

Report of the Department of Health and Human Services Review Group on Research Misconduct and Research Integrity

I. BACKGROUND

The Department of Health and Human Services (HHS or Department) is one of the nation's largest funders of research and is the largest funder of biomedical research. The Department has a responsibility to exercise appropriate oversight over the expenditure of public funds, and to assure the integrity of the scientific record created through research supported by these funds.

HHS has long-standing authority to address misconduct in research conducted by the Department agencies or funded by HHS under its discretionary grant authorities. In addition, the Department has authority under federal criminal and civil fraud statutes related to research misconduct. The Department has been formally involved in addressing allegations of research misconduct since 1981 when this work became the responsibility of the Institutional Liaison Office, Office of Extramural Research, National Institutes of Health (NIH).

The first specific statutory authority on Public Health Service (PHS)¹ research misconduct matters was enacted in 1985.² This provision amended the PHS Act and directed the Secretary to promulgate regulations requiring entities that apply for PHS research funds to establish a process for reviewing reports of "scientific fraud"⁴ and to report investigations to the Secretary.³ The PHS Act further instructed the Director of the NIH to establish a process for responding to reports of scientific fraud.

On August 8, 1989, HHS published its final regulation regarding research misconduct.⁵ The regulation sets out the "responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science," and defines misconduct in science as: "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data."⁶

The definition of research misconduct and procedures for addressing allegations set forth in the regulation apply by their terms only to extramural scientists who conduct PHS-supported research with funds under PHS grants and cooperative agreements. However, PHS administrators have applied an identical definition of research misconduct, and similar procedures for addressing allegations,⁷ to intramural scientists who conduct research in PHS⁸ laboratories. The intramural procedures were revised most recently in 1994.⁹

In June 1992, the Office of Research Integrity (ORI) was created to replace prior organizational units.¹⁰ The NIH Revitalization Act of 1993 (NIH Act) established ORI as an independent entity reporting to the Secretary.¹¹ ORI is organizationally located in the Office of Public Health and

Science, Office of the Secretary, and is administered on a day-to-day basis by the Assistant Secretary for Health (ASH).

In November 1992, the PHS announced an interim procedure that gives respondents an opportunity to appeal adverse findings by ORI of research misconduct in a de novo administrative hearing before the HHS Departmental Appeals Board (DAB).¹² Respondents are entitled to a hearing regardless of whether the level of sanction that is imposed at the conclusion of the ORI process is an administrative sanction, such as required supervision, or debarment from eligibility for federal grants and contracts.¹³

According to the Conference Report of the NIH Act,¹⁴ ORI's statutory mandate is to maintain "confidence in the integrity of the scientific process, in individual researchers, and in institutions which accept Federal funds," so that research can continue to enjoy public support.¹⁵ The 1993 legislation establishes the qualifications for the ORI director, and requires the establishment of a definition for research misconduct. The statute contains details on the administrative processes that must be established by institutions as a condition for receiving PHS funding, including the establishment of a process to be followed for responding to information regarding research misconduct. In addition, the statute requires ORI to establish procedures for: receiving reports from recipients of PHS funds; conducting investigations; and, taking actions to remedy misconduct. Further, the statute requires ORI to: monitor the administrative processes that have been established, or carried out, by institutions receiving federal funds; establish regulations designed to protect whistleblowers; and, remedy institutional defects in whistleblower protection. Regulations have not been issued implementing the amendments to section 493 enacted in 1993.¹⁶

In August 1996, at Secretary Shalala's request, Dr. Philip R. Lee, then the ASH, convened a group of HHS officials to examine the role of the ORI in handling allegations of research misconduct in research funded or conducted by HHS programs. The Secretary's charge to the ASH was to:

- Review and analyze the Department's processes for handling allegations of research misconduct from a policy perspective, and make appropriate recommendations aimed at improving quality, effectiveness, and efficiency of the processes; and,
- Consistent with the policy recommendations, suggest organizational arrangements for the Department that would facilitate achievement of the recommendations and the objectives of improving quality, effectiveness, and efficiency of the processes.

This examination of ORI activities was designed to enable HHS to respond effectively to the recommendations of the Commission on Research Integrity, known as the Ryan Commission, named for its chair, Dr. Kenneth Ryan. The Ryan Commission presented its report to the Secretary in late 1995, and the Secretary's Science Advisor, Dr. William Raub, created the Implementation Group on Research Integrity and Misconduct to evaluate these recommendations for the Secretary. This review of Departmental policies and procedures complements that effort.

Additionally, in 1996, the White House Office of Science and Technology (OSTP), through the Committee on Fundamental Science (CFS) of the National Science and Technology Council (NSTC),

established a working group comprised of representatives from the major research agencies (including HHS), to develop a government-wide policy on research misconduct. The NSTC goal was to develop a definition of research misconduct and a set of guiding principles for Federal agencies and the funded institutions, and to enhance the uniformity of definitions and underlying principles applied by Federal agencies. In May 1999, after an extensive agency review and clearance process, NSTC approved the proposed government-wide policy, which consists of a definition of research misconduct and guidelines for handling allegations of research misconduct. The NSTC plans to publish the proposed policy for comment in the Federal Register. Agencies will be directed to implement the policy, following final publication. HHS intends to coordinate implementation of the recommendations in this report with any final action taken by NSTC. The recommendations in the ORI report are consistent with -- and substantially similar to -- the government-wide policy proposed by NSTC.

The focus of the HHS Review Group has been on evaluating current procedures and exploring ways to improve Departmental action in the area of research misconduct. The Review Group first examined Departmental experience accumulated through the operation of the ORI and its predecessor the Office of Scientific Integrity (OSI). Members of the Group received detailed briefings that addressed ORI operations, statistical analyses of ORI cases, the types of ORI cases, processing times, their dispositions, and educational and outreach activities. Additionally, the Review Group met with representatives of the DAB and the HHS Inspector General. The Review Group consulted and met with experts outside the Department and government, including the Inspector General of the National Science Foundation and administrators and faculty of various research institutions having experience in handling allegations of research misconduct. Throughout the review process, ORI continued to emphasize its oversight and educational functions and many of the changes anticipated by the report recommendations are underway.

The Review Group recognizes that legislative and regulatory changes may be necessary to implement its recommendations. Additional coordination and consultation with parties affected may also be required to refine specific means of implementing the Review Group's recommendations.

II. FINDINGS AND RECOMMENDATIONS¹⁷

The Review Group finds that over time there have been significant improvements in the Department's handling of issues of research misconduct. Although there have been highly publicized reversals of a few cases, a rigorous review of the entire record of the Department's performance leads to the conclusion that the systems and processes have generally performed well. This same review also leads to the conclusion that performance can be further improved and the HHS role in the process potentially streamlined.

A. Recommendations Pertaining to the Definition of Misconduct

Recommendation 1.

HHS should adopt a revised definition of research misconduct.

The Review Group recommends that HHS adopt the following definition of research misconduct:

Research¹⁸ misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.¹⁹
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts.
- Research misconduct does not include honest error or honest differences of opinion.

While the proposed definition is slightly different from that currently used by HHS, the Review Group views the proposed definition as an improved version, focusing attention on improper behaviors that are specific to the conduct of research. Moreover, the public comment process will offer the opportunity for further consideration and refinement.

Recommendation 2.

Protections for human research subjects and animal welfare are covered through other specific regulatory mechanisms and should not be considered to be within the scope of the Department's definition of research misconduct.

The Review Group concluded that the other mechanisms now in place that address human research subject and animal welfare protections involve processes familiar to the research community. Adding conduct relating to these issues to the scope of a definition of research misconduct is unnecessary.

Recommendation 3.

Improper acts and misbehaviors in the conduct of scientific research that do not fit within the proposed definition of research misconduct should be handled through the existing mechanisms of an awardee institution²⁰ or other responsible organization²¹ or through other appropriate mechanisms of redress.

Other improper acts or misbehaviors may be associated with or may form part of complaints or accusations of research misconduct. Examples include theft of property; sexual harassment; and, other types of impermissible discrimination.²² While such acts, if proven, are deplorable, they are not specific to science. Complaints and accusations about these types of activities should be handled through existing mechanisms of an institution or responsible organization, or through other generally available and appropriate mechanisms. Although these behaviors are not appropriately addressed as research misconduct, all intramural HHS organizations and extramural institutions receiving HHS research funding should have procedures that address these behaviors.

B. Recommendations Pertaining to Inquiries and Investigations

Recommendation 4.

The fact-finding processes of inquiry and investigation should be the responsibility of and conducted by an awardee institution or by a responsible organization under a set of policies and procedures approved by HHS.

The Review Group recommends that both the inquiry and investigation phases of the fact-finding process should be conducted by awardee institutions or other responsible organizations. This institutional role places the fact-finding processes as close as possible to the site of the alleged misconduct where research standards and practices are understood in context and access to evidence is facilitated. This recommendation makes clear that fact-finding at the federal level will not routinely occur.

The Review Group has carefully considered and weighed the possible issues that might be raised by placing full responsibility for the fact-finding stages with the awardee institution(s). The Review Group recognizes that it is plausible to predict that bias could affect awardee institutions' and responsible organizations' responses to an allegation of research misconduct. One extreme might be the "white washing" of allegations of misconduct by viewing events and behaviors in the light most favorable to the accused. Alternatively, awardee institutions and responsible organizations could respond with over-zealous pursuit of allegations in order to protect the reputation of the institution at the expense of the alleged transgressor.

The Review Group is persuaded by its consultations that it is in the best interests of awardee institutions -- and thus, of persons accused -- to respond to allegations of research misconduct in a documentable, even-handed, and fair manner. While isolated problems may arise, the recommended actions, carried out within appropriate policies and procedures, should provide adequate checks and balances to assure a fair and even-handed approach. Additionally, the Review Group was impressed with the success of awardee institutions' handling of the fact-finding components of NSF's misconduct processes.

Additional support for the Review Group's high level of confidence regarding the fairness of institutional fact-finding comes from a review of the policies and practices of several large research institutions and from the experience of ORI. The Review Group consulted administrators and faculty from awardee institutions and responsible organizations that receive substantial HHS grant awards. The Review Group was particularly impressed by the universal commitment to even-handedness in fact-finding as an essential element of maintaining the reputation and credibility of an institution or organization.

The Review Group's consultations also support the conclusion that most research-intensive institutions and organizations have the capacity, through infrastructure currently in place, to conduct inquiries and investigations in a competent manner. Where institutions do not have that capacity, institutional representatives with whom the Review Group consulted have cited the availability of reasonable alternative mechanisms to provide these services. HHS would also assist institutions and responsible organizations in developing and securing such alternatives where necessary or indicated (see Recommendation 5).

The policies and procedures of awardee institutions and responsible organizations conducting inquiries and investigations will have to meet published HHS standards. Institutions and organizations would be required to provide assurances to that effect to the HHS granting organization in the same manner that current assurances are provided on policies applying to research on human subjects, for example.

Recommendation 5.

HHS should encourage the development of consortium-based approaches to be used by awardee institutions that do not have the capacity to conduct the fact-finding process, or at which there is otherwise inadequate institutional or organizational capacity.

The Review Group recommends that awardee institutions have the primary responsibility for conducting inquiries and investigations (the two phases of the fact-finding process) into allegations of research misconduct under the general oversight of HHS. Federal fact-finding, other than when conducted within intramural organizations, should be rare. To reduce further any need for federal fact-finding other than for intramural components and to improve the ability of small to middle-sized institutions to discharge their responsibility, HHS should encourage the formation of consortia that can conduct the fact-finding process when establishment of an individual institutional or organizational process is impractical.

The Review Group envisions consortia potentially taking many forms. Consortia may be groups of awardee institutions; groups formed by professional organizations; or mixed groups formed for the specific purpose of providing for the conduct of fact-finding processes on behalf of awardee institutions. The key is that the consortium will be organized to assist a responsible awardee institution that otherwise cannot properly conduct fact-finding. Awardee institutions that engage external fact-finding capacity remain responsible for meeting their obligations with regard to scientific misconduct correction.

The Review Group also envisions consortia as partners in Federal educational efforts. Currently, several professional organizations have committees specifically constituted to address issues of research misconduct. Some of these organizations have already established training and education programs designed to improve institutional capacities to prevent and avoid the occurrence of research misconduct and to perform inquiries and investigations as needed. Although the Review Group sees the educational mission as a fundamental federal responsibility that is tied to the standards setting process, collaboration between consortia and a redesigned ORI charged with oversight is expected to produce valuable results.

Recommendation 6.

Federal fact-finding²³ should be conducted only where all other options fail or where there is compelling reason to do so. Federal fact-finding should be conducted by the HHS Office of the Inspector General augmented, as appropriate, by scientific personnel.

Situations may arise in which it is necessary for HHS to assume the responsibility for fact-finding. It has been noted by the NSF²⁴ that investigations conducted by a federal body may be indicated when: allegations of misconduct also involve a crime; the close association of individuals in a small institution may tarnish the actual or perceived objectivity of an investigation; or when allegations involve institutional officials in the wrongdoing.²⁵ Additionally, complex cases involving conflicts of interest, multiple institutions, or a subject who no longer has an institutional affiliation can provide reason for fact finding to be taken on in a specific case by a federal body.

The Review Group recommends that inquiries and investigations which must be conducted by a federal entity be performed by the HHS Office of the Inspector General (OIG), with appropriate additional scientific advisors/consultants as necessary. The OIG is accustomed to conducting investigations and maintains a skilled staff. However, such staff must be augmented, in some cases, by scientifically

knowledgeable persons. The OIG can expedite fact-finding by the use of its subpoena powers. The Review Group believes that the maintenance of a cadre of investigators apart from the OIG cannot be justified on a cost basis. Also, with the limited number of cases anticipated, the skills of investigators cannot reasonably be maintained. Additionally, separating the federal investigation from any part of the Federal adjudication process would produce a process that is consistent with other inquiry-investigation-adjudication processes in research misconduct.

The Review Group emphasizes, however, that an OIG investigation should be necessary only in very unusual instances. Any awardee institution that cannot or will not conduct the fact-finding process should be assisted to develop its own capacities or to affiliate with an entity or consortium that can do the work. In the view of the Review Group, an institution that fails to discharge its responsibility to perform fact-finding, refuses to perform fact-finding, or fails to conduct the process in an acceptable manner after receiving technical assistance should be reviewed to determine its suitability for continuing eligibility to receive awards.

C. Recommendations Pertaining to Procedural Issues

Recommendation 7.

Fact-finding processes in cases of potential research misconduct should be clearly separated from administrative decision-making and adjudicative processes.

There are two essential phases of fact-finding. One is the inquiry phase and the other, the investigative phase. In the inquiry phase, allegations are examined to determine if there is sufficient basis to warrant an investigation. Where no such basis is found to exist, a matter should be dismissed at this stage. Where the inquiry phase finds sufficient evidence to warrant an investigation, ORI should be so notified, and the case should proceed to investigation.

In processing cases, fact-finding should be separated from decision-making at both the responsible organization and the federal levels. For example, the report and recommendations of an inquiry panel from an awardee institution should be forwarded to an institutional or agency official who had not been involved with the inquiry. That official will make the decision to accept, reject, or modify that panel's recommended action(s). Similarly, the report of an investigative panel at an awardee institution should be forwarded for review to a senior official who had not been involved in the conduct of the investigation. When an inquiry ends with the decision that there is no reason to open an investigation, the matter ends there. ORI need not be informed of that determination.

When an inquiry ends with a decision to move a matter to investigation, that decision should be reported to ORI. Thereafter, the awardee institution will investigate the matter and recommend either to exonerate or to sanction the accused.

If the investigation results in a finding of no misconduct, ORI should be notified of the investigation's conclusion and the reasons that support it. ORI will review the record of the investigation to determine, *inter alia*, that the record supported the outcome and that the procedures used were thorough, objective and competently applied. The ASH will retain the authority to reverse the finding and/or to request that a new fact-finding process be undertaken.

If the investigation concludes with a finding of misconduct, ORI should be notified of the finding and reasons in support of it as well as any institutional sanctions. If the investigating institution

recommends federal action, that recommendation will be forwarded to ORI for review along with supporting documentation.

ORI will have to develop procedures for reporting by responsible organizations of all the decisions above-identified as appropriate for ORI notification.

ORI would review the forwarded documents and make sanction recommendations to the ASH who will then issue a decision regarding the proposed sanctions. Vesting such decision-making responsibility in the ASH rather than the PHS agency heads would do much toward ensuring consistent consideration across cases and over time. The decision of the ASH would be appealable to the DAB.

Recommendation 8.

Guidelines that outline reasonable expectations for the allowable time for each step of the process need to be developed.

Clear expectations for the timely processing of allegations should be developed and published. Several problems associated with the present process stem from the inordinate amount of time that has been taken to address allegations from start to finish. Timely conduct of the inquiry, investigation, and adjudication phases must be a clear commitment among Federal and institutional partners. Additionally, defined time limits for the accused to respond or contest decisions should be established. The Review Group recognizes that actual time frames may vary from case to case because of complexity, collection of evidence, or other factors, and so does not propose adoption of a binding, universal set of time constraints. Nonetheless, the Review Group believes that describing time goals will provide an incentive for expeditious handling of cases.

Recommendation 9.

The role of the complainant, whether at the level of the awardee institution or the responsible organization, or when the case is being handled within HHS, is that of a witness only. Once the complainant has made a formal allegation that research misconduct has occurred, that person should not participate in the fact-finding phase, or in any other aspect of the determination of misconduct, other than as a witness.

On occasions in the past, the complainant has become a more significant part of the investigative process to the net detriment of the efficiency and effectiveness of the procedure. The approach recommended here is based on and consistent with the approach employed by the HHS Office of the Inspector General. This recommendation is consistent with the provisions of section 493(e) of the PHS Act which require the Secretary of HHS to promulgate regulations to protect whistleblowers from retaliation for having made an allegation of research misconduct or cooperated with an investigation of research misconduct. Proposed regulations implementing this mandate are forthcoming.

Recommendation 10.

A determination that research misconduct has occurred must be established by a preponderance of the evidence.

As stated in the Government-wide debarment and suspension regulations, debarment²⁶ and other sanctions are used to protect the interest of the Federal Government and to assure that it conducts business only with responsible persons. Debarment and other sanctions are taken to protect the public's and the Federal Government's interests, not for purposes of punishment.²⁷ The debarment regulations appropriately adopt an evidentiary standard of preponderance of the evidence, the usual standard of proof in civil actions. Awardee institutions, responsible organizations, and HHS should

apply this standard in evaluating whether research misconduct has occurred in a particular instance. The Review Group also considered the appropriateness of applying the more rigorous standard of clear and convincing evidence given the significant reputational interests at stake for scientists found to have engaged in misconduct. Because the government's purpose in imposing debarment or other sanctions is to protect its interest in conducting business only with responsible persons, the Review Group concluded that requiring the application of a more demanding evidentiary standard before sanctions for research misconduct could be imposed would not adequately serve that governmental interest.

D. Recommendations Pertaining to Special Considerations

Recommendation 11.

The principal responsibility for oversight of institutional processes, education, standards setting, and attention to HHS's interests in policing research misconduct should be vested in ORI. The role, mission, and structure of ORI should be changed to become one principally of oversight, education, and review of institutional findings and recommendations.

Although inquiries and investigations should be the province of awardee institutions, there are several responsibilities and functions that are exclusively federal in nature, the most obvious of which is the decision to recommend a federal sanction as the result of an investigation that finds that research misconduct occurred. This function should be assigned to the ASH. Oversight, education, standards setting, and other functions which do not require a decision to sanction should be conducted by a re-designed ORI. The Review Group recommends that the role, mission, and structure of ORI change to become one of preventing misconduct and promoting research integrity principally through oversight, education, and review of institutional findings and recommendations.

A redesigned ORI would have the principal responsibility for providing model guidance to awardee institutions on matters including, but not limited to, the conduct of inquiries and investigations, expectations regarding the various roles to be fulfilled, and the treatment of the accused and witnesses, including the accuser. The ORI would provide educational and consultative aid regarding expectations, as well as guidance on investigative procedures and techniques.

The most substantial federal function assigned to the ORI, however, would be the review of cases in which the institution has conducted an investigation and reached a conclusion about whether or not research misconduct occurred. Each such case record would be reviewed to determine whether the record supported the outcome and that the process was thorough, objective and competently done. ORI would be empowered to examine cases and recommend to the ASH that a finding be accepted or rejected. ORI would also be independently empowered to request additional information or explanations from an awardee institution that had performed a case investigation.

It is important to note that the Review Group does not envision or recommend that a redesigned ORI undertake investigations or make final decisions on sanctions. Its role in the processing of cases would be to assess the record of the institutional fact-finding phases for content, to assure compliance with proper processes, and then to recommend sanctions to the ASH. The Assistant Secretary for Health would review the record of the institutional investigation and the proposed action(s), and, after giving the accused the opportunity to respond in writing to such proposed action(s), including proposed sanctions, would make a determination to accept or reject the conclusions and to impose sanctions. In

making her or his determination, the ASH will consult any persons within HHS whose expertise or assistance the ASH deems necessary or appropriate.

This decision would be final, unless contested where debarment is the sanction imposed (see Recommendation 13.). When the sanction imposed is debarment, the decision of the ASH would be considered a recommendation to the Deputy Assistant Secretary for Management and Budget (Grants and Acquisition Management) who makes the final debarment decision.

Recommendation 12.

Institutions and members of awardee institutional inquiry and investigational panels²⁸ should be provided qualified immunity from tort or related actions for accepting the responsibility of reviewing allegations of research misconduct in connection with the receipt of federal funds pursuant to the HHS policy.

The performance of inquiries and investigations by the awardee institution can expose panel members and institutional investigators to personal legal actions. These legal actions can be a significant disincentive to persons asked to serve as members of inquiry or investigation panels. Although a few states provide qualified immunity for faculty at public universities who engaged in such service, most do not.

The nature of inquiries and investigations dictates that the best and most highly qualified and respected persons be available for service. If increased responsibility is to be borne by awardee institutions, the Federal Government must make every effort to enhance the ability of institutions and organizations to draw on the assistance of their own faculties and employees in the investigation of allegations of research misconduct.²⁹

Recommendation 13.

The Departmental Appeals Board (DAB) should continue to provide hearings for individuals who contest findings of scientific misconduct. Three years after this Report is implemented, HHS should examine and consider whether hearings in non-debarment cases should be eliminated.

Currently, all individuals found by ORI to have engaged in research misconduct are afforded the opportunity to challenge the findings and proposed administrative sanctions in hearing before the Departmental Appeals Board (DAB).³⁰ The accused are permitted "to be represented by counsel, to question any evidence and witnesses presented by ORI, and to present evidence and witnesses in rebuttal to the findings and proposed administrative actions." The DAB's decision to accept or reject ORI's decision at the end of the hearing constitutes final agency action, except in cases involving debarments. DAB debarment proposals are considered recommendations to the Deputy Assistant Secretary for Grants and Acquisition Management who makes the final debarment decision. This official may reject the DAB's conclusions only after determining that they are arbitrary and capricious or clearly erroneous.

³¹ If HHS determines that the DAB is to remain the locus for hearings relating to research misconduct, enhanced procedural and evidentiary rules will be needed to streamline and improve the process. Further, the level of scientific expertise on the panels that hear scientific misconduct cases needs to be increased.

The Review Group believes that, with the following changes, the DAB remains the best institution for managing appeals from decisions to impose sanctions for research misconduct. DAB hearing panels

should be comprised of one DAB member or Administrative Law Judge (ALJ) and two scientists. The DAB would develop a panel of scientists from which two scientists would be selected to serve on research misconduct appeals panels. This change would ensure that each case is heard by panels of which the majority of members are respected scientists, thus ensuring credibility for DAB determinations in the government and in the scientific community. The DAB member or ALJ member of the panel would ensure that each panel had the benefit of a person experienced in the legal issues presented by administrative hearings. A decision to debar reached by the DAB, as is the case with the current process, would serve as a recommendation to the Deputy Assistant Secretary for Grants and Acquisitions Management.

The Review Group also recommends that HHS promulgate procedural and evidentiary regulations to govern the conduct of DAB proceedings. As part of the three year evaluation suggested in recommendation 14 of this report, a determination should be made as to whether or not the procedural and evidentiary processes then in effect adequately strengthen the hearing process. If not, HHS should consider requiring that each DAB panel include an Administrative Law Judge. In addition, HHS may wish to seek legislative changes to permit the DAB to compel witnesses and the production of documents in these cases. Such authority would ensure that all relevant evidence is available to the DAB, thus enhancing the integrity of the process and the credibility of the result.

In addition, the Review Group recommends surveying the due process protections afforded by institutions during the investigative process. Awardee institutions conducting investigations vary widely in the scope and amount of due process afforded those facing allegations of scientific misconduct. Although all institutions provide the respondent with an opportunity to comment on the final report before it is sent to ORI, some provide an early opportunity to confront the evidence compiled and others, though not many, provide a full-scale hearing. The Review Group believes that strengthening procedures used by institutions in developing the record during the fact-finding stage and enhancing due process protections afforded the accused will help minimize the number of cases in which findings of misconduct are contested. Moreover, improving the procedures used during the institutional stage will help ensure a fair process and a stronger record on which the ORI and the ASH can rely during the adjudicative stages of the process.

Although the Review Group recommends, for now, maintaining the current practice of making DAB hearings available in all cases where a finding of scientific misconduct is made, it is important to note that not all such hearings are required by law. HHS is required by the U.S. Constitution to provide respondents facing a recommended sanction of debarment with an opportunity for a hearing. The Department is not, however, required to provide such hearings to respondents facing non-debarment administrative actions such as prohibition against service on advisory bodies, required certification of data or sources, plans of supervision, or retraction or correction of published materials. These administrative actions generally do not constitute a deprivation of a liberty or property interest for which the due process clause of the Constitution would require a hearing, accompanied by the right to be represented by counsel and to confront and cross examine adverse witnesses.

These recommendations may produce significant changes at the institutional level. As the system matures and improves, full hearings in all non-debarment cases may no longer be appropriate. Three years after the changes recommended in this report are implemented, as part of the evaluation suggested in Recommendation 14, HHS should reconsider whether or not the opportunity for a full DAB hearing should be provided for all non-debarment cases.

Recommendation 14.

The plan proposed in this report should be independently evaluated three years after its implementation.

The Review Group recommends that an evaluation be made of the operation of the system proposed here for addressing scientific misconduct in research funded or undertaken by the Department. In order to gather adequate data for a reliable evaluation, some time will be needed both to put the new system in place and to gain experience with its operation. The Review Group proposes, therefore, that at the end of the third year of operation under the system proposed here, an evaluation be done by an independent organization (e.g., the National Academy of Sciences) or by an agency of the Federal Government outside the Department (e.g., the Office of Science and Technology Policy). The evaluation may produce recommendations for change, if necessary, to redirect the Department's activity to assure that misconduct in science is addressed effectively, efficiently and fairly, consistent with the principles described in this report.

III. Conclusion

The Review Group believes the acceptance and implementation of these recommendations would improve HHS's performance in dealing efficiently and equitably with allegations of research misconduct. Most large universities and awardee institutions already have some capacity to conduct inquiries and investigations and already do so as a matter of routine. The Review Group envisions a transition period of one to two years in which significant development activities would need to be undertaken. During this period, new rules and regulations would need to be written, proposed, and adopted; ORI would need to be reorganized and restructured; new model policies and procedures for adoption by awardee institutions would need to be developed; and, an aggressive effort to develop consortia to assist grantee institutions that either do not have or do not wish to develop internal capacities would be needed. The rapid establishment of an expanded educational structure in combination with an oversight structure in ORI would be key to implementing these recommendations.

The Review Group understands that additional resources will be needed to implement its recommendations, and that other resources will need to be redeployed during the transition period. However, the Review Group believes that the plan recommended here will vastly enhance the mission of confronting scientific misconduct in an effective, efficient and equitable way.

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1. The Public Health Service (PHS), with the Secretary of HHS as its head, consists of the Agency for Health Care Policy and Research; the Agency for Toxic Substances and Disease Registry; the Centers for Disease Control and Prevention; the Food and Drug Administration; the Health Resources and Services Administration; the Indian Health Service; the National Institutes of Health; the Substance Abuse and Mental Health Services Administration; the offices of the Regional Health Administrator in each of the ten HHS regions; and, the Office of Public Health and Science, OS.
 2. Public Health Service Act § 493, 42 U.S.C. § 289b ("the PHS Act").
 3. PHS Act § 493(a) (1985).
 4. *Id.* § 493(b).
 5. 42 C.F.R. Part 50, Subpart A: 54 Fed. Reg. 32446.
 6. 42 C.F.R. § 50.102. In accordance with the legislative history of the PHS Act, the regulation substituted the term "misconduct in science" for the statutory term, "scientific fraud." The

definition of research misconduct adopted in the regulation essentially codified the policy that had been followed by the PHS since the early 1980's.

7. When this report refers to "HHS-funded" or to "awardee institutions", the reference should be construed to apply both to HHS intramural research entities and to extramural entities that receive HHS funding.

8. Intramural laboratories operated by the NIH, the Centers for Disease Control and Prevention, and the Food and Drug Administration are included.

9. "General Procedures for Dealing with Possible Scientific Misconduct in PHS Intramural Research." 1994; "Instructions for Assessing Allegations and Conducting Inquiries in Cases of Scientific Misconduct in PHS Intramural Programs" (1994).

10. 57 Fed. Reg. 24262.

11. NIH Act § 161, 42 U.S.C. 289b; 59 Fed. Reg. 2856 (1994).

12. 57 Fed. Reg. 53125.

13. *Id.* See also, 45 C.F.R. Part 76, 48 C.F.R. Subparts 9.4 and 309.4. The hearing procedures were revised on May 5, 1994. 59 Fed Reg. 29809 (1994).

14. H.R. Conf. Rep. No. 100, 103rd Cong., 1st Sess 19 (1993).

15. *Id.* at 107

16. PHS Act § 493, 42 U.S.C. § 289(b).

17. These findings and recommendations do not affect, alter, or modify the Food and Drug Administration's authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to regulate products within its jurisdiction or to conduct investigations of research activity involving such products.

18. Research, as defined herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics.

19. The research record is defined as the record of data or results that embody the facts resulting from scientific inquiry, and includes, for example, laboratory records, both physical and electronic, research proposals, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

20. An awardee institution is that institution which is the recipient of record of HHS funds.

21. Responsible organizations may be consortia or other institutional units that are qualified to conduct inquiries and/or investigations on behalf of an awardee institution. See Recommendation 5, *infra*. An awardee institution would remain accountable in the case where a responsible organization acts in its behalf.

22. The proposed definition of research misconduct does not encompass all acts or behaviors that might be considered incompatible with responsible conduct of research. For example, "research misconduct" as proposed does not include honorary authorship (claiming or accepting co-author status for a report on research in which one had only an inconsequential role or none at all) or bibliography inflation (multiple reporting of the same research results without clear and explicit disclosure of the replication). DHHS recognizes that responsible conduct of research entails more than refraining from fabrication, falsification, and plagiarism. Nevertheless, DHHS also recognizes that research institutions, scientific societies, refereed journals, and other entities within the scientific community are the appropriate parties to address apparent or alleged research improprieties that fall short of research misconduct.

23. Other than those conducted as a part of an intramural process in an HHS operating division.

24. Investigating Misconduct in Science: The National Science Foundation Model. Herman, K.G., et al. *Journal of Higher Education*, Vol. 65, No. 3 (May/June 1994), page 395, endnote 14.

25. The NSF also notes that it will initiate its own investigation when an institutional investigation is deemed to be inadequate.
26. The Government-wide debarment and suspension regulations define debarment as "an action taken . . . to exclude a person from participation in covered transactions." 45 C.F.R. § 76.105(f). "Covered transactions" include grants, cooperative agreements, scholarships, fellowships, contracts of assistance, and any non-procurement transaction between a Federal agency and a person. 45 C.F.R. § 76.110.
27. 45 C.F.R. 76.115.
28. Panels that operate as a part of a responsible organization acting on behalf of an awardee institution would be treated in the same manner for purposes of limited immunity.
29. A useful model for such a statute can be found in provisions that provide qualified immunity for medical professional peer review activities in the Health Care Quality Improvement Act, 42 U.S.C. § 11101, § 11111.
30. The current policy of providing a de novo hearing opportunity for anyone found to have engaged in scientific misconduct is not a regulatory creation. The opportunity for a hearing was announced in the Federal Register as an "interim procedure." 57 Fed. Reg. 53125 (1992).
31. 57 Fed. Reg. 53125 (1992). See 45 C.F.R. Part 16 and DAB Guidelines for Hearings Before the Research Integrity Adjudications Panel, published June 4, 1994.