CUR Focus

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Responsible Conduct of Research: Administrative Issues Concerning Research Integrity and Compliance

Science is built on a foundation of trust, which grows out of the scientific community's adherence to the values associated with ethical scientific conduct (NAS, 1995). Research misconduct undermines public trust and, in some cases, potentially could harm the public.

Yet Martinson et al. (2005) found that 33 percent of the respondents of a survey to randomly selected scientists who had received extramural support from the National Institutes of Health (NIH) admitted to engaging in the three previous years in at least one of the top 10 negative behaviors (e.g., plagiarism; removing data that conflicted with their own previous research; changing the design, methodology, or results of a study in response to pressure from a funding source; overlooking others' use of flawed data; circumventing aspects of human-subjects requirements; or using confidential information without authorization). While no percentage of the total respondents is given, percentages of those who admitted to engaging in at least one of six other negative behaviors (including inadequate record keeping, dropping observations or data points from analyses, inappropriately assigning authorship credit, or publishing the same data or results in two or more publications) were higher than those recorded for the top 10 negative behaviors. The authors of the study concluded that U.S. scientists "engage in a range of behaviors extending far beyond FFP (fabrication, falsification and plagiarism) that can damage the integrity of science."

So what constitutes the responsible conduct of research? And who is responsible for ensuring that research is conducted in a manner that upholds the highest principles of ethical conduct?

Clearly, multiple parties are involved in ensuring that research is conducted responsibly, among them the institutions, investigators, students, and post-doctoral researchers who are engaged in the research. Responsible practices related to research integrity include:

1) Compliance with regulations related to research misconduct, animal welfare, and welfare of human subjects;

2) Avoidance of conflicts of interest;

3) Utilization of commonly accepted practices for handling data, including acquisition, sharing, ownership and management, publication, authorship, peer review, and collaboration; and

4) Assumption of responsibilities associated with mentoring, training, and managing funds (Fischer, 2008; Steneck, 2007).

In all these areas, the institution, the investigator, and involved students have roles to play. If an institution accepts federal funds, it must have in place procedures for investigating and reporting research misconduct and conflicts of interest; policies that review human and animal research; training programs for those who use humans or animals in their research; procedures for approval and management of grant funds; procedures that ensure laboratory-safety rules are followed; and policies that ensure the appropriate use of hazardous substances (Steneck, 2007).

Further, recent National Science Foundation (NSF) guidelines call for all undergraduates, graduate students, or postdoctoral researchers who are participating in funded research to receive training in the responsible conduct of research (NSF, 2009). The purpose of this article is to help administrators understand institutional responsibilities connected with research integrity and compliance and to provide helpful resources for developing institutional policies if they do not exist (See Table 1).

The federal government defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" (OSTP, 2000). Making up data or results and recording or reporting them constitutes fabrication. Falsification involves manipulating research materials, equipment, or processes, or changing or omitting data or results that inaccurately represent the research findings. Plagiarism involves using another person's ideas, processes, results, or words without giving them credit (OSTP, 2000). Many institutions have expanded the federal government's definition to include compliance with other aspects of federal and/or institutional regulations. Steneck (2007) provides some examples of additional elements that have been

Table 1. Resources for institutions to establish policies related to the responsible conduct of research, as well as registration and filing of assurances.

Resources	Web address
Examples of institutional elements added to the definition of research misconduct	http://ori.dhhs.gov/documents/rcrintro.pdf
Sample Institutional Research Misconduct Policy and Procedures document	http://ori.hhs.gov/policies/documents/SamplePolicyandProcedures-5-07.pdf
Office for Human Research Protections—IRB registration and assurances	http://www.hhs.gov/ohrp/
Institutional Review Board Guidebook – identifies institutional requirements	http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
Definitions of human-subjects research covered under federal human-subjects assurances	http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
Sample Animal Welfare Assurance document	http://grants.nih.gov/grants/olaw/sampledoc/assur.htm
Conflict of Interest Policy	http://grants.nih.gov/grants/policy/coifaq.htm Frequently asked questions: general, institution-specific, investigator-specific
NIH review of conflict-of-interest policies of grantee institutions	http://grants1.nih.gov/grants/policy/coi/nih_review.htm
Samples of data-retention policies	http://www.dartmouth.edu/~osp/submitting/policies/dataretention.html http://www.pitt.edu/~provost/ethresearch.html
NSF Grants Award and Administration Guide listing institutional responsibilities	http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_index.jsp?org=NSF
EPA	http://www.epa.gov/waste/laws-regs/rcraguidance.htm Site includes waste laws, policy, and resources
OSHA	http://www.osha.gov/ Site includes regulations, publications, and training materials

Table 2. Web-based training materials on the responsible conduct of research

University of Pittsburgh's Guidelines for the Responsible Conduct of Research	http://www.pitt.edu/~provost/ethresearch.html Site covers plagiarism, data integrity, use of data, ownership, access, misuse of privileged information, storage and retention of data, authorship and publication issues, conflict of interest, human research, animal use, responsibilities of investigators, responsibilities to funding agencies
Human research subjects training materials	http://bioethics.od.nih.gov/
Training videos for working with vertebrate animals	http://grants.nih.gov/grants/olaw/TrainingVideos.htm
Videocassettes related to animal care, use, and welfare	http://www.nal.usda.gov/awic/pubs/aw200001.htm
Poynter Center	http://poynter.indiana.edu/tre/resources.shtml
Online Ethics Center	http://onlineethics.org/
A Guide to Training and Mentoring in the Intramural Research Program at NIH	http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/mentor-guide.htm
Project for Scholarly Integrity	http://www.scholarlyintegrity.org/Resources.aspx
Entering Mentoring: A Seminar to Train a New Generation of Scientists	http://www.hhmi.org/resources/labmanagement/downloads/entering_mentoring.pdf

Paula Dehn (center) and students celebrating the presentation of their research.

included in institutional definitions of research misconduct (Table 1).

Institutions have responsibilities for establishing compliance policies, procedures for receiving and investigating reports of research misconduct, and effectively communicating policies and procedures to faculty members. However, both the institution and the investigators are responsible for reporting and investigating allegations of misconduct (Fischer, 2008; Steneck, 2007). Compliance plans must include specific items. For example, the National Science Foundation has suggested seven elements of a good compliance program, which include:

1) Establishing reasonable compliance standards and procedures;

2) Identifying a specific high-level person responsible for receiving and adjudicating allegations and/or findings of misconduct;

3) Assuring that there are mechanisms in place for effective communication of standards and procedures;

4) Utilizing due care in assigning personnel who have substantial discretionary authority;

5) Establishing monitoring, auditing, and reporting systems, the latter of which should have adequate protection against retaliation for those who report allegations of misconduct;

6) Utilizing mechanisms that will allow consistent enforcement of standards and that will be able to detect both misconduct and lack of misconduct; and

7) Clearly articulating appropriate responses to an offense, i.e., reporting it to the funding agency or to law enforcement, modification of the research program, prevention of future misconduct (Kroll, 2005).

A sample research-misconduct policy, designed to help institutions develop a document that meets federal regulations, can be found on the Office of Research Integrity's Web site (Table 1). Once a policy has been developed, two important legal responsibilities for administrators are ensuring that it is clearly understood by individuals who will play a role in implementation and that the policy is followed in practice (Fischer, 2008). Therefore institutions should establish a training program to ensure that faculty, staff, and students clearly understand what is required of them.

Research with Human Subjects

Both the National Science Foundation and the National Institutes of Health require additional institutional assurances in order for a college or university to be eligible to receive federal funding. Among these are assurances related to the welfare of both human subjects and animals used in research. Both require oversight by committees that review and approve research proposals before research may be done. An Institutional Review Board (IRB) approves research involving human subjects. The Office for Human Research Protections in the U.S. Department of Health & Human Services oversees IRB registrations and assurances. Its Web site has a wealth of information to guide institutions in the processes of registering and filing an assurance document (Table 1). IRBs must have five members, including at least one non-scientist, one scientist, and one person who is not affiliated with the institution and is not a family member of someone at the institution (45 CFR 46.107(d)). IRBs have authority to approve, require modification of, and disapprove all research activities involving human subjects. IRBs also must conduct continuing reviews of all human-subject research, at least once per year (Steneck, 2007).

It is not always clear what constitutes research with human subjects. Definitions of such research may be found in the federal regulations (45 CFR 46.102). IRBs consider many factors before approving proposals, among them steps aimed at minimizing risks to subjects; analyzing the risks versus the benefits to be gained; determining how informed consent will be acquired and documented; determining whether the privacy of the subjects and confidentiality of the data will be protected; and examining

Table 3. Resources for institutions to create documents to monitor federal compliance requirements.

Sample Annual Report to OLAW	http://grants.nih.gov/grants/olaw/sampledoc/index.htm
Sample Semiannual Report to the responsible institutional official	http://grants.nih.gov/grants/olaw/sampledoc/index.htm
Sample Institutional Semiannual Program Facility Review	http://grants.nih.gov/grants/olaw/sampledoc/index.htmand
Sample Animal Study Proposal	http://grants.nih.gov/grants/olaw/sampledoc/animal_study_prop.htm

the provisions that exist to ensure safety of the subjects (45 CFR 46.111(a)). Some studies involving humans may be exempt from the regulations, for example, research conducted in established or commonly accepted educational settings or research involving the use of educational tests. However, decisions about whether studies are exempt must be made by the IRB and not by the investigator (Steneck, 2007). NIH currently requires that all investigators submitting proposals for NIH funding or who are receiving non-competing awards involving human subjects' research must undergo training in the protection of human research subjects (NIH, 2000). NIH (2008) has a Web site that contains numerous links to training materials for investigators; of special note is the link to tutorials and case studies (Table 2).

Research Using Animals

Institutional Animal Care and Use Committees (IACUCs) are required to review and ensure the humane care and use of animals used in research. Laboratory studies, observational, and field research may be covered by the U.S. Department of Agriculture (USDA) animal-welfare regulations (United States, 1966) or by the Public Health Policy on the Humane Care and Use of Laboratory Animals (Public Health Service, 2002). Oversight of these regulations is the responsibility of the institution.

To meet federal regulations that cover the use of vertebrates in research, the institution must have an animal care and use program with clear lines of authority and responsibility. It must include an IACUC; procedures for self-monitoring; a veterinary care program; an occupational health and safety program; a personnel training program; an environment, housing, and management program for animals; and appropriately maintained facilities for housing and support (ARENA/OLAW, 2002). The USDA requires registration of facilities. A sample animal-welfare assurance document that meets Public Health Service (PHS) requirements may be downloaded for institutions as they develop their own policies (Table 1).

IACUCs are composed of members who represent different groups. USDA regulations (9 CFR 2.31 (a) (b)) requires a minimum of three members, while Public Health Service policy (IV.A. 3. a. b.) requires a minimum of five members (ARENA/OLAW, 2002). Both agencies require a committee member who holds a doctor of veterinary medicine degree and has training or experience in laboratory animal science and medicine; this person must have authority and responsibility for activities involving animals at the institution. Both agencies also require one member who is not affiliated in any way with the institution. This second person must not be someone who uses laboratory animals (USDA, 2006). The USDA regulations also stipulate that no more than three members from the same administrative unit of the institution may serve on an IACUC (ARENA/OLAW, 2002). PHS Policy (2002) stipulates that, in addition to the two members listed under USDA regulations, the IACUC must also have one practicing scientist experienced in research involving animals; one member whose primary concerns are in a nonscientific area (for example, an ethicist, lawyer, or member of the clergy); and one public member who must not be a laboratory-animal user.

IACUC members are appointed by their institutions, and their responsibilities are mandated by federal laws. They must: 1) review the animal care program; 2) inspect the facility; 3) review, approve, require modification, or withhold approval

of all research proposals using vertebrate animals; 4) review concerns involving the care and use of animals; and 5) submit all required reports (ARENA/OLAW, 2002). Sample documents that cover the semiannual program review, the semiannual report, and the annual report to Office of Laboratory Animal Welfare (OLAW) may be found on the OLAW Web site (Table 3).

The Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (NIH, 2002) require investigators to "follow the rules and regulations for the transportation, care, and use of animals; design and perform research with consideration of relevance to human or animal health, the advancement of knowledge, or the good of society; use appropriate species and the minimum number of animals to obtain valid results, and consider non-animal models; avoid or minimize pain, discomfort, and distress; use appropriate sedation, analgesia, or anesthesia; painlessly kill animals that will suffer severe or chronic pain or distress that cannot be relieved; feed and house animals appropriately and provide veterinary care; assure that everyone who is responsible for the care and treatment of animals during the research is appropriately qualified and trained; and defer any exceptions to these principles to the appropriate IACUC" (NIH, 2002; Steneck, 2007).

In addition, the USDA animal-welfare regulations require a written narrative of the methods used and sources consulted to determine the availability of alternatives. Therefore, most IACUCs use a standardized form to ensure that the required information is provided by investigators to assure compliance. A sample animal-study proposal that addresses regulations for the use of vertebrate animals may be found on the OLAW Web site (Table 3). Training programs are designed to meet the needs of personnel working at each institution. The OLAW's Web site has online training materials for working with rodents, dogs, and non-human primates, while the USDA has numerous videocassettes related to animal care, use, and welfare (Table 2).

Conflicts of Interest

Researchers receiving funds from the Public Health Service or the National Science foundation must comply with those agencies' conflict-of-interest (COI) policies; however, many institutions have adopted policies that apply to all researchers, whatever their source of funding. Federal regulations require that all conflicts of interest must be reported, managed, or eliminated. Steneck (2007) provides examples of how conflicts of interest may be managed so as to not adversely impact the outcomes of a study. If conflicts of interest cannot be managed, they must be eliminated. It is important to note that decisions about how conflicts of interest should be managed or eliminated should rest with an administrator or conflicts-of-interest committee, not the researcher (Steneck, 2007).

Typically, three types of conflicts of interest are addressed in policies—financial, work commitments (time), and personal and intellectual. Steneck (2007) lists numerous policy statements and resources dealing with conflicts of interest, which can be modified for a particular institution's use. Additionally, NIH's Office of Extramural Research provides links to Web-based information resources and to suggestions for formulating a conflict-of-interest policy based on an extensive review of NIH-funded institutions (Table 1).

Management and Ownership of Data

Data-management and ownership issues also require institutional oversight. In the case of federally funded research, the support is awarded to the institution, not to the individual researcher. Therefore institutions must provide oversight not only for regulatory compliance, budgets, and contractual obligations, but also for data management. Issues of who owns the data depend on who funded the work, and this may have implications for whether or not the results may be published (Steneck, 2007). Institutions need to understand their responsibilities concerning data ownership, and they must convey this information to the investigators who are conducting the research.

Institutions also have responsibilities concerning the collection, protection, and retention of research data. Of paramount importance in data collection is the date the information is collected, as this may influence intellectual-property rights. Electronic data collection needs to be validated in some way to ensure that it was actually recorded on a particular date. Once collected, data must be properly protected, as the raw data may be needed later to confirm research findings, establish priority of the findings, or be reanalyzed. Data that are subject to privacy restrictions must be accessible only to authorized personnel. The researcher who collects or uses the confidential information has the primary responsibility for its

protection. Institutions should establish periods for retention of data. NIH requires data to be retained for three years after the submission of the final financial report, but other government agencies require retention for up to seven years (Steneck, 2007). Dartmouth's Office of Sponsored Projects has a data-retention policy that aligns with NIH's three-year rule, while the University of Pittsburgh has guidelines that aligns with the seven-year rule (Table 1).

Institutions have additional obligations concerning oversight of the management of funds and the timely submission of financial, progress, and final reports. A recent report by the grant-fraud committee of the National Procurement Fraud Task Force (NPFTF, 2009) found that grant-awarding agencies often do not devote sufficient resources to the oversight of how their grants are spent. Survey respondents indicated that many funding agencies do not make sure that grantees submit required financial and progress reports. In addition, if these reports are submitted, funding agencies often do not ensure that they are submitted in a timely manner. Similarly, awarding agencies often inadequately monitor grantee activities by not reviewing supporting documentation for grant expenditures; establishing performance goals for programs; ensuring that grantees submit performance data to demonstrate that grant monies are being used effectively and as intended; or seeing that grant closure occurs in a timely manner (NPFTF, 2009).

NSF's Grants Award and Administration Guide lists requirements and standards for grant administration, oversight, and reporting of both financial and technical outcomes; financial management and payments; required policies for procurement and property management; information on what costs are allowable; grantees' obligations for acknowledgment of support; and requirements that grantees submit copies of all publications resulting from the supported work to the appropriate program officer (Table 1). Each funding agency or foundation has particular requirements and/or standards. And it is the institution's responsibility to ensure that all these requirements and timelines are met.

Institutions also are responsible for ensuring that a safe working environment exists and that hazardous materials are used, stored, and disposed of as mandated by state and/or federal guidelines. Several different federal laws and agencies oversee these issues, among them the Environmental Protection Agency (EPA) and the Department of Labor's Occupational Safety and Health Administrations (OSHA). Both the EPA's and OSHA's Web sites have numerous links to regulations that must be met, as well as online training designed to help individuals and institutions meet compliance standards (Table 1)

Authorship and Publication Rules

Authorship is generally is limited to individuals who make significant contributions to the work that is reported. The Uniform Requirements for Manuscripts Submitted to Biomedical Journals, (International Committee of Medical Journal Editors, 2008) defines an author as "anyone who: was intimately involved in the conception and design of the research, or who assumed responsibility for data collection or analysis and interpretation, participated in drafting the publication, and approved the final version of the publication." According to this definition, authors should meet all three conditions to be included. However, these recommendations are not always followed, and typically it is the researchers who decide whether or not authorship should include only those who contribute to all phases of the research or those who play a more limited role (Steneck, 2007). Burks & Chumchi (2009) recently published an article on how to write, publish, and negotiate authorship with undergraduates; administrators may find this useful for research-integrity training programs for faculty. In addition to authorship rules, responsible publication involves not breaking publications into small units, duplicating publication of the same data, or making premature public statements about research findings (Steneck, 2007). Institutions can help to avoid these practices through procedures that scrutinize and reward faculty scholarship used for annual reviews, promotion, and tenure decisions.

Mentoring and Training

These are important activities at primarily undergraduate institutions. What constitutes a productive mentor-trainee relationship has been addressed in several excellent publications and online resources (Burroughs Welcome Fund and Howard Hughes Medical Institute, 2006; Merkel & Baker, 2002; NAS, 1997; University of Miami, nd). One central component of a good mentor-trainee relationship is ensuring that students learn about research integrity. Institutions have a responsibility to ensure that both researchers and their students know and understand their responsibilities for how research is conducted. Recent NSF guidelines call for training in the responsible conduct of research for all undergraduate students, graduate

students, or postdoctoral researchers who are participating in funded research (NSF, 2009).

There are many online resources available for teaching about the responsible conduct of research. The Poynter Center (Table 2) has an intensive workshop in teaching research ethics for scientists who train graduate students. Resources for teaching research ethics include a searchable bibliography, and case studies. The site also has essays on using short writing and group assignments and case studies, as well as plans for how to assess student learning. Another good online source for teaching research ethics to undergraduates may be found at the Online Ethics Center (Table 2). This site has numerous resources, including a plan that encompasses teaching ethics across the four-year curriculum, numerous case studies, assignments, and evaluation tools.

NIH has a site designed to train its intramural investigators that also has information that can be incorporated into outside training programs, as does the University of Pittsburgh's Web site (Table 2). Similarly, the Web site hosting the Project for Scholarly Integrity has numerous links to case studies, online training modules, and reports. The Howard Hughes Medical Institute has an online seminar to train new researchers (Table 2). Steneck's (2007) book, which may be obtained in a pdf format on the NIH Web site, also has numerous case studies that can be used to illustrate the complex issues that often arise. These resources will provide ample information to help institutions develop training programs for faculty, staff, and students engaged in research.

Clearly, many excellent resources are available to help institutions meet their obligations to comply with federal regulations related to research integrity, and the references that follow provide much more information about the issues, regulations, and policies needed to promote the responsible conduct of research.

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