INSTITUTIONAL STRUCTURE TO ENSURE RESEARCH INTEGRITY

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While professional organizations have responsibilities and opportunities to influence the ethical behavior of their professional practitioners, the main locus of effective effort for ensuring that researchers observe good practices is the academic or research institution in which they work. This paper surveys the wide range of activities that institutional leaders should be undertaking, from teaching ethics (*cf.* Bulger) to handling misconduct forthrightly. Gunsalus emphasizes the importance of adopting an administrative structure that fits the institution, in order to respond to allegations fairly and promptly. Unfortunately, there are as many ways to go wrong in dealing with misconduct cases as there are to make errors in research! — **PJF**

Institutional Structure to Ensure Research Integrity

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Abstract—The single most important component in an institutional culture of research integrity is institutional leadership committed to ethical conduct. If the institution's leaders are committed to integrity in research and act on that commitment, the campus will follow that lead; conversely, if the perception develops that the leaders pay only lip service to ethical conduct, the campus will adopt the same attitude. An institution must pay attention to both prevention and education, and many are developing codes of conduct. Further, institutions must establish a misconduct review process that can render objective, fact-based decisions untainted by personal bias and conflicts of interest. In developing such a process, leaders must be aware of probable pitfalls, create an accessible structure, and provide for consistent assessment of allegations and complaints, focusing on facts, not personalities. Increased demands for accountability and a heightened public interest in ethical issues portend increasing pressures on institutions to monitor the conduct of their members. The institution that builds effective, credible structures for preventing and resolving ethical issues will be well equipped to cope with these external pressures. Ultimately, however, institutional structures for such monitoring accomplish far more than preserving institutional autonomy: they protect the principle of scholarly and scientific inquiry that is at the core of the institution's mission. *Acad. Med.* 68 Supplement 3(1993): S33–S38.

The single most influential component in an institutional culture of research integrity is institutional leadership committed to ethical conduct. If top academic administrators and key faculty members model ethical behavior, stress the importance of research integrity, and translate these beliefs into action, the campus will take note. Conversely, if research integrity is not addressed, or if the perception develops that it receives only lip service, that too will have an effect across the institution.

A commitment to ethical issues requires attention to both preventive and reactive mechanisms. For prevention, an institution should undertake efforts to educate students and researchers about standards for the responsible conduct of research, as well as about their responsibilities when confronted with possible research misconduct.[1] When institutional officials become aware of possible misconduct, they must have mechanisms in place for rapid, responsible, and thorough examination of the situation. These mechanisms must be designed to be effective and credible and must be based upon a realistic understanding of the complexities surrounding allegations of research misconduct. Together, structures for education and response to allegations will enable the institution to comply with current and looming federal regulations and to protect and maintain the integrity of its research environment.

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EDUCATION FOR AN ETHICAL ENVIRONMENT

The ultimate goal of any institutional plan must be prevention and education. The number of "bad actors" who will break the rules for their own benefit is probably fairly small and probably irreducible. Most people will do the right thing if their actions are set within the right context and if they learn to explore the ethical issues associated with their work and their behavior. The most important opportunities for education occur in working environments and among direct colleagues, including peers and supervisors. Now that National Institutes of Health (NIH) training grants require an ethical component, institutions are scrambling to comply. This situation presents an opportunity to stimulate offerings in the area of ethics and to design a delivery structure that meets both the grants' narrow requirements and the institution's broader needs.

Educational offerings on ethical issues must be tailored to the institution. Comprehensive universities will not be able to adopt just one offering, or even just one approach: the needs and standards across disciplines will differ, as will those among laboratories. For example, the authorship practices in high-energy physics are quite different from those in English departments, both of which differ from practices in the biological sci-

ences.

In general, one of the most effective ways to get students and researchers engaged with ethical issues is to tell them stories. Stories that are based on real events or that explore research obligations quickly attract attention and directly involve people in the issues. Case studies (academia's stories) that illuminate specific ethical dilemmas and issues that arise in research abound.[1] The next step is getting them put into use in classrooms and laboratories. At the University of Illinois, each department with a graduate program has been asked to schedule at least one combined graduate student and faculty seminar each year to discuss the ethics of scholarship, research, and practice in the department's discipline. A central office collects materials to support these efforts, providing case studies, readings, ethical codes of various disciplinary societies, bibliographies, and information about other relevant resources. This decentralized approach fits the nature and traditions of the institution and has led to a number of creative approaches among the departments. Several colleges are now considering college-wide events and/or curricula. Other institutions have adopted different approaches to ethics education, ranging from specialized courses concentrating on ethics to special events on a periodic basis to integration in established courses.

In addition to educational efforts directed to its students and faculty, an institution should consider informational support for its administrators or designated officials who receive complaints of questions about research ethics, both on approaches to ethical issues and on institutional policies and procedures. These efforts should be designed to ensure institutional consistency in allegation assessment and review, as well as to acquaint administrators with the resources available to assist them when problems arise.

Finally, many institutions are now developing codes of conduct that address standards for the responsible conduct of research. Many professional societies and scientific associations have also considered ethical issues and have prepared thoughtful statements that can provide a foundation for institutions, especially those whose educational efforts have only just begun. These aspirational statements can provide the foundation for educational offerings by alerting faculty and students as to the conduct the institution expects. The debate surrounding the development of such statements (or the adoption of those promulgated by other institutions or professional societies) can be very useful in raising awareness of ethical issues. Once developed, a set of standards can guide and inform those within the institution. The range of existing statements demonstrates the diversity of institutions: they are from one to scores of pages long and span the spectrum from the vaguely general to the painstakingly explicit.[2]

COMMITTED LEADERSHIP

Even though it is likely that scientific misconduct* is not a widespread problem, it is no longer possible to assert that it does not occur. When it does, it is critical for institutions to have in place structures that promote the rendering of objective, fact-based decision untainted by personal bias and conflicts of interest. I refer to this mechanism as the misconduct review process.

Support from the highest levels of institutional leadership is the foundation upon which the misconduct review process depends. Top administrative and research officials must support the process with advocacy, persuasion, and appropriate sanctions where necessary, or the process will be ineffective. Failure to reinforce the process will undermine ethical science at the institution by giving the appearance that academic misconduct is tolerated, if not endorsed.

A commitment by an institution's leaders should include a personal review and knowledge of procedures to assure that they support fact-based, rather than personality-driven, outcomes. A sense on the part of the institution's leaders of the national environment surrounding these issues—including an awareness of events at other universities, policy developments, and media portrayals of reported cases—is also a valuable asset. It is hard to provide accountability in this area without understanding the pressures and demands of the broader context.

There must also be a commitment to making public final findings of misconduct. The public revelation of all final findings of misconduct is a critical component of a system that supports the integrity of research. Misrepresented data in the literature damage the efforts of other researchers and waste public resources. Misrepresentation about authorship of words or ideas undercuts the basic reward structure of the academic community. Revelation of findings is the best way to combat these and other such effects of misconduct. Furthermore, if misconduct findings are concealed, the perpetrator can simply move on to another institution (as some have in the past) and continue the pattern of misconduct there.[3] Finally, public revelation of proven misconduct is a tangible expression of the institution's commitment to the integrity of its research environment and demonstrates to all audiences (both internal and external) that the

*"'Misconduct' means (1) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from activities funded by 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." [National Science Foundation. Misconduct in Science and Engineering; Final Rule. *Fed. Reg.* **45**(689):22286–22290, May 14, 1991.]

"'Misconduct' or 'misconduct in science' is defined . . . 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." [Department of Health and Human Services, Public Health Service. Policies and Procedures for Dealing with Possible Scientific Misconduct in Extramural Research Procedures. *Fed. Reg.* **56**(114):27383–27394, July 13, 1991.]

institution takes it seriously.

In 1989, the AAAS/ABA National Conference of Lawyers and Scientists recommended:

> The public has a legitimate interest in knowing the outcome of a formal investigation, and the university should release the investigatory committee's report to the public.[4]

The commitment to revealing such findings may weaken in the face of the obstacles encountered in carrying it out. The specter of litigation will loom large, for instance, especially to lawyers involved in the process. Although it is not always possible to release the entire report of an investigation in the face of legal objections, an institution's leaders should work to release as much relevant information as possible. Reports can be redacted to keep confidential the names of students or innocent bystanders, and they can be summarized for the same purpose; but an institution must not conceal the outcome when a finding of misconduct has been reached. If the academic and scientific grounds for revealing findings give way to defensive legal considerations, the institutional environment for ethical research will suffer.

When the final conclusion is that no misconduct has occurred, different considerations arise. Where the accused was entirely exonerated, the institution will need to work to redress any damage done to that individual by the misconduct process. If, however, the accused was found not guilty of misconduct, but guilty of lesser practices (sloppiness, negligence, dereliction of duties, etc.), the institution will have to balance the competing scientific, academic, and legal considerations. Again, scientific and academic considerations should carry priority over defensive legal ones.

DESIGNING THE STRUCTURE

Although committed institutional leadership is the critical component for maintaining research integrity, policies and procedures used to review allegations of misconduct will also play a major role. Both policy and procedures must be designed to anticipate and forestall the problems inherent in these matters.

All institutions face similar obstacles to designing effective structures for the support of research integrity, but individual institutions will respond differently depending on the culture, configuration, and nature of the institution. For example, a large public institution that is part of a university system with multiple campuses faces different challenges in designing procedures and educational programs than does a small private institution with a strong tradition of faculty governance. An effective process will be based on a policy that fits the institution and appropriately places responsibility for required actions according to the nature and traditions of the institution.

There are a number of resources available to help institutions assess and improve their policies, including the regulations issued by the National Science Foundation and the Public Health Service and guidance documents developed by the Association of American Universities and the Association of American Medical Colleges.[5] Every institution should review its policies in light of the information contained in those resources.

The procedures must complement other institutional policies and regulations such as those on sexual harassment, grant and contract administration, patents and licensing, and conflict of interest. (Public universities will also have to assure that the procedures are in harmony with applicable state laws.) The procedures must achieve all these ends and still be acceptable to the researchers to whom they will apply. This may require educational efforts of some magnitude. No institution should adopt the policy of another without considering such factors.

Pitfalls and prevention. Anyone who has ever undertaken a misconduct investigation can testify that there are many ways to go wrong. The pitfalls in research misconduct processes include the ways in which disparities in power, position, and behavior affect perceptions of credibility and can divert investigations from a stringent examination of relevant facts. Built-in conflicts of interest, if not acknowledged and corrected, can prevent appropriate review and/or follow-through. Goodwill is necessary but not sufficient: a sound investigation plan and appropriate expertise to support its implementation are also required.

Several characteristics are present in a procedure that effectively addresses these and other pitfalls. These include an accessible structure for lodging allegations; consistent assessment of allegations; checks and balances to ensure that facts, not personalities, drive the process; appropriate allocation of tasks among participants; and correction for bias and conflicts of interest.

An accessible structure. If the mechanism for initial receipt of questions or allegations is rigid and restrictive, individuals who have legitimate questions may be dissuaded from asking them within the institutional setting. For example, if regulations require those with questions or complaints to start within the unit where the problem arose, those who fear retaliation or retribution may never raise their questions (to the institution's detriment if a problem truly exists) or may go outside the institution to the courts, federal oversight agencies, legislators, and/or the media (also to the institution's detriment). Alternatively, if the process seems forbidding or the intake person is dismissive, the result may be the same.

If there are multiple entry points for lodging allegations or complaints or for simply asking questions, it is more likely that serious questions will be raised within the institution rather than outside it. This is to the advantage of all participants. An effective institutional review that relies largely upon internal reviewers will have as participants individuals who do not have to learn institutional procedures and regulations before assessing compliance. They will know the participants and the institutional culture, and thus have access to the sources of

information and the knowledge to ask the right questions. Their presence on the scene means fewer travel expenses and scheduling problems, resulting in a less costly and faster process. Thus, designating and publicizing several routes for raising questions promotes strong institutional procedures.

Consistent assessment of allegations and complaints. A risk of providing multiple entry points is the possibility that complaints might be handled inconsistently. Therefore, the various participants in the process must be trained to apply the procedures consistently, and they must communicate with each other. In practice, department heads are usually involved, whether they are officially designated or not, because they are the first or second closest figures of authority and they almost always have information important to the assessment of the allegation. With so many parties involved, an effective training process will require a continuing effort to be truly effective. A one-shot process, especially in a large institution may not "take" on the first try and its efficacy will be affected by staff turnover: the training program should provide reinforcement and be repeated regularly.

Additionally, a growing number of institutions have designated a central official with whom individuals at the entry points consult and collaborate.[6] The involvement of such an official (who may also serve as an entry point) can help preserve objectivity in the earliest stages of allegation assessment. For example, if a unit head must explain to a central official why —in a factual sense— a set of allegations is unworthy of further review, the reasons must be articulated and documented. This process of articulation is sometimes all it takes to reveal logical or factual flaws in the allegation or bias in its assessment. Similarly, if the campus official has no personal ties to any of the participants, he or she can endorse a conclusion that no further action is necessary with greater credibility than can an individual with such associations. Finally, a more detached party can help devise solutions, make referrals, and provide mediation in that majority of allegations that prove to involve problems other than research misconduct.[7]

Examination of facts, not personalities. Research institutions attract and accommodate difficult personalities because selection and retention focus upon excellence of work rather than collegiality or other interpersonal skills. Many allegations of research misconduct are catalyzed by some damaged personal relationship: the allegation may be the cause or a symptom of the break in the relationship, but the underlying personal tensions will inevitably complicate assessment of the situation. Seemingly unstable and malicious whistleblowers have made claims that investigations revealed to be well founded. (Of course, there have also been claims made by such persons that had no foundation whatever, yet consumed disproportionate institutional resources for their review and refutation.)

One of the hardest principles to follow is that allegations brought by seemingly disturbed individuals must still receive prompt, thorough, and objective review. It is human nature to give short shrift to "crazy-sounding" allegations, especially when brought against valued and productive researchers. This tendency is especially great in the earliest stages of the process when allegations are first lodged—and, not coincidentally, this is the phase of the process that most often fails, leaving an institution (and its accused faculty members) vulnerable later.

Last year, a faculty member sought advice as to his recourse against a federal investigative auditor who had reviewed his program and issued a clean bill of health after a two-day visit to campus and a one-month follow-up (remarkable speed for such a review). When the administrator expressed confusion about why the faculty member was pursuing the matter when he was cleared of any wrongdoing, the faculty member replied that he thought the auditor had behaved improperly by not investigating the *whistle-blower* and establishing his motives before reviewing the program. The auditor did not have that option; his job was to substantiate or refute the allegation, once received, not to discredit the allegation without reviewing the underlying facts. Understanding this constraint and accepting it are prerequisites to designing institutional procedures that work and are credible in the eyes of external observers, including those at the federal agencies responsible for the disbursement of and accountability for tax-generated funds.

An institution's mechanism for review of allegations must ensure that objective, relevant facts are being evaluated, rather than personalities, motives, and positions. *The motive of a person bringing allegations is irrelevant if the basic facts being alleged are true.* Even if the whistle-blower is seeking to cause harm, this motive is not relevant if data have been compromised or other serious misconduct has occurred. Credibility assessments must be grounded in the underlying facts to the largest possible extent. It is acceptable to dismiss allegations as unfounded when they lack factual support, but it is not acceptable when the allegations have been weighed solely on the basis of the personal feelings, knowledge, and judgment of institutional administrators.

The facts upon which the assessment is based must be recorded, organized, and retained, or much of the value of the rigorous assessment can be lost. If facts have been reviewed and recorded, a wrongly accused person can be protected from repeat allegations. If an accusation has been dismissed without full review or documentation, however, the persistence of so many would-be whistle-blowers and the availability of alternative avenues provided by government regulations can leave a faculty member permanently at risk. Once the institution has performed a review, it has the facts available for subsequent inspection by whatever external parties the whistle-blower may approach with the same allegations. While not invariable, this development occurs frequently enough to warrant devel-

oping a routine for documentation of the internal process and its conclusions. Institutions have no choice but to assess all remotely credible allegations. It is disconcerting to be perennially vulnerable to the moods and accusations of the disaffected, but this has become a reality of modern life.

Although the institutional process must screen out unfounded accusations, it cannot set the threshold so high that it rejects allegations that are not conclusively supported when first made. A balance must be struck between not requiring factual evidence for allegations and requiring the accuser to present an airtight case at the onset. The procedures adopted should recognize that the accused is presumed innocent until misconduct is established, but that innocence must be subject to examination. The process of investigating to exonerate the innocent can be unpleasant, but there is no substitute for doing it; the presumption of innocence cannot stand as a substitute for confirmation of the relevant facts. In the rare case where no facts are available either to substantiate or to refute the allegations, the accused remains presumptively innocent.

The right participants, properly deployed. The caliber of an institution's responses to allegations is a measure of the integrity of the institution: it will be judged by others and affect the institution's reputation. The institution's integrity deserves the attention of the institution's best researchers and staff. For a misconduct review to work well, the participants must be of unquestioned personal integrity, professional competence, and objectivity (as to both the individuals and the subject matter of the investigation). The service they provide to the institution, and to the scientific community, must be recognized and appreciated, as it can be stressful, difficult, and time-consuming, and is inherently thankless.

Careful thought should be given to the allocation of tasks. Appropriate staff support should be provided for all logistical and routine functions. In addition, participants must have access to appropriate experts in investigation, interview techniques, collection and protection of evidence, and other specialized tasks that arise in the course of investigations. Whatever support is provided, however, the substantive judgments must be made by qualified researchers of the first rank. Because questions of misconduct go to the heart of the scientific process—the truth or falsehood of knowledge—their resolution should not be delegated to others (e.g., lawyers, staff with specialized expertise, etc.), however necessary those individuals may be to the process.

Finally, the process for accepting and reviewing investigation reports should be thoughtfully constructed. When an investigation panel loses its bearings, as sometimes happens, there must be a mechanism for reorienting it.

Control of bias and conflicts of interest. Although many resist the notion that their objectivity may at times take a back seat to personal feelings, it is a fact that investigating one's "own" is fraught with the potential for bias. This bias involves both personal conflicts of interest (because the parties to the dispute are personally known to those evaluating the allegations) and institutional conflicts (if the allegations are true, the institution's reputation and coffers many suffer). Reviewers may identify with other well-established researchers and display a natural inclination to disregard a young whistle-blower's charge against someone with whom they might identify. Such bias must be guarded against.

The most effective way to deal with conflicts of interest is to acknowledge them forthrightly and then design mechanisms to prevent bias. One of the truisms of dealing with conflicts of interest is that appearances often matter as much as, if not more than, actual conflicts. Apply the "red face" or "front-page" tests: if information about the allegations and the institutional response to it appeared on the front page of a national or local newspaper, how would you feel about each aspect of the arrangement of the review? Would it make your face red, or could you read it with serenity?

Participation in the misconduct investigation process by the institution's top faculty members and researchers is one of the best safeguards against institutional conflicts of interest—if they have been appropriately screened. The best researchers are usually independent of institutional pressures because their funding is generally external, their reputations are national or international, and they have many career options. Given the decentralized structure of most institutions, an outcome that might require the rebate of funds to a research sponsor would have little or no effect on the investigator's own program. A conflict may arise from the desire to protect the institution's reputation, but whether or not this desire causes bias in a given case, outsiders are almost uniformly skeptical of findings made by insiders.

One further effective counterbalance, therefore, is the inclusion on the investigation panel of one or more participants from outside the institution. Their participation can add objectivity and provide additional safeguards against institutional conflicts. This step is especially valuable in a formal investigation, after an inquiry or allegation assessment has found evidence of misconduct that requires further review and analysis. (This step is usually overkill at earlier stages, although occasionally useful when the nature of the allegations is extremely serious.) An institution that is serious about the credibility of its internal misconduct reviews should give strong consideration to the use of external experts on a review panel.

Scientific misconduct issues are not likely to slip into the background anytime soon. Increased demands for accountability and a heightened public interest in ethical issues portend increasing pressures on institutions to monitor the ethical practices of their members. An institution that is committed to the integrity of the research conducted within it and has built effective, credible structures for preventing and resolving ethical issues will be well equipped to cope with

these external pressures. Ultimately, however, institutional structures accomplish far more than preserving institutional autonomy: they protect the principle of scholarly and scientific inquiry that is at the core of the institution's mission.

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Notes

1. The developers of many case studies will share them upon request and can provide helpful advice on using them successfully. Some examples of case studies are those developed by Indiana University Poynter Center, Massachusetts Institute of Technology, Illinois Institute of Technology, University of Pittsburgh, and University of Illinois at Urbana-Champaign, each available on request from the institution. Relevant case studies can also be found in: Editorial Policy Committee, Council of Biology Editors, *Ethics and Policy in Scientific Publication* (Bethesda, Maryland: Council of Biology Editors, 1990).
2. Examples include Panel on Scientific Responsibility and the Conduct of Research, *Responsible Science Ensuring the Integrity of the Research Process*, 2 vols., National Academy of Sciences, National Academy of Engineering, and Institute of Medicine, (Washington, D.C.: National Academy Press, 1992 and 1993); American Educational Research Association, *Ethical Standards of the American Educational Research Association*; American Historical Association, *Statement on Standards of Professional Conduct*; American Physical Society, *Guidelines for Professional Conduct*; American Psychological Association, *Ethical Principles of Psychologists and Code of Conduct*; American Society of Civil Engineers, *By Laws and Code of Ethics*; The American University, *Code of Conduct*; Association of American Medical Colleges, *The Maintenance of High Ethical Standards in the Conduct of Research*; Boston University, *College of Liberal Arts Academic Conduct Code*; University of California, Los Angeles, *Integrity in Research*; University of California, San Diego, *Policy on Integrity of Research*; University of California, Santa Cruz, *UCSC Academic Dishonesty Policy*; Cornell University, *The Code of Academic Integrity and Acknowledging the Work of Others*; Dartmouth College, *Student Handbook, "The Academic Honor Principle"*; Drexel University, *University Policy on Research Integrity*; East Carolina University, *Policy and Procedures on Ethics in Research and Creative Activities*; Harvard University Faculty of Medicine, *Guidelines for Investigators in Scientific Research; The Johns Hopkins School of Medicine, Rules and Guidelines for Responsible Conduct of Research*; The Johns Hopkins University, *Undergraduate Academic Manual*; Massachusetts Institute of Technology, *Education in Research Ethics*; University of Michigan, *Report of the Medical School Committee to Develop Guidelines for the Responsible Conduct of Research*; Modern Language Association of America, *Statement of Professional Ethics*; Montefiore Medical Center, *Policy to Prevent and Investigate Misconduct in Scientific Research*; National Institutes of Health, *Guidelines for the Conduct of Research*; Northwestern University, *Policy on Integrity in Research and Procedures for Reviewing Alleged Misconduct*; Northwestern University, *Guidelines for Investigators in Scientific Research*; Stanford University School of Medicine, *Guidelines for the Responsible Conduct of Research.*
3. Broad, William, and Wade, Nicholas. *Betrayers of the Truth: Fraud and Deceit in the Halls of Science* (New York: Simon & Schuster, Inc, 1982), Ch. 3, p. 38 *ff*; Mallon, Thomas, *Stolen Words: Forays into the Origins and Ravages of Plagiarism.* (New York: Ticknor & Fields, 1989), Ch. 4, p. 144 *ff.*
4. AAAS/ABA National Conference of Lawyers and Scientists, Project on Scientific Fraud and Misconduct, *Report on Workshop Number Two* (1989), p. 24
5. Department of Health and Human Services, Public Health Service. Policies and Procedures for Dealing with Possible Scientific Misconduct in Extramural Research Procedures. *Fed. Reg.* **56**(114):27383-27394, July 13, 1991. National Science Foundation. Misconduct in Science and Engineering; Final Rule. *Fed. Reg.* **45**(689):22286-22290, May 14, 1991. Executive Council, Association of American Medical Colleges. *Beyond the "Framework": Institutional Considerations in Managing Allegations of Misconduct in Research* (Washington, D.C., 1992). Association of American Universities, *Framework for Institutional Policies and Procedures to Deal with Fraud in Research* (Washington, D.C., 1989).
6. Public Health Service (PHS) regulations require institutions to have an individual who serves the function of a "misconduct policy officer," but this designation within an institution has not always served an institutional function aside from compliance with the PHS requirements.
7. See, for example, University of Illinois experience cited in Gunsalus, C. K. On Scientific Misconduct in University Research. *Knowledge: Creation, Diffusion, Utilization* **14**, No. 2 (December 1992):162-167.