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The History and Future of the Office of Research Integrity: Scientific Misconduct and Beyond

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ABSTRACT: *This paper looks at the issues and controversies that led to creation of the Office of Research Integrity (ORI) and that dominated its agenda in the early years. The successes and failures of ORI are described and new problems identified. This paper then looks ahead to the future, considering what issues will dominate ORI's agenda and affect the research institutions, individual scientists, and the scientific community in the next several years.*

Establishment of ORI

In June 1992, the ORI was established as a new entity in the Office of the Assistant Secretary for Health in the Department of Health and Human Services (HHS) to replace the earlier Office of Scientific Integrity (OSI) and the Office of Scientific Integrity Review (OSIR).[1] This reorganization of the Department's offices designated to handle scientific misconduct matters was designed to separate the function from the principal Public Health Service (PHS) agency providing research funding, the National Institutes of Health (NIH), and to establish a new administrative review process for scientists accused of misconduct. What events led up to this change, and how was it designed to work?

In the late 1970's and early 1980's, several high profile cases of alleged misconduct captured the nation's attention.[2] In response to these cases and public and

* The opinions expressed herein are those of the author and do not necessarily represent the views of the Office of Research Integrity, the U.S. Department of Health and Human Services, or any other federal agency. Decisions on pending policy and regulatory matters may affect issues addressed in this paper.

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Congressional reaction, NIH undertook its first efforts to centralize its response to alleged misconduct by placing responsibility for investigations and oversight in the Institutional Liaison Office of the Office of Extramural Research. In 1982, NIH was asked to take the lead in developing policies and procedures for responding to misconduct for all the PHS agencies.[3]

The first major legislative step in institutionalizing the Department's role in handling misconduct cases and the role of the research institutions which receive PHS funds occurred with the enactment of the Health Research Extension Act of 1985.[4] The Act required that the Department mandate, by regulation, that research institutions establish an administrative process for reviewing allegations of "scientific fraud" and report to the Department those allegations which appeared "substantial". Through policy and later rulemaking, the statutory term "scientific fraud" was implemented as scientific misconduct or "misconduct in science".[a] The Act went on to require the Director of NIH to establish a process for responding to allegations of scientific fraud, including procedures for receiving reports from research institutions and "taking appropriate action with respect to such fraud." In many ways this first piece of legislation has established the basic principles for the PHS response to allegations of misconduct that continue to this day. These principles require the research institutions to assume primary responsibility for reviewing and reporting allegations of misconduct to the funding agency, and the funding agency to consider such reports (the oversight role) and to take "appropriate action" (the federal administrative or corrective action role). Although the oversight role is no longer lodged in the PHS funding agencies, these same principles apply to the Department's current approach to the handling of misconduct allegations.

Following issuance of interim policies and then a Notice of Proposed Rulemaking, final regulations implementing the requirements of the Act were established in 1989.[5] These regulations followed the basic statutory outline by requiring institutions receiving PHS research funds to establish policies and procedures which follow the regulatory requirements and, when they find misconduct allegations to warrant a formal investigation, to report the allegations and the results of that investigation to the Department for its oversight and further action. The regulations also codified two new offices for handling misconduct allegations in the Department, the Office of Scientific Integrity and the Office of Scientific Integrity Review.[6] OSI and OSIR were intended to formalize and centralize the efforts of PHS to review and act upon misconduct allegations and to provide additional resources for handling the function which substantially exceeded that which had been anticipated when the Institutional Liaison Office was established in 1981.

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[a] "Misconduct or Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data." 42 C.F.R. §50.102.

The OSI was assigned the responsibility for conducting oversight of institutional reports of misconduct and making recommendations on whether misconduct occurred and, if so, what administrative actions should be taken. It also was authorized to conduct its own investigations of misconduct when necessary. The OSIR reviewed the investigation reports, whether conducted by OSI or the institutions, and any recommended findings or administrative actions, and made final recommendations on findings and administrative actions to the Assistant Secretary for Health (ASH). The ASH's decision was final except in cases of a proposed debarment from Federal funds.[b]

In what in hindsight may be considered extremely naive, the regulations failed to clearly specify what the legal standards were for interpretation of the definition of scientific misconduct or to provide for an independent review of the Department's proposed misconduct findings and administrative actions when debarment was not proposed. The failure to address adequately public concerns regarding "due process" resulted in severe criticisms of proposed PHS "Procedures for Dealing with Possible Scientific Misconduct in Extramural Research" following their publication in 1991.[c]

These public concerns over due process and the perceived threat to OSI's independence by its placement in NIH led to the decision by the PHS, at NIH request, to assign the investigative and oversight function to a newly constituted ORI in the Office of the Assistant Secretary for Health. This reassignment of responsibilities was ratified by statutory amendment in 1993.[7]

Thus, when ORI was established in June 1992, it had two key issues to address immediately. One was to establish itself as a new, independent office with its own system and procedures for responding to misconduct. The second was to implement a system for handling proposed findings of misconduct that addressed the due process concerns of the scientific community. However, there were also less obvious problems brewing beneath the surface that needed attention and would cause their own difficulties.

The Early Years

The first major issue to confront ORI was the need to develop standardized procedures to guide its staff in conducting investigations and in overseeing investigations conducted by institutions. NIH management and outsiders who interacted with the

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[b] The debarment regulations provide for an opportunity to contest the proposed debarment if a genuine dispute over material facts is raised. 45 C.F.R. §76.313; 48 C.F.R. Subparts 9.4 and 309.4.

[c] 56 Fed. Reg. 27384 (June 13, 1991). This Federal Register notice, which described proposed PHS procedures for responding to alleged misconduct, did not provide for an independent review of proposed PHS misconduct findings following the ASH's decision, except in cases of debarment. See note [b] above. Comments by the scientific community on the proposed procedures led to extensive criticism of this perceived lack of "due process" and ultimately helped lead to the establishment of ORI and an independent review of misconduct findings by the Departmental Appeals Board.

former OSI on specific cases had criticized OSI for the lack of codified procedures. ORI put together a team of senior staff, including representatives of the Office of Inspector General and the Office of General Counsel, to develop detailed procedural guidance for handling scientific misconduct cases. The resulting staff manual addressed standard office issues such as personnel, handling of correspondence, media contacts, and office files. More importantly, it addressed significant issues involving ORI's handling of misconduct investigations. These topics included developing investigation plans, conducting interviews, working with legal counsel, analyzing forensic and scientific evidence, and preparing cases for an independent review when misconduct was found.[d]

In addition to developing written procedures for the guidance of staff, ORI completed and extended a program begun in OSI to have all of its scientific and investigative staff attend formal investigator training at the Federal Law Enforcement Training Center in Brunswick, Georgia. All of its current and new scientific/ investigation staff received basic training and many received advanced training. These two developments in ORI, adoption of standard investigative procedures and formal investigator training of staff, unlike the many high profile misconduct cases that attracted publicity, never received significant media attention. However, together they represented a significant departure from the sometimes ad-hoc, serendipitous approach taken by OSI in handling cases. This effort was recognized by the General Accounting Office which acknowledged that ORI's investigative procedures were generally sound and in accord with federal standards.[8]

The events that attracted the most public attention, and that ultimately raised the most concerns, were ORI's experiences with a new procedure established to provide a forum for scientists to challenge findings of misconduct. In November 1992, ORI published a notice in the Federal Register announcing the availability of an administrative hearing for those formally accused by ORI of misconduct (following an investigation by ORI or the institution).[9] This hearing was to be provided by the Department of Health and Human Services' Appeals Board (DAB) which had extensive experience in handling grant disputes and other matters.

In the months following the announcement of the new review process, scientists were eager to try the new system and nine scientists filed an appeal out of 22 cases in which ORI made findings of scientific misconduct.[10] ORI had two early successes with this process but neither received significant publicity. In one case, the DAB issued a written decision upholding a three year debarment of an intramural scientist whom ORI found had falsified and fabricated data.[11] In the second case, the accused

[d] Investigative portions of the ORI staff manual are considered exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552. However, ORI subsequently published a guidance document for extramural institutions on investigative procedures entitled, "Model Policies and Procedures for Responding to Allegations of Scientific Misconduct," (April 1995), which addresses many of the standard investigative techniques and procedures that are followed by ORI. This document is available on the ORI home page (http://ori.dhhs.gov) or from ORI upon request.

scientist settled the case with acceptance of the full penalty proposed by ORI, also a three year debarment.[12] In several other cases, the DAB issued a number of significant legal rulings which supported ORI's overall framework for handling misconduct cases. The most important of these was that ORI and the Department had longstanding, plenary authority to address scientific misconduct findings and take administrative actions, even for events that occurred prior to the 1989 adoption of the Department's regulations defining misconduct.[13] This ruling was based in part on a recognition that the 1989 definition was consistent with the existing norms of the scientific community which had already established certain practices as unacceptable, such as falsification and fabrication of research data.

Following these initial successes, ORI lost two high profile cases during the summer of 1993 that received significant attention in the public and science media.[14] The first case involved a proposed finding against Dr. Rameshwar K. Sharma from the Cleveland Clinic. This case had received publicity because Dr. Bernadine Healy, the NIH Director, had been involved when she was at the Clinic and because of a Congressional hearing on the case. Although the Cleveland Clinic had found that Dr. Sharma engaged in "anticipatory writing", it did not find misconduct. ORI reviewed the case and found misconduct based on its determination that Dr. Sharma had given inconsistent explanations of his conduct and misrepresented the state of his research in a grant application. However, the DAB ruled in his favor, finding that ORI had not shown intentional misrepresentation.[15]

The next case involved charges against Dr. Mikulas Popovic, an NIH researcher, arising out of an investigation into allegations concerning discovery of the AIDS virus by Dr. Robert Gallo's lab. The DAB also ruled in this case that ORI's findings were not substantiated.[16] Subsequently, ORI also dropped its proposed findings against Dr. Gallo which involved related issues. Published reports of ORI's failure to prove misconduct in the Sharma, Popovic, and Gallo cases raised concerns that ORI was in disarray and could not defend its findings before the DAB. However, during the same time period, two other cases resulted in favorable rulings for ORI, one a default judgment when the accused scientist dropped his appeal and the other a DAB decision affirming ORI's proposed five year debarment.[17]

Thus, the early years of ORI were a mixture of successes and failures. ORI had success in establishing a sound policy and procedural footing with adoption of standardized investigative procedures, and a new hearing process that permitted an independent review of ORI findings. Its primary failure was an inability to win the confidence of the scientific community that it could successfully defend its findings before the DAB. New issues were also awaiting attention involving changes to ORI's authorizing legislation, including provisions on establishing a Commission on Research Integrity, proposing a new definition of research misconduct, and issuing new regulations on whistleblower protections.[7]

The Later Years: Consolidation and Change

As ORI headed into 1994, it turned its attention to more mundane, but nevertheless significant issues involving improved operational management and development of guidance documents for research institutions and the scientific community.

ORI undertook a management initiative to work down its backlog of unresolved allegations and formal cases. It established a senior level group to review all open misconduct cases on a monthly basis to establish priorities and set target dates for closure or significant intermediate steps, such as completion of interviews or drafting of reports. These activities led to immediate results with 44 case closures in 1994 and 58 in 1995, exceeding the previous record for case closures by a substantial margin. The total backlog of formal cases was reduced from 78 when the office opened in June 1992 to 58 by the end of 1995. There was also substantial improvement in reducing the backlog of unresolved allegations and in improving the timeliness of doing so.[18]

The improvement in case management for ORI is much more than just a numbers game. All participants in the system have an important stake in the timely processing of allegations. The institution that has either conducted the investigation or is awaiting completion of ORI's investigation has a need to close its books on the matter and take any final follow-up actions that are appropriate. The whistleblower who makes the initial allegation is often waiting for word on whether it will be pursued and, if so, what will become of it. Most importantly, the accused scientist whose reputation, and sometimes research position, is at stake has the most pressing interest in getting a final resolution to the matter. By the end of 1998, ORI had closed 275 cases and resolved over 1500 allegations since the office first opened and reduced its backlog to a manageable level of 35 cases. It also had reduced the average processing time for the large majority of its cases to under 12 months from the date it received the institution's final report and decision.

Another area of significant management attention during this period were a series of efforts to assure that the cooperative system ORI had developed with the research institutions was working well and to improve it where needed. To this end, ORI undertook an initiative to develop model policies and procedures that could be used by institutions to meet their regulatory requirements and would be effective in helping them assess and resolve allegations of misconduct.[19] In 1995, these documents were sent to all research institutions eligible to receive PHS grant funds.

ORI also began a systematic review of institutional policies for conformity with the regulatory requirements and to ensure that all institutions receiving PHS research grants had such policies in place. This effort led to the review of over 1200 policies in the years 1994 to 1998 with 75% of the policies requiring some level of revision. Approximately 25% of the institutions adopted the ORI model policy. In addition, through ORI's review of annual report forms and audit of institutions which lacked a misconduct assurance, ORI obtained new policies from approximately 400 institutions. More recently, ORI has issued a research integrity officer handbook intended to

provide comprehensive guidance to institutions in handling, investigating, and reporting allegations to ORI. ORI also developed an introductory workshop for institutional officials to train them in their regulatory responsibilities. This course has been presented three times since 1997.

ORI's efforts to provide technical assistance and written guidance to institutions is continuing, and overall ORI believes it has been successful in assisting institutions in developing an effective system for responding to misconduct allegations. During this time period, ORI also began its efforts to implement the requirements of the 1993 statutory amendments, including the establishment of the Commission on Research Integrity and development of a new definition of misconduct and whistleblower protections.

The Commission held regular public meetings from June 1994 until October 1995 and issued its report to the Secretary of HHS and to Congress in November 1995.[20] The Commission made a series of 33 recommendations for improving the procedures and policies of the Department in handling misconduct allegations and promoting research integrity. The two most significant and controversial recommendations involved the definition of misconduct[e] and a whistleblower bill of rights. Dozens of letters received by ORI and the Department and much of the reaction in the science press criticized the definition as being overly broad and the whistleblower bill of rights as being slanted toward the whistleblower at the expense of the accused.

A Departmental working group headed by Dr. William Raub reviewed the Commission recommendations and issued a report in the summer of 1996.[21] It suggested that the Office of Science and Technology Policy (OSTP) consider the issue of a federal-wide definition of scientific misconduct and that the Department pursue a whistleblower protection regulation that was cognizant of the need to strike a fair balance between the needs of institutions, the whistleblower, and the accused. The report also observed that a number of other recommendations were already effectively in place under current ORI policy and that others could be easily implemented. To date, a final Departmental response to the Commission recommendations has not been completed pending decisions on other issues, including the proposed OSTP federal-wide definition.

When it became apparent that ORI would not be able to issue whistleblower protection regulations quickly, ORI turned its attention to developing program guidance for institutions on how to implement the existing regulatory requirement to undertake "diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations" of misconduct.[22] Based on ORI's experience with actual cases of alleged retaliation, it developed model guidance for institutions to

[e] The Commission proposal recommended replacing the current definition with a totally new definition of "research misconduct" that included separately defined examples of misconduct of "misappropriation", "interference", and "misrepresentation". Commission Report at 34. The Commission also recommended that the Federal Government develop a common federal definition of misconduct applicable to HHS, the National Science Foundation, and other federal agencies.

follow in responding to complaints of retaliation.[23] This model offered the institution essentially three options for resolving the allegations: (1) an investigation by the institution into the allegations under established procedures, (2) binding arbitration by an independent arbitrator, or (3) settlement agreed to by the institution and the whistleblower. ORI would monitor the process and review the outcome for compliance with the guidelines but would not become involved in reviewing the substance of the decision. Furthermore, the whistleblower would have to agree to participate in the process. Otherwise, the whistleblower could pursue any other remedy authorized by law, such as filing of a wrongful termination lawsuit against the institution. Since adoption of the guidelines in 1994, several institutions have followed them in resolving whistleblower complaints.[24]

ORI continues to work on additional guidance documents that it expects will prove useful to institutional officials and others with a stake in the process. Documents currently under development include two on investigative issues: (1) reviewing and investigating allegations of misconduct involving clinical trials, and (2) gathering and securing research data and other evidence when an allegation is made. Other documents are targeted toward specific audiences: guidance to the accused scientist on his rights and responsibilities in responding to allegations; guidance for whistleblowers in making good faith allegations; and guidance to journal editors on how to handle misconduct allegations involving articles which have been submitted or published.

In the midst of ORI's accomplishments in a number of areas, it experienced a major setback involving the last of the high profile cases that ORI inherited from OSI. This case concerned allegations of misconduct against Dr. Thereza Imanishi-Kari involving a paper published in the journal *Cell*. The case received wide-spread publicity because of the involvement of Dr. David Baltimore, a Nobel prize winner, as a coauthor on the paper.[25] Hearings held by the House Subcommittee on Oversight and Investigations also increased its notoriety.

The case was finally decided by the DAB in June 1996 when it ruled in favor of Dr. Imanishi-Kari. While the decision found numerous errors in the *Cell* paper and discrepancies in the lab notebooks of Dr. Imanishi-Kari, it concluded that ORI did not prove by a preponderance of the evidence the charge of deliberate fabrication and falsification of lab results.[26] This reversal led to severe criticism of ORI and other participants in the process, including concerns about delays in the case and unfair adverse publicity involving Dr. Baltimore. ORI noted that Dr. Baltimore had never been the subject of its investigation or that of its predecessor office. It also acknowledged that extensive delays in resolving misconduct allegations were unacceptable, but that this problem had largely been solved in the past few years.[27]

Challenges were also raised during this period to the misconduct response system that had been established by the Department which relies heavily on research institutions to assume the primary burden to respond to misconduct allegations. Perhaps the most significant of these challenges involved a lawsuit filed by Kimon Angelides, Ph.D., formerly a research scientist at the Baylor College of Medicine, against Baylor and several of its employees in Texas State court seeking several

millions of dollars in damages arising out of his employment dismissal by Baylor.[28] Dr. Angelides' claims included alleged defamation by Baylor officials and committee members who investigated allegations of scientific misconduct by Dr. Angelides and reported their findings of misconduct to ORI. The case was later removed to federal court.

After the defendants' attempt to have the case dismissed was rejected by the Federal district court in 1996, ORI and the HHS asked the Department of Justice to file an *amicus curiae* brief in the case, asserting the legal argument that Federal statute and regulations require research institutions and staff to investigate and report alleged misconduct to ORI, thus shielding them from liability under State law. ORI relies on extramural institutions, such as Baylor, to conduct over 90% of the investigations into alleged misconduct that occur under PHS research grants, cooperative agreements, and contracts. Exposing the institutions and their scientists who assist in the investigations to legal liability for their actions would severely limit ORI's ability to rely on institutional cooperation.

Following rejection of their request for dismissal in federal district court, the defendants appealed the court's ruling to the United States Court of Appeals for the Fifth Circuit. In its *amicus* brief supporting the appeal, the federal government asserted that federal law, which mandates the reporting of misconduct investigations to ORI, provided a defense against State liability for defamation: "These Federal requirements preempt state tort liability for such actions since compliance with state and Federal requirements is a practical impossibility and state tort liability stands as an obstacle to the accomplishment of the full purposes and objectives of Congress."

In July 1997, the 5th Circuit denied the appeal on jurisdictional grounds and the case was returned to State court.[29] In 1999, the civil case was settled and dismissed largely because the underlying findings of scientific misconduct against Dr. Angelides were upheld by the Departmental Appeals Board.[30] ORI and HHS are continuing to consider whether additional actions are needed to protect research institutions and their staff from unwarranted liability.[31]

Concerns have also been raised by institutional officials of the possible interference with institutional investigations of suits filed under the False Claims Act.[f] These suits authorize the federal government, or private individuals suing on behalf of the federal government, to recover damages from institutions who make false claims in federal research grant applications submitted to funding agencies. While recovery is clearly warranted in certain situations,[32] it can be argued that frequent reliance on False Claims suits will jeopardize the ability of institutions to vigorously investigate misconduct allegations through the administrative process set forth in the PHS regulations.[g] To date, ORI has responded to these concerns by evaluating

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[f] 31 U.S.C. 3730, et seq. Litigation under the False Claims Act is discussed in more detail in a paper by Barbara Mishkin (see pp. 283-292, elsewhere in this volume.)

[g] In response to institutional concerns regarding the use of the False Claims Act in scientific misconduct cases, the Commission on Research Integrity recommended that HHS seek a suitable amendment to the Act. Commission Report at 28. See reference 20.

potential False Claims suits on a case by case basis and recommending to the Department of Justice against active federal involvement when the facts do not appear to support a strong case on the merits. However, ORI continues to monitor these concerns to determine whether a more systematic response to the affect of the False Claims Act on institutional investigations appears warranted.

A Look Towards the Future

There remain new and unresolved issues that ORI expects to address in the next few years. One important issue needing resolution continues to be the definition of scientific misconduct. The Commission on Research Integrity has recommended a new, expanded definition and OSTP is considering a common federal definition. (See Francis, pp. 261-272, this volume.) A key question remains whether any new definition will retain the "other practices" clause of the current definition which has continued to be a point of controversy within the scientific community.[33] In 1992, the National Academy of Sciences[34] and ORI's Advisory Committee on Scientific Integrity[h] recommended a new definition that would delete that clause. Consistent with these recommendations, ORI has generally not relied on the "other practices" clause in making findings of misconduct. However, the National Science Foundation has continued to argue that the clause has worked well for its purposes and should be retained.[35] Accordingly, the possibility of a split in the federal agencies over the definition exists, which could delay adoption of a uniform federal definition.

In addition to a new definition, ORI also has other regulations that need development or updating. A regulation implementing the statutory requirement to establish whistleblower protections is under review in the Department. Revisions to the existing regulation "Policies and Procedures for Dealing with Possible Scientific Misconduct in Extramural Research" are needed to incorporate administrative review procedures for proposed findings of misconduct, the required standards of evidence and burden of proof, and other issues not adequately addressed in the 1989 version. Also, certain procedures for ORI's oversight review of extramural cases and the process for handling intramural cases of misconduct may also need attention.[i]

In addressing these and other issues, ORI will continue to try to strike a fair balance among the needs of research institutions, the rights of scientists accused of misconduct, and those who bring forward good faith allegations. Research institutions are critical partners in the Department's efforts to root out fraud in research and to train scientists in ethical and high quality research practices. Thus, their practical

[h] The Advisory Committee on Scientific Integrity was established to provide policy advice to OSI, OSIR, and subsequently ORI on scientific misconduct and research integrity issues. It was subsequently disbanded in 1993 after ORI's authorizing legislation called for the appointment of the Commission on Research Integrity.

[i] Final regulatory decisions will be made by the Secretary, HHS, with input from the Assistant Secretary for Health, the PHS agencies, ORI, and other HHS offices.

administrative needs require careful consideration in implementing both old and new requirements. Furthermore, basic fair play and the confidence of the scientific community in the rules that are put in place dictate that procedural protections be adopted to protect both the accused and the accuser. ORI efforts to provide a fair balance in these sensitive areas require more than just good technical regulation. They also require efforts to provide consumer friendly information that reasonable people can understand and follow. For this reason, ORI will continue to develop guidance targeted toward specific audiences to provide information on how to participate in both institutional and ORI processes.

ORI will continue to work with institutions to maintain and improve their institutional capacity to respond to misconduct. To ensure that the partnership with institutions is working well, ORI will continue to monitor civil litigation and False Claims Act suits filed against institutions that may jeopardize their ability to vigorously investigate and report on suspected scientific fraud to ORI. Changes in the misconduct response system will be considered to correct any serious problems.

ORI will also utilize a variety of compliance, educational, and technical assistance activities to support institutional capacity. ORI has reviewed and approved over 900 institutional policies and procedures for responding to alleged misconduct. This group includes the institutions with the largest share of PHS research funds. Thus, those institutions that receive the great bulk of PHS research grants have at least minimally adequate systems in place to respond to misconduct.[j] In addition, ORI has issued a Research Integrity Officer Handbook which contains detailed information to guide those institutional officials with responsibility for responding to allegations of misconduct through the institutional steps and the PHS requirements. An ORI course has also been developed to provide basic introductory material to institutional officials with newly assigned responsibilities or who want a refresher. Because allegations of misconduct occur with a low frequency at any one institution and can raise extremely complicated administrative and legal issues for institutional officials, ORI will continue to target institutional capacity for handling these matters with education programs and technical assistance.

An important new area of ORI interest is the wealth of opportunities to promote research integrity throughout the research enterprise. Activity in this area includes steps to ensure integrity in the conduct and reporting of research that do not rely solely on detection and response to fraud after it occurs.

The research integrity activity that is probably the best known is the NIH requirement for institutions to provide research ethics training to all students, fellows, and others who are receiving training under an NIH research training grant.[36] Some institutions have expanded the availability of such courses to include all graduate students in the research disciplines or other groups besides NIH trainees.[37]

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[j] Some institutional policies are clearly superior, but ORI will accept an institution's policy whenever it meets the regulatory requirements.

ORI has sponsored several conferences with research institutions to explore research integrity issues in a variety of contexts.[38] Some of the issues being looked at are: What is research integrity? How can an institution organize itself to maximize incentives to promote integrity? Are there certain policies and administrative practices that are correlated with a high incidence of integrity, such as recordkeeping, data management, and laboratory peer review of data and papers?

In one conference co-sponsored with the University of Arizona on "Managing Biomedical Research Laboratories", a variety of issues related to research quality, productivity, and ethics were discussed. These included data management, collaborations, mentoring, and assigning of credit.

By working with institutions and individuals to explore issues of research integrity, ORI expects ultimately that the scientific community will identify those research practices that appear to make a difference in preventing scientific misconduct or, alternatively, to create conditions which are ripe for misconduct to occur. Ultimately, this should lead to improving the overall ethical climate in the research community.[39] Of course, in pursuing this goal, it is necessary to be sensitive to the overarching need to promote conditions in which high quality and creative research can also thrive.

As a corollary of its interest in promoting research integrity, ORI wants to work with the scientific community to develop a research agenda to identify the important issues in misconduct and integrity. In two areas, the effect of misconduct allegations on the whistleblower and the accused, ORI has already begun the process of raising questions and getting preliminary answers.[40] (See also, Lubalin & Matheson, pp. 229-250, this volume.) It is currently working on a proposal to examine institutional policies on common research practices, such as recordkeeping, publications, and grant proposals, to determine if there are any standard practices in the research community. It will attempt to conduct this study with Departmental funds set aside for evaluation purposes.

Elsewhere in this volume, Steneck (pp. 161-176) asks what the incidence of scientific misconduct is. He opines that some 10 years after national attention began to focus on misconduct cases this basic question is still unanswered. Thus, it is difficult to know what level of resources should be expended on the problem and how they should be directed. ORI believes there are also other important issues involving incentives and disincentives to misconduct that should be explored. Efforts will be made to engage the scientific community in identifying the important issues that need answering and then seeking the answers.

Observations and Conclusions

The history of ORI's development has been one of progress, integration, and bumps in the road. However, several important principles have held constant. The primary one is ORI's reliance on institutions to assume the major responsibility for investigating

allegations of misconduct. This is the approach taken in both the statute enacted in 1985 and the regulations adopted in 1989. While there will always be fears that some institutions will be reluctant to investigate themselves due to concerns involving reputation and funding issues, ORI's experience has shown that most institutions, and their scientific and administrative staff, are able to navigate those concerns and successfully carry out their responsibility to forthrightly assess allegations received and report their results to ORI. ORI relies heavily on this delegation of responsibility to institutions which currently conduct approximately 95% of all investigations involving extramural support compared to approximately 75% under the former OSI.[41]

The Department's role in providing oversight of institutional investigations nevertheless remains critical. Over 50% of all misconduct findings result in debarment from federal funds for a given period, usually three years. Imposition of this sanction requires assessment of the federal interest at stake and assertion of federal authority that is beyond the scope of any individual institution. ORI also provides public notice of its findings and a means for institutions to check on the eligibility of its staff to conduct PHS supported research.[42] This is a function that could not be carried out by any one institution. Furthermore, ORI's independent assessment of institutional findings has sometimes resulted in a decision not to go forward. This has occurred in over 10% of the cases.[43] This provides an important second opinion that protects an accused scientist from a public and federally recognized finding of misconduct even before the HHS hearing process is triggered.[k]

Another important principle is the opportunity of an accused scientist to seek administrative review after ORI makes a proposed finding of misconduct. While ORI has sometimes been criticized by its perceived inability to prevail in cases before the DAB, the process itself has been well recognized as providing an independent review fair to the accused. While recommendations have been made to revise the process by the Commission and others, the principle of independent review has been accepted[20(see p. 29), 25]

Confidentiality for both the accused and other affected individuals has been an important principle recognized in the 1989 regulation. ORI has successfully supported this principle in federal litigation,[l] and it has become an established part of the misconduct review process at both the institutional and federal levels.

These key principles of institutional front-line responsibility, federal oversight, independent review, and confidentiality have been successfully developed since 1992 and should serve ORI and its institutional partners well in the coming years. However, several important challenges remain.

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[k] An ORI decision not to go forward with an institutional finding of misconduct is not tantamount to a reversal. Institutions have plenary authority to establish the terms and conditions of employment (or conditions for research performed by a student or fellow) that differ from ORI's definition and legal standards for finding misconduct. *ORI Newsletter* **4**(2):2 (Sept. 1994).

[l] The D.C. Federal Court of Appeals ruled that ORI is not required to release the names of accused scientists where no finding of scientific misconduct was made. *McCutchen v. DHHS*, 30 F. 3d 183 (D.C. Cir. 1994).

There is a need for continued integration at both the federal and local levels. Agreement on a common federal definition and common principles and approaches to federal oversight would strengthen the federal and institutional capabilities in the area. This would lead to greater efficiency in carrying out the federal and institutional responsibilities, and greater affirmance of the agreed upon standards through uniformity and repetition.

ORI believes it is time to move beyond misconduct as the sole focus of the federal and institutional missions and devote more attention on reinforcing the principles of ethical research practices. This should more closely align federal and institutional efforts with the core mission of the research enterprise to conduct high quality and reliable research. While a vigorous response to individual incidents of misconduct will always remain an essential element of an effective system, an increased focus on promoting and establishing sound, ethical research practices may ultimately lead to prevention of misconduct and greater confidence in the research enterprise by scientists and the public alike.

Finally, ORI and its institutional partners must continue to strive to achieve a fair and appropriate balance between the interests of competing parties. The accused scientist fears false or frivolous allegations and a process slanted toward a finding of guilt. The whistleblower fears being branded an outsider, retaliated against, and disenfranchised by questions regarding research in which he or she may well have been an important contributor. The ORI and the institution must strive to be objective and neutral assessors of facts, often under trying circumstances. The challenge is to create a climate where the whistleblower feels safe in bringing forward good faith allegations of misconduct, and the innocent accused feels safe in responding to them.

New challenges will continue to arise in the coming years, but ORI is confident that the funding agencies, research institutions, and scientific community will continue to meet them.

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