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IMPORTANT SUBSCRIBER INFORMATION

The Role and Activities of Scientific Societies in Promoting Research Integrity

by Elizabeth DuMez

Elizabeth DuMez recently retired as Manager, Office of Ethics and Professional Review at the National Association of Social Workers.

Scientific societies were the subject of a conference in the spring of 2000 co-sponsored by the American Association for the Advancement of Science (AAAS) and the U.S. Office of Research Integrity (ORI). The proceedings included presentations on the recent history of the roles and activities of scientific societies in promoting ethical conduct, codes of ethics and activities that support them, and conclusions and recommendations for research and action related to societies *(1)* roles in promoting research integrity. The full report of the conference proceedings appears on the AAAS

website at *http://www.aaas.org/spp/sfrl/projects/integrity.htm*

Historical Roots

The impetus for convening a conference on how research integrity is and can be promoted by scientific societies lies in forerunner events. In 1980, an AAAS survey of the professional ethics activities of its affiliate societies concluded that "little attention and only minimal resources have been directed toward professional ethics" among the scientific and engineering societies.[1] In 1989, the Institute of Medicine issued a report recommending that "scientific organizations representing the research community should develop educational and training activities and materials to improve the integrity of research [and that] scientific journals should develop policies to promote responsible authorship practices." *(2)*

In 1992, the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine issued a report, *Responsible Science*, that found that ethics were still marginal in most scientific societies, and recommended far more systematic efforts to foster responsible research practices.[3] Finally, in its 1995 advisory report to the Secretary of Health and Human Services (DHHS) and the U.S. Congress, the Commission on Research Integrity recommended that "Professional societies [should] adopt a code of ethics in research…[and] should consider initiating activities that will further promote the ethical conduct of research." *(4)* The 2000 conference was, at least in part, an effort to determine what the societies are doing in light of these earlier studies and recommendations.

Codes of Ethics, Ethical Standards, and Enforcement

Many scientific societies have developed codes of ethics that encompass a broad range of behaviors and practices as a means of fostering research integrity. These codes presumably represent the ideals and core values of a profession, and can be used to transmit those values and more detailed ethical prescriptions as part of the education of scientists and practitioners. They also provide a benchmark of standards for reviewing claims of misconduct and for sanctioning improper behavior. The potential for and the limitations of codes of ethics to ensure research integrity provoke varying points of view. While codes are intended to codify standards of behavior in professional roles, their limitations are such that conduct cannot be guaranteed and, in some instances, cannot be predicted. The contexts of scientific research can present unique circumstances that create difficulty in describing behavior that is uniformly right or wrong. Ethical guidelines may be useful primarily as a means of countering pressure to advance predetermined results in research, to affirming the essential values of a profession that transcend other values derived from family heritage, culture, financial interests, and religion or ideology, and educating and conditioning the attitudes of young professionals.

One of the pivotal questions faced by a scientific society is whether to institute measures to enforce its code of ethics with disciplinary proceedings and sanctions. Many societies choose not to engage in enforcement, using their ethics code primarily for educational purposes. For others, ethics code enforcement enables the societies to demonstrate their willingness to hold their members accountable for their conduct. Another alternative is the referral by a society of a grievance to the institution or corporation that owns the data while reserving the right of publicizing infractions and consequences.

Society Activities

Many scientific societies realize that the adoption of a code of ethics can be an important, but insufficient step for fostering responsible research practices. In seeking ways to reinforce the message carried by their codes, societies may engage in a range of activities, some of which were highlighted in a recent AAAS survey and at the conference. The survey found that 57% of the societies currently engage in or plan to engage in activities to promote research integrity; 41% did not have or plan to have such activities. Of those engaged in activities designed to promote research integrity, these included:

- programs at annual/regional meetings (41%)
- ethics committees (37%)
- columns/articles in professional journals/newsletters (33%)
- publications on research ethics (30%)

- workshops (17%)
- resource materials (15%)
- discussion groups (13%)
- mentorship programs (7%)
- special activities for students/trainees (7%) and
- awards to members exemplifying integrity in research (2%).

Four percent indicated other activities that did not fit the designated categories. The range of activities reflects, at least in part, the fact that the societies are highly heterogeneous, and some activities are a better fit than others.

As the public increasingly demands greater accountability on the part of the scientific community and as societies seek effective ways to promote research integrity, these activities must be subject to rigorous evaluation. But neither resources nor strategies in support of evaluation appears to be a priority among the societies responding to the AAAS survey. The survey results revealed a dearth of methods by which societies determine the effectiveness of their activities. The societies responded that the following activities appear to be most effective in promoting research integrity:

- publications on research ethics
- programs at annual meetings
- columns/articles in professional journals and newsletters
- resource material with which mandatory compliance is specified
- mentoring, and oversight of journal article reviewers.

Ethics committees, resource materials, and posting materials on a web site (unless a focal point of the site) were reported as least effective. But none of these appears to have been evaluated with any rigor. Indeed, it is not even clear what would constitute the criterion of "effectiveness" in order to draw valid conclusions. The reality is that these responses are more reflective of seat-of-the-pants judgments than any empirical evidence.

FINDINGS AND RECOMMENDATIONS

While no vote of conference participants was taken to determine the extent of any consensus, a number of findings and recommendations clearly emerged that most of those attending would likely support. While conference participants did acknowledge that a scientific society may not always be a sufficiently impartial judge of allegations of research misconduct, there was little argument with the notion that societies can play a key role in developing initiatives to help prevent ethical infractions and promote responsible research conduct. Below are key findings and recommendations that flow from conference deliberations.

Ethical Standards

- Codes of ethics should be developed by all scientific disciplines, with the process of development offering ample opportunity for contributions from all sectors of a society's membership.
- Ethics and publication standards are not always effectively transmitted from one generation of scientists to the next, or even to current members of a society. Hence, any effort to develop standards should be linked to a plan for their dissemination and for the education of those to whom they (will) apply. Ethics consultation service by societies can prevent specific acts of misconduct and educate members for future decision making.
- If a society decides to enforce its standards with review and disciplinary procedures, it should be prepared to devote adequate resources to do so effectively.
- Enforcement procedures should accord due process and ways to initiate a grievance should be commonly known.
- When misconduct allegations are reviewed by societies, the results may not be made public, thereby diminishing the potential deterrent effect. Societies should, therefore, consider making public the outcomes of their misconduct review.

Education

- Educational curricula in the discipline should include an ethics component, which should be reflected in accreditation standards of educational institutions. Societies should work with the appropriate institutions in order achieve these outcomes.
- Societies should sponsor learning opportunities in responsible research for their members, including activities at society meetings, articles in their publications, and the development and dissemination of educational materials, especially examples of ethical practices involving complex circumstances.
- Societies should develop initiatives that foster the preparation of ethics curricula and materials that incorporate the values and ethical prescriptions reflected in the society's code of ethics.
- Collaboration among professional associations and scientific societies in developing and applying codes of ethics should be encouraged to bridge gaps in practices and enhance understanding of ethical requirements across disciplines.

Collaboration and Mentoring

- In planning a research project, a clear delineation of roles, working relationships, credit allocation, and intellectual property policies is desirable. The design of methods of dispute resolution may help to promote responsible research practices and support collegial models for conducting collaborative research. Societies should consider adopting partnering agreements, conflict resolution mechanisms, and mentoring strategies in support of scientists and students.
- More research is needed on the importance of the societies (and other forces in the research system) in shaping the ethical climate in which scientists work. Individual scientists do not act in isolation from their professional peers. The exercise of professional discretion by individual scientists affected by standards prescribed by his or her society warrants exploration
- At present, there has been very little formal evaluation of the effectiveness of the society initiatives described in this report. More rigorous evaluation is essential if resources are to be efficiently allocated and if scientists and the larger public are to have confidence in the self-regulatory functions of the societies. Such evaluation should be sensitive to the heterogeneity of the population of scientific societies.

Publication

- In their role as publishers, societies have the opportunity to influence research conduct. Societies should review their codes of ethics to determine whether they appropriately cover publication ethics, a critical element in promoting research integrity.
- The society's leadership should work closely with new editors and new generations of researcher-scholars regarding ethical standards and their crucial role in helping to ensure the integrity of research.
- Society journals should develop educational programs regarding publication policies that promote integrity in publishing scholarly work.
- The scientific societies should establish a consortium of journal editors to develop, where appropriate, consistent standards for publishing scientific research.
- Scientific societies should work together to establish a uniform policy regarding authorship in the context of multi-disciplinary research collaborations.
- Criteria for authorship and the responsibilities of authors should be clearly stated by society journals
- Specific standards for online publication should be developed by the societies.

References

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[2] Institute of Medicine (1989) *The Responsible Conduct of Research in the Health Sciences* (Washington, DC: National Academy Press), pp. 36, 37.

[3] Panel on Scientific Responsibility and the Conduct of Research (1992) *Responsible Science: Ensuring the Integrity of the Research Process,* Committee on Science, Engineering, and Public Policy, National Academy of Sciences,

National Academy of Engineering, and Institute of Medicine. (Washington, DC: National Academy Press), p. 147.

[4] Commission on Research Integrity (1995) *Integrity and Misconduct in Research*. (Washington, DC: U.S. Department of Health and Human Services, Public Health Service), p. 20.

IN THE NEWS

REVISED PHS GUIDELINE ON INFECTIOUS DISEASE ISSUES IN XENOTRANSPLANTATION

On May 25, the Department of Health and Human Services (DHHS) published revised Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplan-tation. The Guideline addresses the potential public health safety issues associated with xenotransplantation by identifying general principles of prevention and control of infectious diseases.

The revisions include a modification of the definition of xenotransplantation to include not only any procedure that involves the transplantation, implantation, or infusion of live cells, tissues, or organs from a nonhuman source into a human recipient, but also includes human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs. The Guideline stresses that in addition to review by appropriate local review bodies, the FDA has regulatory oversight for xenotransplantation clinical trials.

The Guideline emphasizes that primary responsibility for designing and monitoring the conduct of xenotransplantation clinical trials rests with the sponsor. The regulations call for long-term or life-long surveillance of xenotransplantation recipients regardless of the outcome of the trial and suggest that recipients and their close contacts be actively deferred from donation of body fluids and other body parts. The Guideline also describes the development of a pilot national xenotransplantation database to collect data from all clinical centers that conduct xenotransplantation trials and all animal facilities providing source animals.

The Guideline acknowledges the strong opposition to the use of nonhuman primates for both public health and ethical reasons. Since the scope of the Guideline is limited to infectious disease issues, this topic, and all other scientific, social, medical, public health, ethical, social, and legal issues, will be addressed by the Secretary's Advisory Committee on Xenotransplan-tation (SACX), currently under development within the DHHS. The SACX will not only facilitate analysis, discussion, and public awareness of the aforementioned issues, but will also review proposed clinical trial protocols and make recommendations to the Secretary of HHS. The revised Guideline is available at *http://www.fda.gov/cber/gdlns/xeno0500.txt*

MH

NIH ISSUES STEM CELL GUIDELINES

On August 23, the National Institutes of Health released the *Guidelines for Research Involving Human Pluripotent Stem Cells* enabling scientists to use federal funding for research on human embryonic stem cell lines.

In an attempt to reconcile the views of advocates and opponents, the Guidelines call for privately-funded isolation of the stem cells from embryos, but permit federal funding for research on the stem cells themselves if their derivation meets criteria outlined in the Guidelines. The conditions for utilizing stem cells from human embryos state that researchers may only use embryos marked to be discarded, that no financial or other inducements should have been offered for the donation, and that there must be a clear separation between the decision to create and the decision to donate the embryo for research. Unlike stem cells isolated from embryos received from in vitro fertilization clinics, stem cells from fetal tissue obtained from terminated pregnancies may be derived as well as utilized using federal funds. All stem cell usage must be preceded by extensive informed consent requirements and IRB approval. The Guidelines also clearly identify the areas not eligible for research funding, including research in which stem cells are

used to create a human embryo, are derived from somatic cell nuclear transfer, or are combined with an animal embryo. A new review committee, the NIH Human Pluripotent Stem Cell Review Group (HPSCRG), will be established to review compliance with the Guidelines, hold public meetings to review proposals for using a newly derived line of stem cells or deriving a new stem cell line from fetal tissue, and to recommend to the NIH any revisions to the Guidelines and the need for policy conferences. The Guidelines for Research Involving Human Pluripotent Stem Cells is available at *http://www.nih.gov/news/stemcell/stemcell guidelines.htm*

An expert panel in Britain recently urged the government to accept human cloning of embryos for research purposes. British law already allows scientists to conduct research on spare embryos donated by clinics, as long as the embryos are destroyed within 14 days. The new report recommends that the government expand the rules to allow scientists to clone human embryos if there is no other way to conduct the research. Scientists propose cloning of embryos as a method of overcoming problems of transplant rejection, because the cloned stem cells would be perfectly matched to the person being treated. The expert panel proposed keeping the 14-day rule, introducing legislation to reinforce the nation's ban on creating cloned babies, and requiring individual approval of each project by the Human Fertilisation and Embryology Authority. The vote on the legislation is expected to take place in Parliament this fall. The report on Stem Cell Research: Medical Progress with Responsibility is available at *http://www.doh.gov.uk/cegc/stemcellreport.html*

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PARTY PLATFORMS ON STEM CELLS
"We applaud congressional Republicans for the steps they have taken for protection of human embryos and against human cloning, the trafficking in fetal tissue organs, and related abuses." **Republican Platform** http://www.rnc.org/2000/2000platform5
"We should allow stem cell research to make important new discoveries." **Democratic Platform** http://www.dems2000.com/AboutThe-Convention/03c_progress.html

EEOC ISSUES POLICY GUIDANCE ON GENETIC DISCRIMINATION

On July 26, the Equal Employment Opportunity Commission (EEOC) released "Policy Guidance on Executive Order 13145: To Prohibit Discrimination in Federal Employment Based on Genetic Information."(See *http://www.eeoc.gov/docs/guidance-genetic.html*) This action stems from an Executive Order (EO) signed by President Clinton in February that prohibits genetic discrimination in the federal workplace. [*PER* Vol.13 No1]. The EO bans federal employers from requiring or requesting genetic tests as a condition of being hired or receiving benefits, and prohibits federal employers from using protected information to classify employees in a manner that deprives them of advancement opportunities or denies promotion due to a genetic predisposition for certain diseases. The EO assigned the EEOC responsibility for coordinating "the policy of the Government of the United States to prohibit discrimination…based on protected genetic information, or information about a request for or receipt of genetic services."

The EEOC policy guidance explains how the EO affects the collection, use, and disclosure of protected genetic information, and through examples shows federal agencies how to comply. Included in the policy is an explanation of how an individual can establish that s/he has a disability based on protected genetic information under section 501 of the Rehabilitation Act of 1973, as amended. Procedural guidance for asserting noncompliance with the EO and reporting allegations of genetic discrimination is also provided.

RG

QUI TAM SUITS DEALT A BLOW BY SUPREME COURT RULING

On May 22, the U.S. Supreme Court ruled that private individuals could not use the qui tam provision of the False Claims Act to sue state institutions. In the decision, *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, the Court ruled that states did not fall under the category of "persons" subject to liability as defined in the False Claims Act.

Under the qui tam provision of the False Claims Act, individuals (called relators) file suit in the name of the federal government, alleging that someone has submitted a false claim for payment to the United States. The U.S. Attorney General, after reviewing a relator's claim, decides whether the United States should intervene on the relator's behalf. If the Attorney General declines the case, the relator can still bring suit on his or her own behalf.

Many qui tam suits filed on behalf of the National Institutes of Health (NIH) against state institutions are currently pending. Most of these actions are based on allegations of research misconduct, violations regarding protections or other assurances of human or animal welfare, and misuses of grant funds. Because the *Vermont* decision now renders these actions involving state agencies impermissible, trial courts will most likely dismiss them. Individuals can, however, still pursue administrative remedies such as recovery of funds, or file their accusations with the Office of Research Integrity.

Individuals can continue bringing qui tam suits on behalf of the government against private institutions. On June 6, Thomas Jefferson University, a private institution in Philadelphia, agreed to pay the United States $2.6 million in settlement of a claim that it used false data to receive and maintain two research grants funded by the NIH. In addition to the monetary settlement, Thomas Jefferson entered into a three-year institutional compliance agreement with the U.S. Department of Health and Human Services, and agreed to ask several scientific journals to publish corrections to its scientific papers originally published in 1994 through 1996. The suit alleged that a former post-doctoral fellow and a physician used false research data to support their initial application and continued funding of a governmental gene therapy research grant. The United States contended that these false claims defrauded the government of $836,712. Both researchers refuted the allegations. The university also denied any misuse of funds, stating that it agreed to the settlement because it wanted to "avoid further legal costs."

MS

CALL FOR INTERNATIONAL CODE OF ETHICS

Philippe Lazar, president of the Institut de Recherche pour le Développement, the French national agency of scientific research for development purposes, has drafted an international code of research ethics in an effort to balance power in research collaborations between developed and developing countries. Lazar hopes to focus international attention on the principles embodied in it.

Some critics question the scope of the proposed code, arguing that it should not be limited to north/south collaborations, but instead should apply to any research alliance. Others believe that the code does not address issues such as who benefits from research conducted by north/south collaborations, that research needs vary between third-world and industrialized countries, and that developing countries do not have the amount of research administrators necessary to effectively negotiate details of proposed research collaborations. Still others state that the prospective code does not address scientific issues vital in developing countries, such as malaria and other tropical diseases. The draft code can be found at *http://www.ird.fr/fr/inst/ird/debat/.*

MS

RESEARCH MISCONDUCT IN GERMANY

A new report indicates that the German scientific fraud scandal that first made headlines in 1997 [PER Vol. 10 No. 3] was actually much more widespread than originally thought. The report, released this past June, concludes that data falsifications existed in 52 articles co-authored by Frieldhelm Herrmann, a hematologist working at the University of

Ulm and the University of Freiburg Medical Center, and that fraud is suspected in 42 more articles. Indications of data falsification were also identified in the "habilitations" (qualifying exams) of three graduate students in Herrman's department at Freiburg, the department of hematology and oncology, and in the work of several other investigators in the department.

Allegations of fraud by Herrmann and his frequent collaborator Marion Brach were first revealed in 1997, after a postdoc in his lab reported that data had been manipulated in four papers. A subsequent national task force found that data falsification had been committed in 37 papers co-authored by Hermann or Brach. Both left their academic positions following a release of the 1997 report, although they continued to deny their own culpability.

The new report was based on a two-year investigation by a task force jointly sponsored by the Deutsche Forschungsgemeinschaft (DMG), the German public funding organization, and the Deutsche Krebshilfe, Germany's largest cancer charity. The task force analyzed data for all 347 papers co-authorized by Herrmann during the years 1988-1992. A sampling of articles authored by other members of the department were also investigated, and "inconsistencies" suggesting data fraud were also found in an article co-authored by the department chair, Roland Mertelsmann. An investigation of his work, along with those of the other co-authors of his paper, is now underway.

The news that evidence of fraud has been found in the work of other members of the University of Freiburg's department of hematology and oncology has generated concern that the there a fundamental lack of safeguards against misconduct in German science. An editorial in *Nature* (June 29, 2000) was highly critical, stating that these cases are "a sign that the system of clinical research and promotion in Germany provides a breeding ground for bad scientific practice." The editorial cited a combination of factors in German clinical research which contribute to the problem: the lack of a formal requirement for training in research methods, the requirement of numerous publications for advancement in clinical medicine, and the fact that "clinicians are not given leave from their wards for their research; data must be collected after hours."

No charges have yet been brought against the researchers by the universities where the fraud was committed or by the funding agencies sponsoring the research.

MI

SCHOLARS-AT-RISK NETWORK ESTABLISHED

On June 5-7, a conference on "Scholars at Risk: New Responses to Attacks on Academic Freedom" was convened at the University of Chicago, where participants approved a resolution establishing the Scholars at Risk Network. The network's primary aim will be to assist scholars outside the U.S. whose work faces threats from displacement, discrimination, violence, censorship, harassment or intimidation by establishing a network of universities and research centers willing to serve as temporary hosts to persecuted scholars. Information about eminent at-risk scholars will be disseminated within a network of potential host institutions in hopes of matching individual scholars with the needs of a particular institution.

According to the resolution, the Scholars at Risk Network will also "charge itself with raising awareness, understanding of and respect for academic freedom, higher education, scholarship, and the free exchange of ideas," through intervention and advocacy activities. The Network currently hosts the internet-based "Academic Freedom Institute," which provides an online discussion forum and periodic reports on the state of academic freedom in countries throughout the world, and in the future hopes to include an electronic journal featuring works by threatened scholars.

Colleges and universities, research centers, academic societies, professional associations, individual scholars, students, members of the public, and organizations active in academic freedom and education issues will be able to join the Scholars at Risk Network in a variety of capacities appropriate to the participant, ranging from the receipt and dissemination of information about network activities to serving as a potential host institution for a threatened scholar.

The "Resolution Establishing the Scholars at Risk Network," is available at *http://scholarsatrisk.uchicago.edu*.

SLW

HUMAN SUBJECTS NEWS

GOVERNMENT PROPOSAL FOR NEW INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH

Institutions conducting research or research training with Public Health Service (PHS) funds may soon be required to provide their staff members with instruction in the responsible conduct of research (RCR). Under the proposal, all institutional staff members engaged in research supported by grants, contracts or cooperative agreements from any PHS agency must successfully complete an RCR training program encompassing up to ten core instructional areas: research misconduct, data acquisition, human subjects protection, conflicts of interest, publication practices and responsible authorship, peer review, mentor/trainee responsibilities, collaborative science, research involving animals, and compliance with existing PHS and institutional policies. Among the goals of the new policy are to increase awareness of issues surrounding research misconduct and responsible research, to improve the ability of investigators to make ethical choices concerning research-related conflicts, and to supply information on the regulations and guidelines that apply to PHS-funded research.

The authority to determine whether an employee has successfully completed an integrity training program will rest with the institution, though the proposal recommends that educational programs contain both practice and evaluative components to assess competency and reinforce new knowledge. The training requirements may be fulfilled through workshops, seminars, CD-ROMs, Internet activities or self-study guides, as well as through other educational programs deemed to be consistent with the policy's goals.

The new education requirements were announced in October 1999 by DHHS Secretary Donna Shalala, along with a number of other changes in departmental policy designed to bolster DHHS research integrity efforts. Public comments on the policy will be accepted through September 21, 2000 and announce a final policy by the beginning of November. The proposed policy would be phased in over a two-year period following its publication date. The proposal can be found at *http://ori.dhhs. gov/TheRCRPolicy.htm*.

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CHANGING OF THE GUARD IN HUMAN SUBJECTS PROTECTION

Founded in 1972, the Office for Protection from Research Risks (OPRR) was, until recently, the prominent federal agency regulating and monitoring NIH-funded research. But in June 2000, OPRR, which was housed within the NIH, was replaced by the new Office of Human Research Protections (OHRP), which is located in the office of the Assistant Secretary for Health of the Department of Health and Human Services (HHS). OHRP will have broader responsibilities than OPRR, since it is responsible for monitoring and regulating all HHS funded research. OHRP will be assisted in its tasks by the National Human Research Advisory Committee, a twelve member independent panel, whose members have not yet been chosen. Unlike its predecessor, OHRP will not oversee NIH-funded research involving animal subjects. Instead, animal research will be monitored by a new office at the NIH, the Office of Laboratory Welfare.

The first director of the newly formed OHRP is E. Greg Koski, the current director of human research affairs at Partners HealthCare System, Inc. and an associate professor of anesthesiology at Harvard Medical School. He will take over as director of OHRP in September, and will report directly to the Assistant Secretary of Health, Surgeon General David Satcher.

The OHRP's chief responsibilities will be regulatory and educational. In its regulatory capacity, OHRP will monitor over 4,000 institutions performing human subjects research funded by HHS to ensure that they are in compliance with federal rules governing the use of human subjects in research. OHRP will also work with all 17 federal agencies involved in human subjects research that adhere to the Common Rule, a code of federal regulations governing human subjects research. On the educational side, one of OHRP's primary tasks is to ensure that all clinical investigators, IRB members, and others involved in human subjects research receive adequate training in bioethics. Further information about the Office of Human Research Protections is available at *http://ohrp.osophs.dhhs.gov/*.

JB

FINES FOR VIOLATIONING RESEARCH ETHICS

In December, President Clinton asked the Department of Health and Human Services (HHS) to "develop a plan to ensure that mandatory safeguards for individuals participating in clinical trials are upheld." This action responds to public fears about the safety of clinical trials, some of which stem from recently publicized lapses of patient/subject protections. HHS set forth steps to enhance human subject safety in clinical trials, including sending Congress a legislative proposal to authorize civil monetary penalties for researchers and institutions found to be in violation of regulations governing human clinical trials. [*PER* Vol. 13, No. 3]

The penalties proposed range up to $250, 000 per clinical investigator, and up to $1 million on the institution that employs them. The fines are part of a broad plan by HHS Secretary Donna Shalala "to better protect the thousands of patients who volunteer in medical experiments each year." However, punishing clinical investigators with monetary fines is controversial. Senator Bill Frist (R-TN) declared that the idea is "somewhat premature, " and Gerald Levy, dean of the medical school at the University of California at Los Angeles, said that the imposition of fines will " drive people out of doing clinical research" and will "cause a great deal of chaos." But Shalala maintains that the actions "are designed to further strengthen government oversight of all biomedical research" and "to reinforce institutions' and researchers' responsibility to follow internationally accepted ethical standards."

Additional Congressional action has been taken by Representative Dianne DeGette (D-CO), who has proposed legislation (H.R. 4605) titled "Human Research Subjects Protection Act of 2000," aimed to strengthen the Institutional Review Board's network.

RG

ETHICS, LAW AND PUBLIC POLICY

Conflicts of Interest in Human Subjects Research

by Margot Iverson and Sheryl L. Wallin

Margot Iverson is Assistant Editor and Sheryl L. Wallin is a Contributing Editor for *Professional Ethics Report* .

In the year since Jesse Gelsinger died while participating in a gene therapy trial at the University of Pennsylvania, concerns have grown that the financial interests of some clinical researchers may be jeopardizing the safety of human subjects. In response to these concerns, the federal government, along with several scientific associations and academic medical centers, are attempting to address this issue. What follows is an update of some of many recent events that have taken place relating to financial conflicts of interest and the protections of human subjects.

NIH clarifies position

In May, NIH issued a new set of guidelines and initiatives intended to clarify existing policies on financial conflicts of interest for researchers, and to further improve current safeguards protecting human research subjects. The guidelines re-emphasized requirements for institutions receiving NIH grant money, stressing their responsibilities for maintaining written and enforceable policies on conflicts of interest, for keeping their research investigators informed of such policies, and for reporting any conflicts which may exist. Under the new guidelines, Institutional Review Boards (IRBs) were also provided with strategies for considering conflict of interest issues in their review of specific protocols.

Conflicts of Interest Meeting convened

On August 15-16, the Department of Health and Human Services (DHHS) sponsored the *Conference on Human Subjects Protection and Financial Conflicts of Interest* at NIH. Over 700 government officials, IRB members, academic administrators, and representatives of professional associations and patient advocacy groups attended the meeting, which was convened in order to obtain community responses on what the Department can do to manage financial conflicts. Discussion at the meeting focused on the definition of conflicts for individuals, IRBs, and institutions; the obligation to disclose financial interests to subjects; and the appropriate role for the federal government. Representatives from the federal government, professional societies, and academic medical centers spoke about what needs to be done to protect human subjects adequately. Presentations were made detailing current financial conflict policies at several institutions, including Johns Hopkins University and the Children's Hospital of Boston. Breakout sessions and a public comment period did not yield much consensus aside from the clear preference that the government not over-regulate this issue, but instead allow institutions and societies to establish their own policies. At the meeting's conclusion E. Greg Koski, the new head of the OHRP, called financial conflicts in clinical research a "real and serious threat," and promised that this issue will be a priority for the new office. He warned that if guidelines did not work regulations would be forthcoming. See *http://aspe.hhs.gov/sp/coi/index.htm*

Congress Holds Hearing on Financial Conflicts in Vaccine Development

As part of an ongoing investigation into federal vaccine policy, House Government Reform Committee Chairman Dan Burton (R-IN) called a hearing in June to investigate potential conflicts of interest in federal oversight of vaccine development. Burton's concerns focused on individuals' participation on FDA/CDC vaccine advisory committees while holding financial ties to the pharmaceutical companies that manufacture the vaccines, provided that such interests are disclosed to the agency. In Burton's view, this practice has interfered with evaluations of the efficacy of several vaccines, including the rotavirus vaccine, which was removed from the market last year when it was found to have caused serious side effects in several children.

Not all members of Congress appear to share Burton's concerns regarding conflicts of interest in federal oversight panels. Just last year, Rep. Henry Bonilla (R-TX) introduced the Sound Scientific Practices Act (H.R. 2639), a bill stating that "Persons with substantial and relevant expertise shall not be excluded" from panels charged with reviewing the scientific data underlying OSHA safety standards "merely because they represent entities which may have

potential interest in a standard under consideration," provided the interest is "fully disclosed." The bill does, however, make an exception for panelists evaluating standards meant to apply to a single company, in which case representatives of the firm in question would be prohibited from serving as the panelists. The bill has not yet reached the House floor.

Human Research Subjects Protection Act of 2000 Bill Introduced

In June a bill was introduced in the House of Representatives by Rep. Diana Degette (D-CO). The "Human Research Subjects Protections Act of 2000" (H.R. 4605) seeks to amend aspects of the human subjects protection regulations of the Public Health Services Act. Among the proposed amendments is a requirement that as part of a consent form "an investigator engaged in research in human subjects shall disclose to the subjects investigator financial interest in the research, including capitation payments…sponsors of the research and any conflicts deemed necessary by the Institutional Review Board." The bill has not yet reached the House floor.

Harvard Medical School Retains Strict Conflicts Policy

After considering a change to its policy on permissible financial interests for faculty members, Harvard Medical School decided in May to retain its current policy. The retained policy, considered stringent in comparison to those of many other universities, places limits on the amount of money faculty members may receive from companies and consulting firms. Researchers are not allowed to own more than $20,000 worth of stock in companies for which they do research, and are not allowed to receive more than $10,000 from a company for royalty or consulting fees. The proposed changes would have increased the dollar limits for both of these policies. The only aspect of the policy that will now change is that new guidelines will be developed to protect students from conflicts they may arise because of

their faculty supervisors' financial interests.

NEJM Takes Stand

An editorial in the May 18 edition of the *New England Journal of Medicine* (*NEJM*) called for a ban on certain kinds of financial interests on the part of researchers. The editorial "Is Academic Medicine for Sale?" stated that "certain financial ties should be prohibited altogether, including equity interest and many of the writing and speaking arrangements." Marcia Angell, a former editor-in-chief of the journal who wrote the editorial, also spoke on this topic at the NIH conflicts conference. The *NEJM* announced in February 2000 that it had broken its own financial conflicts guidelines 19 times over the last three years [*PER* Vol. 13 No.1].

Professional Societies Address Conflicts

At the NIH meeting Koski challenged scientific societies to "take bold steps" and enact specific policies regarding financial conflicts of interest. Several scientific societies have already made efforts to address the issue. The Association of American Universities (AAU) has established a task force to study human subjects protection, and the group plans to meet again in October to consider how to address the issue of financial conflicts of interest with regards to IRBs. Both the American Society of Human Genetics (ASHG) and the American Society for Gene Therapy (ASGT) have issued policy statements on financial conflicts of interest in clinical trials. [*PER* Vol. 13 No.2]

IN THE SOCIETIES

ISEE CREATES INTEGRITY AWARD

At the Annual Meeting of the International Society for Environmental Epidemiology (ISEE) in August, the society established a new award for researchers who have demonstrated exceptional integrity in protecting public health above any other interest. The field of environmental epidemiology often touches on issues that have policy implications. Hence, research in this arena may affect or be perceived to affect parties with vested interests, either social or financial. Epidemiologists may then be subjected to pressures that run counter to the goals of scientific endeavors designed to provide understanding of the environmental influences on human health.

The ISEE Research Integrity Award will recognize environmental epidemiologists demonstrating integrity in the face of unusual pressure from special

interests to: (1) not conduct an investigation of a sensitive issue; or (2) suppress the publication of results unwanted by an entity with a vested interest in maintaining the status quo; or (3) alter the results and interpretation of a study to better suit a position held by a vested interest.

SS

ANNOUNCEMENTS

The *Journal of the American Medical Association* and the BMJ Publishing Groups invite abstracts for the **Fourth International Congress on Peer Review in Biomedical Publication**, to be held September 14-16, 2001, in Barcelona, Spain. Abstracts on any aspect of editorial peer review, scientific publishing, and the dissemination of scientific information will be considered. Topics of interest include: mechanisms of peer review and editorial decision making, online and Web-based peer review, conflicts of interest, scientific misconduct, economics of peer review and scientific publication, and the future of scientific publishing. Abstracts are due January 15, 2001. Contact Annette Flanagin, JAMA, (312)464-2432, Email *jama-peer@ama*; or Jane Smith, BMJ Publishing Group, London, [44]171-

383-6109, Email *jsmith@ bmj.com*. WWW *http://www.jama-peer.org*.

A **Research Conference on Research Integrity** will be held on November 18-20, 2000, in Bethesda, Maryland. The Conference, which will have international participation, is the first comprehensive effort to bring together scholars from different disciplines to share research results, discuss methods, and advise on future research directions. The Program includes over 70 papers and poster presentations and will be followed by a Grant Writing Workshop. The conference is sponsored by the Office of Research Integrity and co-sponsored by the American Association for the Advancement of Science, the Association of American Medical Colleges, the National Science Foundation, and the National Institutes of Health. Contact Nicholas H. Steneck, Professor of History, LSA, & Ethics, Engineering, University of Michigan, (734)764-6305, Fax (734)647-4881, Email: nsteneck@umich.edu, or Mary Scheetz, U.S. Office of Public Health and Science Office of Research Integrity, (301)443-5302, Email *MScheetz@osophs. dhhs.gov*. WWW *http://ori.dhhs.gov/whats new.htm*.

Grant Program Announced—The Office of Research Integrity (ORI, DHHS) and the National Institute of Neurological Disorders and Stroke (NINDS, NIH) invite applications to support research on research integrity. "Integrity" in this context is understood as "adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms." The purpose of the proposed grant program is to foster empirical research on the institutions, processes, and values that positively and/or negatively influence integrity in research. The sponsoring agencies are particularly interested in studies that will inform policy making at DHHS, NIH, and research institutions, with the goal of fostering appropriate attention to integrity in publicly funded research programs. The grant application deadline is December 15, 2000. See the NIH RFA announcement for details about the grant application *http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-01-008.html*

The **International Ethics Survey** is hosted on the World Wide Web by Science's Next Wave. You are invited to participate in an international Web-based survey of scientists and engineers being conducted by the American Association for the Advancement of Science (AAAS) and UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology (COMEST). The survey seeks to identify the ethical issues that advances in science and technology are likely to raise in the 21st century. To complete the survey, please visit http://www.nextwave.org

The **Third Biennial Friends Research Institute (FRI) Ethics Conference**, The Business of Human Experiments: Ethical, Legal, and Regulatory Issues, will be held November 3-5 in Baltimore, Maryland. The Conference will explore the following topics: the role of biomedical research in society; the evolution of the university/industry relationship in biomedical research; the role of IRB's in protecting the public; the growth of the Contract Research Organizations (CRO's); and the necessity of a National Human Subject Protection Act. Speakers and participants will be from the federal government, industry, and academia, and the public is invited to attend. Contact the Conference Division, Friends Research Institute, 505 Baltimore Avenue, P.O. Box 10676, Baltimore, MD, 21285. (410)763-7620, Email *fri@dmv.com*, WWW *http://www.friendsresearch.org/newsethics.html*.

The **Association for Practical and Professional Ethics Tenth Annual Meeting** will be held March 1-4, 2001, in Cincinnati, Ohio. Submissions of formal papers, pedagogical papers, demonstrations, curriculum projects, and case studies are invited on ethical issues in specific fields (e.g. the environment, engineering, computer science, medicine, research and the academy) and on issues that cut across professions. Deadline for submissions is October 15, 2000. Highlights of the meeting program include: a keynote address by Peter Singer, Princeton University, the mini conference "Taking Stock: Practical and Professional Ethics and the 21st Century," the Ethics Center Colloquium, and the Seventh Intercollegiate Ethics Bowl. Contact the Association for Practical and Professional Ethics, Indiana University, 618 East Third Street, Bloomington, IN, 47405. (812)855-6450, Email appe@indiana.edu, WWW *http://php.indiana.edu/~appe/home.html*.

Public Responsibility in Medicine and Research (PRIM&R) and Applied Research Ethics National Association (ARENA) announce two upcoming meetings. IRBs: Afloat in a Sea of Change, co-sponsored by Tufts University School of Medicine, and University of California at San Diego, will be held on October 29-30, 2000. IRBs: New Directions in 2000, will be held October 31, 2000. Both meetings will convene in San Diego. Theses meetings will help IRBs balance requirements, desires, and realities; develop educational offerings, better understand what can be expected from the newly relocated Office of Human Research Protection (OHRP); and learn about innovative and

successful ways to build a better human research protection program. Contact PRIM&R and ARENA, 132 Boylston Street, 4th Floor, Boston, MA 02116. (617)423-4112, Email *info@primr.org* WWW *http://www.aamc.org/research/primr*.

The **IEEE Technology and Society Magazine** is planning a special issue for September 2001 on "Engineering Ethics: Continuing and Emerging Issues." Submissions are invited on such topics as: engineering ethics and "globalization"; role of professional ethics in research ethics; technology, ethics, and healthcare; ethical issues in product liability; ethical issues and social impacts of information technology; role of professional engineering societies in ethics promotion and support; history of engineering ethics in the late 20th century; and engineering ethics and engineering design. Deadline for submission is December 31, 2000. Electronic submissions preferred. Contact: Joseph R. Herkert, Guest Editor, Division of Multidisciplinary Studies, Box 7107, North Carolina State University, Raleigh, NC 27695-7107. Email *jherkert@ieee.org*.

The Harvard University Center for Ethics and the Professions invites applications for **Faculty Fellowships in Ethics 2001-2002**. Teachers and scholars who wish to develop their ability to address questions of moral choice in such areas as business, education, government, law, medicine, public policy, and social science are encouraged to apply. Applicants should hold a doctorate or professional degree. Preference will be given to those who are at an early stage in their field. Deadline for receipt of applications is December 1, 2000. Contact the Center for Ethics and the Professions, Harvard University, 79 JFK Street, Cambridge, MA 02138. (617)495-1336, Fax (617)496-6104. Email *ethics@harvard.edu*. WWW *http://www.ethics.harvard.edu*.