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IMPLEMENTATION PROPOSALS ON

RECOMMENDATIONS BY THE COMMISSION ON RESEARCH INTEGRITY

PLEASE NOTE: This report has been forwarded to

the Secretary of the Department of Health and Human Services

for her review and consideration.

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I. Background

In 1993, under Section 162 of the National Institutes of Health (NIH) Revitalization Act, Public Law 103-43, Congress enacted legislation that required the Secretary to establish the Commission on Research Integrity. The Commission developed 33 recommendations on issues of research misconduct and integrity. The report was submitted to the Secretary and Congress in late 1995. All recommendations, if implemented, would affect the Department, research institutions and researchers and other staff in the research environment within and outside of the Department. One recommendation is directed at professional societies.

Upon receipt of the Commission's report, the Secretary appointed an intra-departmental group for research integrity and misconduct[1] to develop proposals for implementation. The Implementation Group met nine times, including one meeting with the Chair and two members of the Commission. (Appendix A: Membership List of Implementation Group).

In developing its proposals, the Implementation Group followed three guiding principles: (1) for extramural research, institutions should be primarily responsible for maintaining research integrity and the Department should step in only when institutions fail; (2) changes to the existing approach should be made only after careful consideration of any additional regulatory burden or costs to individuals, institutions, or the Department; (3) the Department must, nevertheless, continue to protect its interest in integrity in research funded by the Federal Government.

II. Summary

The Implementation Group considered each of the Commission's 33 recommendations in depth and reached the following conclusions:

_ Twenty-three recommendations should be implemented. For some of these, the work group recommends implementation as stated by the Commission while for others the group recommends modifications.

_ Action on three recommendations should be deferred.

_ Four recommendations should not be implemented.

_ Two recommendations call for policies or procedures that are already in place in part or as a whole. The concerns that resulted in these recommendations were raised by testimony going back many years and have since been addressed by the Department.

_ One Commission recommendation is not directed toward the Federal Government.

Section III of this report lists and discusses each of the Commission's recommendations and presents the corresponding proposal by the Implementation Group. For convenient reference, Appendix B lists the Group's proposals.

The principal proposals of the Implementation Group are as follows:

_ Publication of an Advance Notice of Proposed Rulemaking (ANPRM) on the Commission's recommended definition of professional misconduct to solicit comments broadly from both the scientific community and the general public. The results will aid Department decision-makers in determining the scope, content, and timing of a subsequent Notice of Proposed Rulemaking (NPRM) should the Department elect to amend the current regulation governing the Department's approach to scientific

misconduct.

_ Active participation by the Department in interagency deliberations under the aegis of the Office of Science and Technology Policy (OSTP) regarding a possible uniform definition of research misconduct for use by federal agencies.

_ Completion and publication of a separate, stand-alone NPRM on Whistleblower Protection as required by the NIH Revitalization Act of 1993. This initiative need not await action on other proposals of the Implementation Group because the NPRM implements an already overdue statutory requirement.

_ Establishment of a working group of representatives of the Office of Research Integrity (ORI), Departmental Appeals Board (DAB), Office of the General Counsel (OGC), and Office of Inspector General (OIG) to streamline the current appeals process for findings by ORI without unduly limiting protections for the individuals associated with a case.

The Implementation Group also proposes that, once the Secretary has considered and made determinations regarding this report, she send a letter to Dr. Ryan, Chairman of the Commission, summarizing the Department's response to the Commission's recommendations and simultaneously issue a public statement including the same general information.

III. Commission Recommendations and Implementation Group Discussions and Proposals

Commission Recommendation 1: Definition of Professional Misconduct,

Including Research Misconduct[2]

The Commission recommends that the Secretary replace the existing definition of misconduct in science with the definition of research misconduct and definitions of other forms of professional misconduct related to research, to follow. The definition of research misconduct is based on the premise that research misconduct is serious violation of the fundamental principle that scientists be truthful and fair in the conduct of research and the dissemination of its results.

The Federal Government has an interest in professional misconduct involving the use of federal funds in research, as covered by the following definitions:

1. Research Misconduct

Research misconduct is significant misbehavior that improperly appropriates the intellectual property

or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record or compromising the integrity of scientific practices. Such behaviors are unethical and unacceptable in proposing, conducting, or reporting research or in reviewing the proposals or research reports of others.

Examples of research misconduct include but are not limited to the following:

Misappropriation: An investigator or reviewer shall not intentionally or recklessly

a. plagiarize, which shall be understood to mean the presentation or the documented words or ideas of another as his or her own, without attribution appropriate for the medium of presentation; or

b. make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.

Interference: An investigator or reviewer shall not intentionally and without authorization take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.

Misrepresentation: An investigator or reviewer shall not with intent to deceive, or in reckless disregard for the truth,

a. state or present a material or significant falsehood; or

b. omit a fact so that what is stated or presented as a whole states or presents a material or significant falsehood.

2. Other Forms of Professional Misconduct

a. Obstruction of Investigations of Research Misconduct

The Federal Government has an important interest in protecting the integrity of investigations into reported incidents of research misconduct. Accordingly, obstruction of investigations of research misconduct related to federal funding constitutes a form of professional misconduct in that it undermines the interests of the public, the scientific community, and the Federal Government.

Obstruction of investigations of research misconduct consists of intentionally withholding or destroying evidence in violation of a duty to disclose or preserve; falsifying evidence; encouraging, soliciting or giving false testimony; and attempting to intimidate or retaliate against witnesses, potential witnesses, or potential leads to witnesses or evidence before, during, or after the commencement of any formal or informal proceedings.

b. Noncompliance with Research Regulations

Responsible conduct in research includes compliance with applicable federal research regulations. Such regulations include (but are not limited to) those governing the use of biohazardous materials and human and animal subjects in research.

Serious noncompliance with such regulations after notice of their existence undermines the interests of the public, the scientific community, and the Federal Government and constitutes another form of professional misconduct.

Discussion

The Charter establishing the Commission specifies "a new definition of research misconduct" as the first of several issues warranting consideration. The Commission responded by making the definition of "research misconduct" the focus of its lead recommendation.

In reviewing the pertinent parts of the Commission's report, the Implementation Group identified four features of special significance. First, the Commission approached its task from the stated premise that inappropriate behaviors by scientists span a range that goes well beyond actions traditionally viewed as "fabrication," "falsification," or "plagiarism"--the triad of wrongdoing that constitutes the cornerstone of the current research-misconduct definitions used by the U.S. Public Health Service (PHS) and the National Science Foundation (NSF). The Commission therefore placed its recommended definition of "research misconduct" within the framework of a broader concept, that of "professional misconduct." As a consequence, some activities logically included within the Commission's definitions fall outside the current responsibilities of the ORI and DAB and relate more closely to functions now performed by the Office for Protection from Research Risks (OPRR), OIG, or possibly other components of the Department.

Second, in addressing "research misconduct" specifically, the Commission noted that, in most instances, acts of sabotage against research projects are not covered adequately by either the current PHS definition or law enforcement by local governments. Also, the Commission opined that some "authorship disputes" or "collaborative disputes" that ORI currently regards as being outside its jurisdiction actually involve significant plagiarism and therefore are appropriate for consideration as instances of possible research misconduct. The recommended definition of "research misconduct," along with a related recommendation within the section entitled "Administrative Processes and Investigations (Recommendation 8e)," attempts to remedy these perceived shortcomings.

Third, the Commission paid close attention to the structure of the various definitions as well as their substance. The current PHS definition was judged neither narrow nor precise in practice because the terms "fabrication," "falsification," and "plagiarism" themselves are not defined in the pertinent regulation. Further, the "other practices that seriously deviate" clause was not considered appropriate for

inclusion in a new definition because, while the clause has not been misused, it is not specific with respect to either its boundaries or the actions it includes. The Commission therefore constructed its recommended definitions with the intent that they be legally enforceable as well as readily understandable by scientists, administrators, and laypersons.

Fourth, notwithstanding the intentionally broader scope of its recommended definitions, the Commission did not propose a major expansion of activity by the Department with respect to promoting research integrity and dealing with alleged or real research misconduct. Among the prefatory comments in the Commission's Report is the expressed hope that the Department will "keep the regulations simple and will delegate as much responsibility to individual institutions as is reasonably possible." Several other recommendations (see below) also are relevant to this goal, because they focus on the relationship and division of labor between the Department and PHS awardee institutions.

The Commission's recommendations, especially its definitions, have elicited considerable commentary from individual scientists, scientific organizations, and administrators within universities and government. Much of this has appeared in science-oriented publications or has occurred in the context of national scientific meetings. A few individuals and organizations provided unsolicited comments directly to the Implementation Group. The assertion of these various commentaries, taken together, is that the Commission has overstated the scope and severity of the research-misconduct problem, posited an excessively intrusive role for the Federal Government in the affairs of individual scientists and research institutions, and recommended policy and procedural changes for the Department and research institutions that will require substantial and unnecessary new expenditures of human and financial resources.

The Implementation Group recognizes that the comments it has received or otherwise learned about may not necessarily be representative of either the scientific community or the general public. Nevertheless, being mindful of the considerable differences between the recommended definitions and the current one and concerned about the decidedly negative tenor of the initial reactions to the Commission's report, the Implementation Group believes that the Department should systematically seek and weigh the views of all interested parties before determining whether to accept the recommended definitions in whole or in part. The Implementation Group therefore proposes that the Department issue and publicize widely an ANPRM that features the Commission's recommended definitions of "professional misconduct" and "research misconduct," identifies associated issues of particular interest to the Department, and invites public comment.

Proposal

The Department should publish an Advance Notice of Proposed Rulemaking presenting the Commission's definition for broad input from the scientific community and the public at large.

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Commission Recommendation 2: Uniform Federal Definition

The Commission recommends that the Secretary encourage an interagency task force to develop a common federal definition of research misconduct and other forms of professional misconduct related to research.

Discussion

The Implementation Group strongly endorses this recommendation. The public interest would be well served if all of the major research agencies of the federal government had a common definition of research misconduct.

Early in the course of the Implementation Group's deliberations, its Chairperson brought the Commission's report to the attention of staff in OSTP in the Executive Office of the President. OSTP subsequently determined that the concept of a uniform definition of "research misconduct" warranted attention on an interagency basis and assigned responsibility to the Committee on Fundamental Science, a subgroup of the National Science and Technology Council. The Implementation Group welcomes the OSTP initiative and urges that the Department participate actively.

Proposal

The Secretary should endorse the OSTP initiative to develop a uniform definition of research misconduct and should ensure that the Department is an active participant in the process.

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Commission Recommendations 3, 4, and 5: Role of Research Institutions and the Federal Government

3. The Commission recommends that the Secretary require that each institution applying for or receiving a grant, contract, or cooperative agreement under the Public Health Service Act for research or research training add to its existing misconduct-in-science assurance a third declaration, one certifying that the institution has an educational program on the responsible conduct of research. Through this mechanism, the current NIH research integrity education requirement, now limited to recipients of institutional training grants at NIH-funded institutions, would be augmented by an assurance applied to all individuals supported by PHS research funds.

4. The proposed research integrity education assurance should be implemented in the following manner: The assurance should be included in the checklist that accompanies every PHS research or training grant application. The institutional official's signature would signify the institution's compliance with the assurance. In addition, the application would state clearly that the signature of

the scientist submitting the application signifies that he/she is familiar with (a) the institution's policies and procedures regarding scientific misconduct; and (b) the institution's educational program on the responsible conduct of research.

5. The Secretary should also encourage:

a. Integration of the explicit teaching of ethics of science into the classroom, laboratory, and other research sites in precollegiate education as well as in undergraduate and graduate schools; and

b. Funding for scholarship, teaching, and research in science ethics. Such funded research should include an experimental audit of the prevalence of data misrepresentation.

Discussion

The Implementation Group endorses these three recommendations. It shares the Commission's view that universities and other research institutions have a uniquely important responsibility for promoting high ethical standards to guide conducting, reporting, and reviewing research.

With regard to Recommendation 3, the Group notes that the current requirement for research-integrity education in association with NIH institutional research-training grants was implemented without notable controversy and seems widely regarded as a useful tool for raising awareness of ethical issues. Extension of the concept to all individuals supported by PHS research funds seems consistent with policies and practices already in place at many universities and other research institutions. Although the proposed new requirement does not seem to present an unreasonable new regulatory burden if implemented in accordance with Recommendation 4, the Department should seek public comment about the expected incremental costs for PHS awardee institutions.

Two other noteworthy issues are associated with Recommendation 3. First, as phrased, it implies that PHS (i.e., through ORI) should only monitor awardee institutions for the presence of research-integrity education programs but not review and approve the content. The Implementation Group concurs that the PHS role should be circumscribed in this way.

Second, the Commission report highlights certain educational topics as being worthy of attention by all awardee institutions, but the Commission stops short of calling for minimum standards for conducting, reporting, and reviewing research. The Implementation Group believes that such minimum standards could do much to focus and enhance the efficacy of institutions' educational programs. Having already done much to promote research integrity, research institutions and scientific societies are best positioned to develop and promulgate such minimum standards on a voluntary basis. The Group is hopeful that they will do so.

With regard to Recommendation 5, the Implementation Group is aware of recent studies indicating that instances of unethical behavior are becoming commonplace among precollegiate, undergraduate,

graduate, and medical students.34 In the absence of effective role models and strong educational programs, such aberrant attitudes and behaviors are likely to continue and perhaps become more prevalent, thereby compromising research programs and eroding public confidence in the research community. The Implementation Group supports the Commission's call for increased emphasis on teaching ethics within the context of science education and increased support for scholarly endeavors related to ethics in science. In particular, the Group would welcome studies--e.g., by scientific journals--that produce statistically sound, peer-reviewed, experimental audits of data that support articles accepted for publication along the lines suggested by the Commission.

Proposals

The Department should publish an NPRM, establishing requirements for (1) creating an institutional assurance of research-ethics training for all staff supported by PHS research funds, and (2) adding to the present individual assurance for principal investigator/program director a statement that (s)he is aware of the institutional policies and procedures related to research misconduct as well as its training program on the responsible conduct of research. Routine documentation of these assurances should be included with each request for funds but limited to a check-off box and signatures, respectively.

When speaking or writing on research integrity on behalf of the Department, the Secretary and other senior staff should encourage the teaching of ethics at all educational levels, in laboratories, and in clinical research settings.

Subject to the program priorities and the availability of funds, DHHS agency heads should fund high-quality studies of science-related ethics in general and research misconduct in particular.

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Commission Recommendation 6: Roles of Professional Societies and Codes of Ethics

The Commission recommends that professional societies each adopt a code of ethics in research and encourage their members to use these codes as a framework for considering emerging ethical issues in science. In addition, professional societies should consider initiating activities that will further promote the ethical conduct of research and professionalism in science.

Discussion

The Implementation Group believes that scientific and other professional societies have an indispensable role in promoting research integrity, as indicated above. The Group recognizes their important initiatives within the last 15 years and hopes that they will continue to provide leadership, especially regarding the

types of wrongdoing that are not readily or appropriately considered as fabrication, falsification, or plagiarism.

Proposal

None. This recommendation is directed specifically to professional societies.

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Commission Recommendation 7: Responsible Whistleblowing

The Commission recommends that the Secretary develop regulations guaranteeing the standards expressed in the following statement of principles:

Responsible Whistleblowing: A Whistleblower's Bill of Rights

a. Communication: Whistleblowers are free to disclose lawfully whatever information supports a reasonable belief of research misconduct as it is defined by PHS policy. An individual or institution that retaliates against any person making protected disclosures engages in prohibited obstruction of investigations of research misconduct as defined by the Commission on Research Integrity. Whistleblowers must respect the confidentiality of sensitive information and give legitimate institutional structures an opportunity to function. Should a whistleblower elect to make a lawful disclosure that violates institutional rules of confidentiality, the institution may thereafter legitimately limit the whistleblower's access to further information about the case.

b. Protection from retaliation: Institutions have a duty not to tolerate or engage in retaliation against good-faith whistleblowers. This duty includes providing appropriate and timely relief to ameliorate the consequences of actual or threatened reprisals, and holding accountable those who retaliate. Whistleblowers and other witnesses to possible research misconduct have a responsibility to raise their concerns honorably and with foundation.

c. Fair procedures: Institutions have a duty to provide fair and objective procedures for examining and resolving complaints, disputes, and allegations of research misconduct. In cases of alleged retaliation that are not resolved through institutional intervention, whistleblowers should have an opportunity to defend themselves in a proceeding where they can present witnesses and confront those they charge with retaliation against them, except when they violate rules of confidentiality.

Whistleblowers have a responsibility to participate honorably in such procedures by respecting the serious consequences for those they accuse of misconduct, and by using the same standards to correct their own errors that they apply to others.

d. Procedures free from partiality: Institutions have a duty to follow procedures that are not tainted by

partiality arising from personal or institutional conflict of interest or other sources of bias. Whistleblowers have a responsibility to act within legitimate institutional channels when raising concerns about the integrity of research. They have the right to raise objections concerning the possible partiality of those selected to review their concerns without incurring retaliation.

e. Information: Institutions have a duty to elicit and evaluate fully and objectively information about concerns raised by whistleblowers. Whistleblowers may have unique knowledge needed to evaluate thoroughly responses from those whose actions are questioned. Consequently, a competent investigation may involve giving whistleblowers one or more opportunities to comment on the accuracy and completeness of information relevant to their concerns, except when they violate rules of confidentiality.

f. Timely processes: Institutions have a duty to handle cases involving alleged research misconduct as expeditiously as is possible without compromising responsible resolutions. When cases drag on for years, the issue becomes the dispute rather than its resolution. Whistleblowers have a responsibility to facilitate expeditious resolution of cases by good faith participation in misconduct proceedings.

g. Vindication: At the conclusion of proceedings, institutions have a responsibility to credit promptly-in public and/or in private as appropriate-those whose allegations are substantiated.

Every right carries with it a corresponding responsibility. In this context, the Whistleblower Bill of Rights carries the obligation to avoid false statements and unlawful behavior.

Discussion

In the NIH Revitalization Act, Congress mandated that the Secretary establish whistleblower protection by regulation. Prior to establishment of the Implementation Group, ORI developed and, with the endorsement of the Commission, issued "Whistleblower Protection Guidelines," which comply with many of the principles contained in the Commission's Whistleblower Bill of Rights. These guidelines are offered as a resource for institutions to use as they see fit in addressing the general requirement in the current regulation that calls for diligent efforts "to protect the positions and reputations of those persons who, in good faith, make allegations."

ORI also prepared a draft Whistleblower Protection Regulation but appropriately held it in abeyance pending receipt of the Commission's report. Because the ORI draft is generally in keeping with the Commission's recommendations, the Implementation Group proposes that ORI revise it, as appropriate, to address any issues identified by the Commission that ORI had not already covered. The Group also proposes that the draft regulation on whistleblower protection and subsequent regulations on ORI and institutional procedures be refined as necessary to ensure adequate protections for respondents and institutions.

The last point stems from the Implementation Group's mixed sentiments about the way the Commission

crafted its recommended Whistleblower Bill of Rights. On the one hand, the topic warrants the special attention the Commission gave it, and careful reading of the statement and associated text makes clear that the Commission envisioned a judicious balance among the rights and responsibilities of whistleblowers, the rights and responsibilities of respondents, and the rights and responsibilities of institutions. On the other hand, the title and organization of the statement create a strong initial impression that the Commission was more attentive to rights of whistleblowers and the responsibilities of other parties than to the responsibilities of whistleblowers and the rights of other parties.

Elsewhere in its report (Recommendation 8f), the Commission recommends that the Department and institutions deal with retaliation against whistleblowers as rigorously as with inquiries, investigations, and adjudications of research misconduct. ORI apprised the Implementation Group that the draft regulation is designed to achieve that level of rigor by developing a comprehensive framework for protecting whistleblowers.

Proposal

ORI should complete its draft NPRM for the protection of whistleblowers, taking into account the recommendations of the Commission and the comments of the Implementation Group.

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Commission Recommendation 8:

Administrative Processes and Investigations

Regarding the federal investigation of allegations, the Commission recommends that:

8a. The Secretary ensures that the investigation of misconduct and subsequent adjudication are organizationally separated in DHHS, as they are, for example, at the National Science Foundation.[5]9966

Discussion

Although the Commission's report recommended organizational separation between the processes of investigation and adjudication, respectively, the report language supporting this recommendation makes it clear that the Commission did not have "adjudication" *per se* in mind but, rather, the process of reviewing an investigative report and rendering a decision based on its findings. The Implementation Group endorses the principle embedded in this recommendation, that is, minimizing if not obviating the potential for conflict of interest by creating an organizational separation between the two functions. However, adoption of this principle to an extent greater than it already is incorporated in DHHS organization and delegations of authority may be impractical, as indicated below.

In the present ORI system, over 85 percent of cases of alleged misconduct are investigated by awardee institutions. Therefore, in the vast majority of cases, there is indeed an organizational separation between the entity that conducts the investigation and the individual who renders a decision--the Director of ORI. In the remaining 15 or fewer percent for which ORI assumes the responsibility for investigating, such separation is not present. Moreover, these tend to be the most complex and controversial cases. This appearance of conflict of interest is inherent in the delegation of authority to ORI. However, whenever a respondent appeals a decision by the ORI Director, the case then falls within the jurisdiction of the DAB, an entity in the Department of Health and Human Services (DHHS) entirely independent of ORI.

In considering potential alternatives to the existing system, the Implementation Group discussed several approaches in which ORI retains a role in the decision-making process or in which ORI is removed from that process. In the former, modifications could include having the Director, ORI, consult with or share the decision-making authority with some other senior official, such as the head of the agency funding the research in which misconduct is alleged. In the latter, the authority for rendering a decision on the results of the ORI investigation would be vested in another agency/office within DHHS. Yet another approach, which most closely approximates the NSF model, is to place the responsibility for investigation within the DHHS' OIG and the responsibility for decision-making within ORI.

All of these strategies either involve an appearance of some conflict of interest, by ORI or the agency head, or call for the investment of significant resources and/or organizational change. The Implementation Group is not persuaded that changes to the existing system would result in material improvements to the process.

Proposal

ORI should retain its current authority to review, investigate, and render initial decisions on cases of alleged misconduct.

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8b. DHHS ensure that legal, law-enforcement, and scientist-investigator staff participate in each federally conducted investigation and ensure that scientists participate in hearings and appeal procedures.

Discussion

The Implementation Group notes that, depending on the issues involved in any particular case and the availability of resources at the time, ORI already uses a mix of legal, law-enforcement, and scientist-investigator personnel. However, ORI does not have traditional law-enforcement investigators on its staff, nor does it have adequate staff resources overall to implement the Commission's recommendation fully. ORI reports that it had been attempting to recruit a law-enforcement investigator, in accordance with a recommendation by the DHHS OIG, and to hire additional legal and scientific staff to fill current

vacancies, but it is unable to do so under current budget constraints.

The Group also notes that the interim guidelines for the Research Integrity Adjudication Panel (RIAP) of the DAB require a scientist be on the panel if either party so requests. This is consistent with the Commission's recommendation.

Proposal

The Department should adopt this recommendation to the extent practicable, taking into account competing priorities and the availability of resources.

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8c. Those conducting investigations have subpoena power over persons and documents, subject to specific case-by-case authorization by the Office of the General Counsel.

Discussion

ORI long has maintained, based on its experience with investigations and hearings, that subpoena power is essential to gather and present evidence effectively. Based on ORI and NSF testimony (the NSF has subpoena power over documents but not persons), the Commission agreed. The Implementation Group endorses this recommendation and proposes that DHHS seek the requisite legislative authorization. Because of uncertainties about whether or when such legislative authority might be obtained, the Group also proposes that ORI develop regulatory language to improve its access to documents and testimony for investigations and hearings.

Proposal

DHHS should seek the requisite legislative authorization. ORI should also develop regulatory language to improve its access to documents and testimony for investigations and hearings.

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8d. The Secretary establish a specific mechanism for reviewing and auditing the record of DHHS in enforcing the laws that prohibit research misconduct and other professional misconduct.

Discussion

The Implementation Group agrees that ORI should be subject to ongoing oversight but believes that this can and should be accomplished through existing mechanisms. Both the DHHS OIG and the General Accounting Office (GAO) have reviewed ORI within the last year, as has the Commission. In addition,

ORI is accountable to the Secretary through quarterly and annual reports. Moreover, the Secretary, the DHHS Inspector General, and the Comptroller General of the GAO all have the authority and means to initiate further reviews of ORI at any time.

Proposal

The Department should continue to rely on existing mechanisms for oversight of ORI.

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8e. ORI address as research misconduct those cases that it previously would have dismissed as mere "authorship disputes" or "collaborative disputes," namely, serious cases of alleged plagiarism (which under the proposed definition would be considered "significant misappropriation") among and between collaborators.

Discussion

This issue is discussed earlier in this report in association with Recommendations 1 and 2.

Proposal

The Department should highlight this issue in the ANPRM associated with the new definitions recommended by the Commission.

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8f. DHHS and institutions deal with retaliation against whistleblowers as rigorously at the inquiry, investigation, and adjudication stages as they do in cases with research and other professional misconduct.

Discussion

See discussion associated with Recommendation 7.

Proposal

See Proposal associated with Recommendation 7.

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8g. The Secretary review the current assignment of responsibility for responding to allegations of

retaliation against whistleblowers to the ORI Division of Policy and Education (DPE) and consider placing it in a unit capable of carrying out investigations.

Discussion

ORI apprised the Implementation Group that the draft NPRM on whistleblower protection (discussed earlier in this report in association with Recommendation 7) proposes that the Department rely on institutions to respond to allegations of retaliation, primarily through the use of an arbitration model. This is consistent with the legislative history of the NIH Revitalization Act, which recommended an arbitration model for addressing whistleblower protection. Because enforcement of such a requirement would involve compliance monitoring primarily, the responsibility seems appropriately placed in ORI's Division of Policy and Education (DPE), which is its focal point for regulatory compliance. The Group therefore proposes that this assignment be maintained pending adoption of the whistleblower protection regulation; if Department-led investigations of whistleblower retaliation become a key feature of the final regulation, the locus of responsibility for such investigations should be reexamined.

Proposal

ORI's Division of Policy and Education should continue to be responsible for responding to whisteblower complaints for the foreseeable future. The Department should defer further consideration of the Commission recommendation until the final whistleblower protection regulation has been promulgated.

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8h. The Secretary seek, through appropriate channels and procedures, to have the False Claims Act amended because it serves as a disincentive for thorough institutional investigations. The principle should be established that institutions may expeditiously investigate scientific misconduct allegations, protected from adverse use of their findings in litigation, if thorough, competent investigations have been conducted.

Discussion

DHHS regulations assign primary responsibility for conducting scientific-misconduct investigations to PHS awardee institutions. Officials at these institutions have expressed concern that the False Claims Act exposes them to potential liability for three times the amount of federal funds expended for research associated with a misconduct case even when their investigation fully meets all applicable requirements. While sharing the Commission's conclusion that the prospect of subsequent litigation under the Act may be a disincentive for institutions to be thorough in their investigations, the Implementation Group notes that, by its existence, the Act also is a strong incentive for institutions to prevent misconduct.

Although the Implementation Group is strongly empathetic to the institutions' concerns, it recognizes the

long tradition and myriad other uses of the False Claims Act and is not optimistic that the Department could gain the broad-based support needed to effect a legislative amendment specific to research misconduct. Nevertheless, consultation with the Department of Justice should be sought to determine whether new procedures within the current statutory framework might provide institutions some of the relief they seek.

Proposal

The Department should initiate a discussion with the Department of Justice to address the legitimate concerns of awardee institutions, as summarized above and as discussed in the Commission's report.

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Commission Recommendation 9: Federal Adjudication

The Commission recommends that DHHS:

9a. Use institutional findings related to misconduct as final and binding if they are supported by the evidence and were obtained through a process that afforded due process and complied with federal regulations and the institution's own policies.

9b. Limit any subsequent federal review of a decision reached after ORI has reviewed and accepted an institutional finding of misconduct. That subsequent review should be confined to the existing record rather than a de novo proceeding, except when DHHS proposes to impose a separate federal sanction. In such instances, if the institutional record is not adequate, further fact-finding by ORI may be required, and, upon request, the respondent should receive a trial-like adjudicatory process to review any such further fact-finding.

9d. Continue to permit a respondent to request a trial-type, de novo hearing when proposed findings of misconduct are based on an ORI investigation. Such hearings should continue to be held before a Research Integrity Adjudication Panel appointed by the Departmental Appeals Board. However, the Secretary should consider steps to strengthen and streamline the process to expedite the proceedings.

Discussion

The Implementation Group considered these three recommendations together because each addresses the Department's review procedures for ORI findings of scientific misconduct. While the existing procedure has gained public acceptance, it has been expensive and time-consuming for all involved parties and generally has not relied on the existing record where findings are based on an institution's investigation. The Group endorses all three recommendations in principle but recognizes that development of specific procedures for putting them into practice is beyond its mandate. It therefore proposes that the

Department immediately convene a working group drawn from all relevant DHHS offices (e.g., ORI, OGC, OIG, and DAB) to determine how far the Department can go within the current framework and what subsequent regulatory changes, if any, are needed to achieve full implementation.

Proposal

The Department should establish immediately a working group drawn from all relevant offices to develop and execute a plan for implementing these three recommendations.

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9c. Permit an institution to contest the decision of the Department's reviewing office if that office has reviewed and disapproved an institutional finding of misconduct or non-misconduct. In addition, the original respondent should be given an opportunity to make a submission to that office in this review process.

Discussion

The Implementation Group endorses this recommendation and suggests that ORI develop a process whereby it consults with awardee institutions before deciding to reverse an institutional finding of either misconduct or no misconduct. The Group also endorses the recommendation regarding respondents' opportunity to furnish materials to ORI and notes that current procedures already allow for this.

Proposal

The Department should explore non-regulatory means of ensuring consultation with awardee institutions prior to reversing institutional findings of either misconduct or no misconduct. The Department should also continue current policies permitting respondents to submit comments on institutional findings directly to ORI.

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9e. Require widespread, systematic public disclosure of all outcomes of federal research and research-related professional misconduct cases, with detailed, specific statements of their rationale, in view of the strong public interest in the disclosure of information underlying such cases. In addition, the Secretary should require public disclosure of all factual information developed in misconduct cases that affects the public welfare, unless disclosure is expressly prohibited by law.

Discussion

The Implementation Group does not agree with this recommendation, which is not accompanied by any specific discussion in the Commission Report. If implemented as proposed, this recommendation would

put all scientists accused of research misconduct in an unfavorable light irrespective of the merits of the allegations or subsequent exoneration. Moreover, the recommended practice could have a chilling effect on ORI's ability to investigate allegations and it would run counter to legal precedent recently established by the U.S. Court of Appeals in connection with litigation brought against DHHS under the Freedom of Information Act.6

The Group notes that current DHHS policy provides considerable public access to information about the activities of both ORI and the DAB. First, when responding to requests from members of the public, ORI discloses information about completed cases to the maximum extent consistent with the simultaneous application of the Freedom of Information Act and the Privacy Act. Second, in contrast to NSF (which does not publicize the outcomes of even those cases in which it finds scientific misconduct), ORI routinely publishes a substantial amount of information -- in particular, information on (1) all cases of confirmed misconduct with identifiers and (2) cases with no misconduct findings without identifiers or with identifiers if the respondent so requests. Third, all hearings conducted by Research Integrity Adjudication Panels convened by the DAB on appeals of findings of scientific misconduct are announced in advance and open to the public.

ORI also has been mindful that disclosure of information about particular cases can affect whistleblowers adversely, especially when the disclosure occurs during the course of an inquiry or investigation. As a result, ORI not only accords whistleblowers the benefits of confidentiality but also has issued a position paper to educate affected parties about the legal protections that a whistleblower has against suits for defamation or libel and the potential for losing those protections if whistleblowers elect to publicize the allegations themselves.

Proposal

The Department should maintain its current policies for disclosure of information related to ORI and DAB activities.

*

Commission Recommendation 10:

Effective Oversight of Assurances and Misconduct Investigations

The Commission recommended that DHHS:

10a. Use procedures that incorporate the experience and knowledge within the institutions it oversees in developing guidance intended for their use.

Discussion

The Implementation Group concurs, noting that such consultation is part of current ORI practice.

Proposal

ORI should continue its current practice of consulting with institutions when developing guidance for them with respect to promoting research integrity and responding to real or alleged scientific misconduct.

*

10b. Oversee institutions more systematically for compliance with federal assurances, using an appropriate array of mechanisms including on-site visits by specially trained staff. During site visits, investigators/reviewers should be available for public or confidential interviews with members of the institution's community regarding compliance with federal assurances.

Discussion

The Implementation Group only partially endorses that a program of systematic analysis of institutional compliance is needed. ORI reports that it annually audits a sample of institutional policies and procedures, initiates individual compliance reviews on a "good cause" basis, and uses site visits as needed. The Group believes that the current procedures are appropriate as far as they go but, if funds were available, could be strengthened significantly by incorporating site visits on a routine basis.

The Implementation Group endorses only partially the Commission's view regarding inclusion within the site-visit process of confidential interviews with members of the institutional community. To the extent that a site visit focuses on particular matters associated with compliance, such interviews seem entirely appropriate. However, if ORI site visits, as a general rule, were to feature invitations for such confidential interviews without specific cause, this could do more to erode than strengthen the role of institutions as the firstline promoters of research integrity and the first party to address research misconduct.

Proposal

The Department should endorse existing ORI procedures for promoting institutional compliance and, within available funds, encourage greater use of site visits.

*

10c. Require from the intramural NIH programs the same assurances and annual reports that are required from other institutions, and monitor NIH accordingly. NIH should have exemplary procedures in place to establish and maintain integrity in intramural research programs, including

responses to cases of alleged misconduct and retaliation against whistleblowers.

Discussion

The Implementation Group shares the Commission's view that the Department's intramural research program should lead by example with respect to research integrity. However, the Group does not believe that introduction of requirements for institutional assurances and annual reports is appropriate for either the NIH intramural program in particular or the intramural programs of PHS agencies in general. The PHS intramural research programs, including those of the NIH, already have in place more detailed policies and procedures related to research misconduct than most extramural institutions. Furthermore, PHS agencies report all their intramural inquiries to ORI, and ORI conducts all intramural investigations--requirements that involve more rigorous ORI oversight than those applied to extramural institutions. Finally, the ORI annual report already includes results of all inquiries and investigations associated with PHS intramural research.

Proposal

The Department should maintain the current policies and procedures for its intramural research programs with respect to research integrity and misconduct. The Department, through appropriate publications, should do more to make the intramural policies and procedures known to the larger scientific community and the general public.

*

10d. Avoid, whenever possible, a separate federal investigation as an acknowledgment of the primary responsibility of institutions. DHHS should not reinvestigate or relitigate factual matters if an institution has substantially complied with its procedures and reached findings of misconduct supported by the evidence, unless required to do so as a prerequisite for imposing a federal sanction.

Discussion

This recommendation is essentially the same as Recommendation 9b.

Proposal

See Proposal associated with Recommendations 9a, 9b, and 9d.

*

10e. Publish criteria, under the Secretary's direction, to be used for rejecting institutional findings and for intervening in ongoing institutional procedures that respond to allegations of research misconduct and other professional misconduct.

Discussion

The Implementation Group concurs with this recommendation and believes these issues should be addressed in an NPRM.

Proposal

The Department should develop criteria for use in determining whether to accept or reject institutional findings and when to intervene with respect to institutional procedures. These criteria should be presented for public comment through an NPRM.

*

10f. Develop a specific mechanism for determining: (a) whether, when whistleblowers contact the federal agency directly because they lack faith in the fairness of the institutional process, a fair process can and will take place at an institution; and (b) when and how to intervene when such intervention is deemed appropriate.

Discussion

The Commission heard testimony questioning the fairness of institutional processes for investigating alleged misconduct and concluded that the Department should develop procedures for responding to such complaints from whistleblowers. Although the Implementation Group concurs in principle, it does not believe that a separate mechanism, i.e., one limited to whistleblowers and this type of complaint, is desirable. A special mechanism could encourage complainants to approach ORI directly and avoid the institutional process, whereas both the Commission and the Group would like to see the latter strengthened. Instead, the Group proposes that ORI develop procedures for how it will deal with all types of complaints related to the fairness of institutional practices.

Proposal

The ORI should develop procedures for (1) determining the fairness of institutional procedures toward all parties associated with allegations of research misconduct and (2) effecting remedial actions where institutional procedures are found wanting. The ORI proposal should be presented for public comment in an NPRM.

*

10g. Adopt a procedure (analogous to that provided by the Whistleblower Protection Act of 1989 for Civil Service disclosures) in which, once the federal agency receives an institution's investigative

report concerning allegations of research or other forms of professional misconduct, it makes available to the whistleblower relevant portions of the institution's response (except where prohibited by law, and with due concern for confidentiality). The federal agency should allow the whistleblower to comment on the adequacy of that response prior to the Federal Government's decision to accept or reject the report as a resolution of the whistleblower's charges. The final judgment is reserved to the Federal Government.

Discussion

Several witnesses before the Commission asserted that current procedures are not adequate to ensure that whistleblowers' comments and concerns are considered as part of institutional investigations and subsequent review by ORI. This recommendation is a manifestation of that testimony.

The Implementation Group recognizes that whistleblowers may have substantive comments that are helpful to those conducting an investigation or to those reviewing the investigative report and determining the appropriate action to be taken. Current DHHS regulations[7] allow for such comments to be received and considered by the awardee institution when it is conducting an investigation. Such comments could be routinely forwarded to and considered by ORI within the context of its review and oversight responsibilities. The Implementation Group believes that this would be a desirable addition to current practices.

Proposal

Within the framework of current policies, ORI should build upon existing mechanisms by which whistleblowers can make comments to awardee institutions related to pertinent investigative reports dealing with possible research misconduct to assure that such comments are forwarded to ORI for its consideration as it reviews the reports.

*****

Commission Recommendation 11: Imposing Federal Sanctions

The Commission recommends that DHHS:

11a. Publicly disclose any instance in which, because an institution did not process a case in good faith, ORI replaced the institution as fact finder in resolving allegations of research misconduct and other forms of professional misconduct.

11c. Use a range of potential sanctions against institutions, including censure, the return of research funds, fines, suspension, and institutional debarment from DHHS funding.

11d. Take enforcement action--after notice and an opportunity for institutional corrective action--to

discontinue PHS funding to institutions that lack a system of rules and procedures for complying with the regulations prohibiting research misconduct and other forms of professional misconduct, or that willfully do not follow their own rules and procedures.

Discussion

The Implementation Group elected to address Recommendations 11a, 11c, and 11d together because they overlap one another and are in effect all sanctions.

The Group notes that the current DHHS scientific misconduct regulation8 refers to loss of funding as a sanction for noncompliance--a termination of all PHS funds to that institution. A separate regulation9 authorizes the suspension and/or termination of individual grants for material failure to comply with the terms and conditions of the award. The Commission's call for a range of institutional sanctions manifests a widely held concern, both within and outside the Department, that draconian sanctions such as the suspension or termination of funding to an institution will be applied rarely, if at all, and that a menu of lesser sanctions, graded to correspond to different degrees of wrongdoing, is needed. The Implementation Group agrees.

Proposal

ORI should identify an array of institution-level sanctions covering a wide range of severity and include these in a subsequent NPRM.

*

11b. Require the federal office responsible for adjudication to formulate criteria for the severity of sanctions, and in each case articulate the specific reasons for the choice of sanction.

Discussion

The Implementation Group concurs in this recommendation and proposes that ORI develop such criteria and invite public comment through an NPRM. In view of the apparent difficulty of developing detailed criteria in this area, the Group suggests that ORI focus on general standards to facilitate case-specific determinations.

Proposal

The ORI should develop general criteria for determining the severity of sanctions to be applied to individuals and institutions under various circumstances and publish the criteria for public comment in an NPRM.

*

11e. Broaden the range of administrative actions applied as sanctions to individuals found guilty of professional misconduct (including research misconduct and obstruction of investigations of such misconduct). The type of sanction used should depend on the seriousness and consequences of the misdeed and any mitigating circumstances. These actions should include reprimands, mandatory supervision of future work, and debarment for varying periods of time. Research misconduct that places human subjects at risk, including data fabrication affecting treatment, should elicit particularly severe sanctions.

Discussion

The Implementation Group notes that ORI already employs a wide range of sanctions insofar as individuals are concerned. These sanctions were recently published in the *ORI Newsletter*, and should continue to be published as necessary.

Proposal

ORI should continue its current practice of applying a range of sanctions to individuals and publish them in a subsequent NPRM or a *Federal Register* notice.

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APPENDIX A

Membership List

Implementation Group on Research Integrity and Misconduct (IGRIM)

Dr. William Raub, Chair, IGRIM, and Science Policy Advisor to the Secretary, DHHS, and to the Assistant Secretary for Planning and Evaluation

Ms. Lily Engstrom, Science Policy Analyst, Office of the Assistant Secretary for Planning and Evaluation (OASPE)

Dr. Lyle Bivens, Director, Office of Research Integrity (retired March 31, 1996)

Dr. Philip Chen, Associate Director for Intramural Affairs, National Institutes of Health (NIH) (Represents Dr. Kirschstein, Deputy Director, NIH)

Dr. Joan Schwartz, Special Assistant to the Deputy Director for Intramural Research**,** NIH

Dr. Alan Schechter, Chief, Laboratory of Chemistry and Biology, NIDDK, NIH**)**

Dr. Joel Goldstein, Acting Associate Administrator for Extramural Programs, SAMHSA

Dr. Terry Hoffeld, Agency Referral Officer and Agency Research Integrity Liaison Officer, , Agency for Health Care Policy and Research (AHCPR) (Represents Ms. Linda Demlo, Acting Director, Office of Scientific Affairs, AHCPR)

Dr. Robert Knouss, Special Assistant to Principal Deputy Assistant Secretary for Health, Office of Public Health and Science (OPHS)

Mr. Robert Lanman, Legal Advisor, NIH

Ms. Susan Sherman, Senior Attorney, Office of the General Counsel (OGC)-NIH

Dr. Kurt Maurer, Deputy Director of the Division of Health Examination Statistics, NCHS (Represents Dr. Snider, Associate Director for Science, CDC)

Mr. Chris Pascal, Director, Division of Research Investigations, and (since April 1, 1996) Acting Director, Office of Research Integrity

Mr. Richard Riseberg, Associate General Counsel, Public Health Division, OGC

Ms. Andrea Selzer, Senior Attorney, DAB

Mr. Stan Woollen, Bioresearch Monitoring Program Coordinator, FDA

Mr. Frank Zuraf, Audit Director, Public Health Area, OIG

Ms. Henrietta Hyatt-Knorr, Executive Secretary, IGRIM, and Assistant to the Director, ORI

APPENDIX B

Summary of the Proposals to the Secretary

by the Implementation Group on Research Integrity

Definitions (Recommendation 1)

The Department should publish an Advance Notice of Proposed Rulemaking (ANPRM) presenting the Commission's definitions for broad input from the scientific community and the public at large.

Uniform Federal Definition (Recommendation 2)

The Department should coordinate, to the extent that it is practical, the content and timing of the

ANPRM with the work of the interagency panel appointed by the OSTP to develop a uniform, government-wide definition of research misconduct.

Role of Research Institutions and the Federal Government (Recommendations 3, 4, 5)

The Department should publish an NPRM, establishing requirements for (1) creating an institutional assurance of research-ethics training for all staff supported by PHS research funds and (2) adding to the present individual assurance for principal investigator/program director a statement that (s)he is aware of the institutional policies and procedures related to research misconduct as well as its training program on the responsible conduct of research. Routine documentation of these assurances should be included with each request for funds but limited to a check-off box and signatures, respectively.

When speaking or writing on research integrity on behalf of the Department, the Secretary and other senior staff should encourage the teaching of ethics at all educational levels, in laboratories, and in clinical research settings.

Subject to the program priorities and the availability of funds, DHHS agency heads should fund high-quality studies of science-related ethics in general and research misconduct in particular.

Roles of Professional Societies and Codes of Ethics (Recommendation 6)

None. This recommendation is directed specifically to professional societies.

Responsible Whistleblowing (Recommendations 7 and 8f)

ORI should complete its draft NPRM for the protection of whistleblowers, taking into account the recommendations of the Commission and the comments of the Implementation Group.

Administrative Processes and Investigations (Recommendations 8a-e, and g-h)

ORI should retain its current authority to review, investigate, and render initial decisions on cases of alleged misconduct**.**

The Department should adopt this recommendation to the extent practicable, taking into account competing priorities and the availability of resources.

DHHS should seek the requisite legislative authorization. ORI should also develop regulatory language to improve its access to documents and testimony for investigations and hearings.

The Department should continue to rely on existing mechanisms for oversight of ORI.

The Department should highlight this issue in the ANPRM associated with the new definition recommended by the Commission.

ORI's Division of Policy and Education should continue to be responsible for responding to whisteblower complaints for the foreseeable future. The Department should defer further consideration of the Commission recommendation until the final whistleblower protection regulation has been promulgated.

The Department should initiate a discussion with the Department of Justice to address the legitimate concerns of awardee institutions, as summarized above and as discussed in the Commission's report.

Federal Adjudication (Recommendations 9a-e, and 10d)

The Department should establish immediately a working group drawn from all relevant offices to develop and execute a plan for implementing these three recommendations (9a, b, and d, and 10d).

The Department should explore non-regulatory means of ensuring consultation with awardee institutions prior to reversing institutional findings of either misconduct or no misconduct. The Department should also continue current policies permitting respondents to submit comments on institutional findings directly to ORI (9c).

The Department should maintain its current policies for disclosure of information related to ORI and DAB activities (9e).

Effective Oversight of Assurances and Misconduct Investigations

(Recommendations 10a-g, except for d)

ORI should continue its current practice of consulting with institutions when developing guidance for them with respect to promoting research integrity and responding to real or alleged scientific misconduct.

The Department should endorse existing ORI procedures for promoting institutional compliance and, within available funds, encourage greater use of site visits.

The Department should maintain the current policies and procedures for its intramural research programs with respect to research integrity and misconduct. The Department, through appropriate publications, should do more to make the intramural policies and procedures known to the larger scientific community and the general public.

The Department should develop criteria for use in determining whether to accept or reject institutional findings and when to intervene with respect to institutional procedures. These criteria should be presented for public comment through an NPRM.

ORI should develop procedures for (1) determining the fairness of institutional procedures toward all parties associated with allegations of research misconduct and (2) effecting remedial actions where institutional procedures are found wanting. The ORI proposal should be presented for public comment in an NPRM.

Within the framework of current policies, ORI should build upon existing mechanisms by which whistleblowers can make comments to awardee institutions related to pertinent investigative reports dealing with possible research misconduct to assure that such comments are forwarded to ORI for its consideration as it reviews the reports.

Imposing Federal Sanctions (Recommendations 11a-e)

ORI should identify an array of institution-level sanctions covering a wide range of severity and include these in a subsequent NPRM.

ORI should develop general criteria for determining the severity of sanctions to be applied to individuals and institutions under various circumstances and publish the criteria for public comment in an NPRM.

ORI should continue its current practice of applying a range of sanctions to individuals and publishing them in a subsequent NPRM or a *Federal Register* notice.

APPENDIX C

National Science Foundation

Framework for Addressing Misconduct in Science

The National Science Foundation (NSF) defines "misconduct in science" as:

(1) Fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from activities funded by the NSF; or

(2) Retaliation of any kind against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith.

Within NSF, the responsibilities for investigating and rendering decisions on misconduct cases are vested in two separate bodies. The Office of Inspector General (OIG), which reports directly to the National Science Board, conducts investigations while the Office of the NSF Director, specifically the Deputy Director, has the authority to make a finding of misconduct and specify actions, if any, to be taken by NSF.

When an allegation of misconduct is brought to NSF's attention, OIG usually initiates an inquiry to determine whether the allegation involves an NSF proposal or award, whether it falls within NSF's regulatory definition of misconduct, and whether the allegation has any evidentiary substance. The subject is usually asked to respond to the allegation, but the institution is not informed. Many cases are closed at this stage because they fail to meet the criteria for an NSF investigation. If the inquiry indicates that the case should continue to be pursued, the institution employing the subject is usually offered the opportunity to conduct an investigation. OIG can, however, conduct its own investigation at any time.

The institution sends OIG its investigative report, which OIG reviews for completeness, accuracy, and fairness. At times, OIG will ask the institution for clarification and/or additional information. If OIG believes that the institution's investigation and any subsequent actions fully resolve the matter, OIG so informs the subject and the institution closes the case. If OIG believes that there is sufficient evidence of misconduct and that NSF should take action to protect the government's interest, OIG prepares an investigation report for the Deputy Director of NSF. This draft report which incorporates any investigation findings received from the institution, is provided to the subject for comments. Any resulting changes as well as the subject's comments or rebuttal are included in the report when it is submitted to the Deputy Director.

OIG's report is also sent to the NSF Office of the General Counsel, which reviews it for legal sufficiency and makes a recommendation to the NSF Deputy Director. The Deputy Director may also consult scientific advisors as appropriate. Decisions of the Deputy Director may be appealed to the Director, NSF. To date, no appeals have been filed since many cases are resolved by settlements between NSF (specifically the Deputy Director) and the subject. NSF's misconduct findings have generally involved plagiarism.

Summary information about NSF's misconduct cases is published in OIG's Semiannual Reports to Congress. However, NSF does not reveal the names or personal identifiers of individuals against whom misconduct findings have been made unless they have been debarred, in which case such information is published in the General Services Administration's list of debarred individuals and organizations.

APPENDIX D

Acronyms

ANPRM Advance Notice of Proposed Rulemaking

DAB Departmental Appeals Board

DHHS Department of Health and Human Services

DPE Division of Policy and Education (in ORI)

GAO General Accounting Office

NIH National Institutes of Health

NPRM Notice of Proposed Rulemaking

NSF National Science Foundation

OGC Office of the General Counsel

OIG Office of Inspector General

OPRR Office of Protection from Research Risks

ORI Office of Research Integrity

OSTP Office of Science and Technology Policy

RIAP Research Integrity Adjudication Panel (in DAB)

PHS Public Health Service

FOOTNOTES:

1. Hereafter referred to as the "Implementation Group" or the "Group"
2. Commission recommendations are shown in italics throughout this report.
3. Swazey, Judith P., Anderson, Melissa S., Louis, Karen Seashore. (1993, Fall). "Encounters with ethical problems in graduate education: Highlights from National surveys of doctoral students and faculty." *Professional Ethics Report* 6(4):6-7
4. Swazey, Judith P., Louis, Karen Seashore, Anderson, Melissa S. (1994, March 9). "The ethical training of graduate students requires serious and continuing attention." *Chronicle of Higher Education*, Section 2
5. For a description of the NSF process, see Appendix C.
6. McCutchen v. HHS, 30 F. 3rd 183 (D.C.C. 1994)
7. 42 CFR 50.103(d)(3)
8. 42 CFR part 50.105
9. 45 CFR Sections 74.60-62+