions are prepared by the field office and the reviewing bureau. Recommendations for regulatory action are concurred in or approved by the Associate Commissioner for Regulatory Affairs.

PROTECTION OF PRIVACY

All information associated with an investigation which has not been adjudicated is considered to be an open investigatory file and therefore is exempt from public disclosure. Information in an open investigatory file may be released by the Commissioner when he finds that disclosure is necessary to protect the public health. When a final disposition of the investigation has been made, the report becomes available under FOI except for privacy or trade secret information protected by law.

REGULATORY OPTIONS

A number of regulatory sanctions can be used to affect correction or to punish violators. These sanctions may be administrative or judicial and are not mutually exclusive.

Judicial -

Criminal prosecution or injunctive proceedings can be brought against individuals or firms for serious violations of the law. Seizure actions may also be taken against violative drugs or devices when necessary.

Administrative -

A number of administrative options can be brought to bear on individuals or institutions to bring about correction of violative conditions. These include:

- a) rejection of a study(s) as support for safety and efficacy considerations,
- b) termination of an investigational new drug or device exemption under which the research is carried out,
- c) restrictions on the addition of new subjects to a study(s) which is not being conducted in accordance with FDA regulations,
- d) restriction on the conduct of new studies at an institution or by a clinical investigator,
- e) consent agreement whereby a clinical investigator voluntarily agrees to restrict or cease further involvement in clinical research of investigational drugs and devices,
- f) formal disqualification of clinical investigator, IRB or laboratory after a regulatory hearing; rejection of all associated studies, and

- g) withdrawal of the marketing approval of a drug or device if such approval was based on studies subsequently determined to be invalid or fraudulent.

FDA maintains a list of disqualified clinical investigators and of those who have voluntarily agreed to limit or give up their entitlement to receive investigational drugs. FDA also maintains a list of preclinical laboratories which have been inspected for compliance with GLPs. These listings are available to Federal agencies, and will be routinely provided to the Division of Management Survey and Review (DMSR), NIH, for possible inclusion in the PHS ALERT system along with the names of clinical investigators who have not adequately responded to allegations of impropriety at their informal conference with the agency.

INTERIM PUBLIC HEALTH SERVICE

POLICIES AND PROCEDURES FOR DEALING WITH POSSIBLE
MISCONDUCT IN SCIENCE

Policies and Procedures
For
Agencies Authorized to Conduct Research

PHS: 735-1-00 Purpose and Coverage
05 Definitions
15 Responsibilities
25 Policies and Procedures

735-1-00 - Purpose and Coverage

- A. Purpose: This Instruction outlines policies and procedures for handling allegations or other indications of possible misconduct directly related to the scientific integrity of research conducted by Public Health Service (PHS) agencies. This guidance applies the DHHS Standards of Conduct (45 CFR Part 73) and Departmental guidance on reporting of misconduct (General Administration Manual (GAM) Chapter 5-10) to particular situations that may arise in association with the intramural research activities of the PHS.
- B. Coverage: These provisions apply to all research investigators employed by the PHS, and to other research investigators to the extent that they conduct research in PHS facilities under the supervision of PHS employees.

735-1-05 - Definitions

- A. Misconduct in Science, for purposes of this Instruction, is defined as (1) serious deviation, such as fabrication, falsification or plagiarism, from accepted practices in carrying out research or in reporting the results of research; or (2) material failure to comply with Federal requirements affecting specific aspects of the conduct of research, e.g., the protection of human subjects and the welfare of laboratory animals. Other forms of serious misconduct such as misappropriation of Federal supplies or equipment may be of equal concern, but the issues involved are not primarily scientific and they can be handled effectively through existing investigative and administrative procedures.
- B. Agency means one of the PHS agencies.

- C. Component refers to the organizational units within a PHS agency, e.g., Bureaus, Institutes, Divisions, or Centers.
- D. Agency Legal Advisor means the staff member of the DHHS Office of the General Counsel who has primary responsibility for providing legal advice to an agency head.
- E. Agency Investigative Liaison means the agency office or official designated to coordinate communications between the agency and the DHHS Office of the Inspector General on matters involving misconduct in science.
- F. Agency Scientific Director means the scientist responsible on behalf of the agency head for oversight of the agency's intramural research program(s). For those agencies that do not have a Scientific Director, the agency head will designate an individual to carry out the responsibilities specified for this official with respect to the provisions of this Instruction.
- G. Component Scientific Director means the scientist responsible for overall direction of a component's intramural research program.
- H. Agency Misconduct Policy Officer (MPO) means the individual designated to oversee and coordinate agency implementation of policies related to misconduct in science.
- I. An "inquiry" consists of information-gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.
- J. An "investigation" is a formal examination and evaluation of all relevant facts to determine if an instance of misconduct has taken place. If misconduct has already been confirmed, an investigation may, nevertheless, be conducted to determine the extent of any adverse effects resulting from the misconduct.
- K. The "ALERT" is a system for collecting, controlling, and disseminating to PHS officials on a need-to-know basis information that an institution, organization, or individual currently receiving PHS funds or likely to submit a grant or cooperative agreement application or a contract proposal: (1) is under investigation for alleged or apparent misconduct, or a decision has been made to undertake such an investigation; or (2) has been subjected to a sanction at the conclusion of an investigation for misconduct (e.g., debarment by the Secretary, DHHS from eligibility for research funding, disqualified by the Food and Drug Administration (FDA) from use of investigational drugs, or in the case of scientists employed by the PHS, termination of employment). The information about an organization or individual is used to aid the PHS official in making an informed decision regarding the award of funds or other PHS benefits to that organization or individual, but such information does not automatically result in a withholding of funds or other benefits.

735-1-15 - Responsibilities

- A. Heads of PHS Agencies and Agency Scientific Directors are responsible for ensuring that heads of components and Component Scientific Directors are familiar with the provisions of this Instruction, relevant portions of the DHHS Standards of Conduct, and the requirements of GAM Chapter 5-10 for reporting misconduct.
- B. Agency Scientific Directors are responsible for (i) ensuring that allegations or other indications of possible misconduct associated with research being conducted by or within the agency are promptly reviewed by the appropriate Component Scientific Director; (ii) determining whether a formal investigation is warranted by the results of the inquiry; and (iii) taking such other actions as may be necessary at the agency level to deal with instances of alleged or apparent misconduct.
- C. Component Scientific Directors are responsible for (i) conducting an inquiry into allegations or other indications of misconduct associated with research being conducted by or within the component; (ii) initiating formal investigation when the Agency Scientific Director determines that investigation is warranted; (iii) coordinating component participation in investigations; and (iv) recommending such action as may be necessary to resolve problems identified by the report of investigation, including proposals to take adverse actions.
- D. Component Directors are responsible for determining appropriate corrective actions based on completed reports of investigative findings that confirm misconduct. Component Directors serve as the deciding official for adverse actions proposed by Component Scientific Directors.
- E. Agency MPOs are responsible for advising Agency and Component Scientific Directors regarding the application of these policies and procedures to individual cases, reviewing and commenting on procedural aspects of intramural investigations, and ensuring that appropriate follow-up actions are taken when an investigation confirms that misconduct affecting eligibility for extramural funding has occurred.
- F. Agency Legal Advisors are responsible for ensuring that Agency and Component Scientific Directors are fully briefed on legal issues that may arise during an investigation of possible misconduct associated with research conducted by or within the agency.
- G. Agency Investigative Liaisons are responsible for (i) notifying the Office of the Inspector General (IG) of all allegations or other indications of misconduct in science of potential concern to OIG; (ii) collaborating with Component Scientific Directors in the design and conduct of such investigations as may be necessary on the part of the agency; (iii) keeping the Agency Scientific Director informed concerning the progress of investigations; and (iv) providing the Agency and pertinent Component Scientific Directors with a written report of completed investigations.

- H. Component Personnel Officers are responsible for providing technical guidance to Component Directors and Scientific Directors on personnel actions that are necessary to resolve problems identified by the reports of investigation and advising on procedural requirements affecting an investigation.
- I. The Office for Protection from Research Risks (OPRR), NIH is responsible for investigating alleged or apparent violations of either (a) Federal regulations governing the protection of human subjects or (b) PHS animal welfare policy.
- J. PHS Employees in general are responsible for reporting real or apparent misconduct in science to their supervisor, the Component or Agency Scientific Director, the Agency Investigative Liaison, or the DHHS Office of the Inspector General.
- K. Research Investigators not Employed by PHS, but who conduct research in PHS facilities or are closely associated with research conducted by PHS, are expected to observe the highest standards of professional conduct and are encouraged to report real or apparent misconduct to appropriate PHS officials.

735-1-24 - Policies and Procedures

A. Policy

1. The PHS expects research investigators within its intramural research programs to observe the highest standards of professional conduct. All allegations or other indications of possible misconduct in science shall be promptly reviewed by the Component Scientific Director, and those which are neither frivolous nor unsubstantiated shall be thoroughly investigated. All allegations that are substantiated after investigation shall result in action by the appropriate component in keeping with the specific circumstances of the case.
2. All agency actions taken in response to instances of alleged or apparent misconduct will take into consideration (a) safeguards for the affected parties—e.g., confidential treatment, prompt and thorough inquiry and/or investigation, and opportunity to comment on all allegations and/or findings; (b) any requests for anonymity made by informants; and (c) the need to ensure that the interests of the Government are protected.
3. When a PHS agency decides to initiate an investigation, the individuals under investigation should usually be notified of that fact before the investigation commences. Exceptions will be made if a law enforcement official or the Agency Investigative Liaison determines that prior notification is likely to interfere with the collection of evidence. If the investigation involves a PHS employee, the Component Personnel Officer should be consulted for guidance on appropriate procedural requirements. When prior notification is provided, it should include information on the nature of the allegations or concerns and the focus of the investigation. The recipients of the notification will also be informed of the opportunity to provide comments and other relevant information to the agency.

4. As a general rule, allegations or information developed in the course of an ongoing investigation will be made available only to individuals who (a) are involved in or associated with the actual conduct of an investigation; or (b) have direct responsibility for the research project in which misconduct is alleged to have occurred. Component Directors will be informed of the existence and general nature of investigations affecting their component, but should not become involved to the extent that such involvement or knowledge might compromise their ability to act as deciding officials under B.5., below. The Agency MPO will be provided with such information as is relevant and necessary to assess the procedural adequacy of investigations and determine the nature and extent of implications for extramural funding opportunities.
5. In responding to any request(s) from a non-DHHS source for information about ongoing investigations, agency staff shall maintain the confidentiality of such information to the greatest extent possible under the provisions of the Freedom of Information Act and the Privacy Act.
6. If the investigation does not establish misconduct, the official responsible for the investigation shall promptly notify all concerned parties in writing.
7. Upon completion of an investigation that confirms misconduct, the agency shall consider the imposition of appropriate sanctions.

B. Procedures

1. All allegations or other indications of possible misconduct in science shall be referred to the Component Scientific Director for an inquiry. The Component Scientific Director, in consultation with other officials as appropriate, should assess the information in light of:
 - a. the content of the information itself (e.g., degree of specificity, supporting documentation, statements concerning the reasons for making allegations);
 - b. prior knowledge of the individuals and events associated with the possible misconduct; and,
 - c. other information which can be obtained without disclosing unnecessarily or prematurely to potentially affected individuals that the possibility of misconduct is being explored.

Normally, this inquiry will be completed within ten work days. The results of the inquiry will be submitted to the Agency Scientific Director.

2. Based on the results of the inquiry, the Agency Scientific Director or other designated individual, after consultation with the Component Scientific Director, the Agency Investigative Liaison and Agency Legal Advisor, may determine that a formal investigation of misconduct in science is not appropriate because:
 - a. the matter is not covered by the definition of misconduct in science;

- b. the information pointing to possible misconduct is contradicted by other information which the Agency Scientific Director knows to be correct; or
- c. there is insufficient information to support an investigation into the possible misconduct.

The Agency Scientific Director shall notify the relevant Component Scientific Director and other appropriate individuals (e.g., the source of allegations) of the decision not to refer the matter for investigation and the rationale for that decision (i.e., a, b, or c above). These actions will normally be completed within ten work days after the Agency Scientific Director receives the results of the inquiry.

- 3. If further investigation is appropriate, the Component Scientific Director, in collaboration with the Agency Scientific Director, Agency Investigative Liaison, and the Agency Legal Advisor, shall determine how to proceed in those cases that agency staff are authorized to investigate. This includes determining both the investigative methods to be used and the extent of communications with the affected employees. If a related investigation exists, the OIG should be consulted for the purpose of coordinating the investigations.
- 2. All allegations or other indications of possible criminal violation will be referred to the Office of the Inspector General.
- 4. When the results of an investigation confirm misconduct, the following procedures shall normally apply:
 - a. The Component Scientific Director shall provide the report of investigation to the individual(s) under investigation for comments or rebuttal. As a general rule, the subject(s) of the investigation shall be allowed no more than 30 days to provide a response.
 - b. All comments submitted by the subject(s) of the investigation shall receive full consideration and, where appropriate, may lead to revision of the report before it is forwarded to the Component Director. Such comments shall be appended to the report unless it is determined that such action would constitute an unwarranted invasion of an individual's privacy.
 - c. The report and comments shall be provided to the agency MPO, who will assess the procedural adequacy of the investigation.

Under unusual circumstances, the Component Scientific Director may determine, in consultation with the Agency Legal Advisor, and the OIG, when there is a possibility of criminal violations, that an exception to these procedures is warranted.

- 5. When the report of investigation or other follow-up action is completed, the Component Scientific Director shall recommend to the Component Director the administrative actions to take. If the final investigative

report or other action indicates that misconduct in science has occurred, the Component Scientific Director's recommendations shall include appropriate action with respect to the individuals who committed the misconduct. If those individuals are current Federal employees, the Component Scientific Director shall consult the Component Personnel Office concerning the options that may be proposed, including removal from the Federal service. If the individuals are not employees but work in PHS facilities under the supervision of PHS employees, the Component Scientific Director must consider terminating or restricting their continued use of those facilities. Component Directors will decide on the recommendations and take action in accordance with applicable administrative procedures.

6. In cases where the removal of a Federal employee is proposed by the Component Scientific Director, the rights of the employee in responding to that proposal shall depend on his/her particular employment status.
 - a. Actions against Civil Service employees shall generally be processed in accordance with the provisions of Chapter 75, Title 5 of the United States Code, which provides for an advance written notice of 30 days containing specific charges on which the proposal is based, the right to representation, an opportunity to reply to the notice, a decision that takes the reply into account, and an appeal to the Merit Systems Protection Board if the removal has been effected. In cases where Civil Service employees are not subject to Chapter 75, they shall be given an advance written notice of at least seven days, an opportunity to respond, and a written decision.
 - b. Actions against PHS Commissioned Officers shall be processed in accordance with the provisions of the Public Health Service Act (42 USC) and Chapters 43 and 46 of the Commissioned Corps Personnel Manual. If there is evidence that an officer has committed acts of misconduct covered by the above references, a Board of Investigation may be convened. The Board shall hear the case and make a report of its findings. When the investigative findings confirm misconduct, the Board shall recommend appropriate disciplinary action to the Assistant Secretary for Health (ASH), DHHS. The ASH shall review the record, report, and recommendations of the Board and determine what action shall be taken. The decision of the ASH shall be final.
7. The Component Scientific Director shall provide a copy of the investigative report and a summary of actions taken to the Agency MPO, who will take steps to determine whether the nature of the misconduct warrants consideration of restrictions on a research investigator's eligibility for future funding via PHS grants, cooperative agreements, and contracts. All actions taken on such information shall be in accordance with "Policies and Procedures for Agencies and Programs Authorized to Make Awards for Research and Research Training" and when applicable, policies and procedures related to the "PHS ALERT for Misconduct in Science."