

# Professional Ethics Report



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## THE ETHICAL RESPONSIBILITY OF MONITORING SCIENCE AND TECHNOLOGY – Is the Focus of Ethicists in Developed Nations Too Narrow?

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On March 9, 2009, many within the scientific community rejoiced when U.S. President Barack Obama lifted the ban on government funding of stem cell research. Additionally, with President Obama's memorandum on scientific integrity and plans to "restore science to its rightful place," [1] many scientists reveled at the opportunity to do more with their work. This, sequentially, provoked fervent reaction of elation, caution, or worry from numerous ethicists and others exploring the social implications of research. However, how far do these sentiments travel beyond the United States and other industrialized countries? The scientists that rejoiced at the expanded opportunity and the ethicists that acutely responded may be localized in select nations with enough capacity to support new innovation. But, the "rightful place" of science may differ depending on whether one views it from a Western or global perspective.

"Hot-button" issues that currently bombard and rattle the U.S. landscape of science ethics include stem cell research, emerging technologies such as neurotechnology and nanotechnology, responsible conduct of research, and the acceptable uses of human reproductive

technology. Yet, these pursuits may seem esoteric to a developing world overwhelmed by poverty and spread of infectious disease. According to a 2008 study by the World Bank, 1.4 billion live in poverty [2], and the World Health Organization has estimated that 14-17 million die each year of infectious disease [3]. Science and technology (S&T) have the potential to address these problems, yet many advances do not reach the places in most need of them.

More ethicists examining the implications of S&T may want to raise the question of why S&T is *not* bringing more benefits to developing regions. Ethicists may want additionally to examine how innovation can migrate or thrive in nations with urgent need for the potential benefits of S&T. For example, in the field of bioethics, Leigh Turner, a professor from McGill University, states, "Many of the questions that bioethicists address only make sense within the context of wealthy developed nations. . . Greater consideration of global ethical issues related to health, illness, and suffering might generate a richer, more meaningful research agenda for bioethics" [4].

If it does become normative for ethicists from developed nations to incorporate international concerns into their work, they should stay clear of imposing the ideals of their given society and Western culture. At a 2002 meeting organized by the European Group on Medical Ethics, Dr. Nicholas Meda, an epidemiologist from Burkina Faso, cautioned his European audience by stating, "Dogmatic interpretation of universal ethical principles in medical research will paralyze research efforts to improve HIV/AIDS prevention and treatment in sub-Saharan Africa" [5]. In both Turner

and Meda's scenarios, some Western ethicists are thinking through a narrow lens by either ignoring the rest of the world or spreading their particular version of ethics.

Developed nations have the capacity to push continually the boundaries of S&T, and more resources than developing countries to examine the ethical implications of newfound innovation; but they do so, perhaps, with an extremely limited scope. The impacts of advances developed by higher income nations extend beyond their borders. Because science is a global enterprise, ethicists from developed regions may, in turn, want to broaden their focus, consider the international impact of the science and technology they monitor, and be respectful of different cultures and values in order to critique *responsibly* and *comprehensively* the social, ethical, and legal implications of S&T.

### *Where Work in Science Ethics is Taking Place*

In 2005, the United Nations Educational, Scientific, and Cultural Organization (UNESCO) launched a Global Ethics Observatory (GEObs), an online network of databases containing information from throughout the world on ethics experts in S&T, ethics institutions, ethics teaching programs, ethics related legislation and guidelines, codes of conduct, and resources in ethics of S&T. UNESCO designed GEObs as a way to support advancing ethics activities across the globe by allowing GEObs' information to be used for consultation and comparison purposes. However, of the 2431 total entries of experts, institutions, programs, legislation, codes, and resources in GEObs, almost half are from Europe and North America [6].

The majority of scholarly work in applied ethics in S&T is not occurring in developing nations. This is reflected in the number of journal publications in the field of bioethics. Based on articles published from 1990 to 2003 in the world's leading peer-reviewed journals in bioethics, Borry, *et al.*, found that authors from developed countries submitted 96.1% of research articles, whereas scholars from developing nations contributed only 3.9% [7]. Furthermore, they observed no rising trend in the amount of published work from developing countries. This is also reflected in the number of institutions tackling the issue of global climate change and ethics. For example, 10 out of the 16 members of Collaborative Program on the Ethical Dimensions of Climate Change, launched by the United Nations Framework Convention on Climate Change in 2004 [8], are from Europe and the United States.

Low-income nations are, perhaps, not doing more in terms of science ethics because structures fostering good biomedical and scientific practices, like a stable economy, fair government, or an established health care system, are largely absent. Local institutions and individuals may feel it imperative to ameliorate immediate socio-economic injustices before building ethical frameworks for S&T. Conversely, without ethical frameworks, the benefits of science and technology, which may alleviate injustices such as those

addressing resource allocation and food and water scarcities, may not be realized. Because scientific dilemmas and ethical issues in developing countries can be so entrenched and associated with structural conditions that perpetuate poverty, inequity, instability and corruption, local and foreign ethicists may feel ill-equipped to tackle a complex milieu of problems. However, the complexity should not deter ethicists from acknowledging barriers and doing what they can to help developing nations build their science and ethics capacities.

#### *Whose Responsibility?*

Individuals in developing nations do not have the means to pursue the science and associated ethical research in these areas. Hence, if those in lower income countries wish to proceed with cultivating an ethical culture in S&T, they could proceed in either of two ways – 1) rely on developed nations, and presume their models fit the scientific and ethical needs of the local community, or 2) take the initiative to begin dialogue with developed nations, learn from their models, and apply them to local institutions.

China has taken the latter approach. Its expansion in research and research ethics presents a promising example of successfully building an ethics framework outside Western borders. China's role in research has increased in recent years. For its research to be recognized in prestigious, peer-reviewed journals, China has sought to establish an ethical culture acceptable to the nations publishing these journals, which mainly are the U.S. and the UK. For instance, China has developed stronger rules and guidelines on research ethics, as exemplified by its 2007 release of human subjects regulations by the Ministry of Health. Prior to 2007, human subjects regulations were only applied to human subjects in drug clinical trials. Whether or not the expansion of the rules may have been motivated to genuinely protect human subjects, Article 4 of the

regulations state, "Ethical review shall comply with the country's laws/regulations/rules, and recognized bioethical principles" [9]. Where do these "recognized principles" come from? Considering that Yale University, Harvard School of Public Health, University of Chicago, University of Minnesota and the University of San Francisco were involved in the first human subjects research training workshops in China in 2004-2006, and the U.S. National Institutes of Health was involved in the first training workshop after the new regulations [10], one can infer that many of these recognized principles are Western-influenced.

If nations, like China, build their capacity for ethics in S&T to be recognized solely in the broader scientific community and respected in Western publications, there is a danger of standardizing ethics to the point that indigenous values and principles are no longer recognized. For instance, autonomy – a principle to uphold while conducting human subjects research, as highlighted by the Belmont Report – might have different meanings across societies. Autonomy may be granted differently to persons in different states, as illustrated by Egyptian society. Rashad, *et al.*, observe that a woman's autonomy is subordinated to male authority, and that the patriarchal Muslim society in Egypt contributes to the lower rate of literacy among Egyptian women. Both of these factors affect decisions about informed consent of Egyptian women in human subjects research [11]. How can practices such as these be reconciled with "recognized" notions of ethics?

To ignore local values and practices in order to adhere to acceptable ethics of S&T is problematic. To be embraced, self-sustaining, and enduring in developing nations, standards, whether in ethics of S&T or in any other field, must be relatable and deeply rooted in the indigenous culture. For example, Dr. Veerabhadran Ramanathan, a climate scientist at Scripps Institute of Oceanography who determined that black carbon emitted from cookstoves of third world villages "[is] the second strongest contribution to current global warming, after carbon dioxide emissions," [12]

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**Letters to the Editor:** The editors welcome comments from our readers. We reserve the right to edit and abridge the letter as space permits. Please address all correspondence to the deputy editor.

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acknowledges that acceptance from local communities of new technology that emit less soot is vital [13]. Practices established to satisfy only recognized notions of ethics will not be wholly reflective of a nation's identity and its need to improve its scientific and technological capabilities. Neither will these practices have the potency to be sustained in the community. Hence, to establish a strong culture of ethics in science and technology, guiding nations must be careful not to impose their ideals, and developing nations must not surrender their culture for the sake of efficiency and acceptance in the broader scientific and ethics communities.

#### *Future Directions for Science Ethics in a Globalized Environment*

Funding organizations (mainly based in developed nations), international bodies, academic institutions, knowledgeable actors, local participants, and peer-reviewed journals must encourage more publications from developing nations that investigate how S&T impact the developing world. An international body of original research is out there. On March 28-29, 2009, the American Association for the Advancement of Science, in collaboration with Arizona State University, École Nationale Supérieure des Mines de Paris, George Mason University, George Washington University, Georgetown University, and Virginia Tech hosted an international graduate student conference on the social, legal, and ethical implications of S&T [14]. Representatives from across the globe presented original research on topics such as the absence of engineering ethics in China [15], achieving energy justice in all sectors of society [16], innovative ways to apply information and communication technologies (ICTs) to farming techniques in Ghana [17], and exploring the impacts of technological globalization on the mobilization of indigenous peoples in Latin America [18].

Research is being done on the globalized impact of S&T. However, at the conference, much of the research that considered science ethics in a global perspective was from foreign students studying in U.S. universities with student

visas, or U.S. students observing S&T's impacts in foreign countries – not from students studying in developing countries. Perhaps in the current context, there is a dearth of ethics education outside high-income nations. Yet, it should not hinder students from developing countries and their nations to encourage more education programs abroad. UNESCO has established an Ethics Education Programme (EEP), which maps ethics teaching programs throughout the world and aims to develop a core standard of curricula, using input from various regions [19]. Other international organizations like the InterAcademy Panel (IAP), a network of science academies throughout the world, the International Council for Science (ICSU), a non-governmental organization that promotes international activities in the different scientific disciplines and its applications for human benefit, and the Academy of Sciences for the Developing World (TWAS) are taking steps to build science and ethics capacities in developing nations, with the cooperation of local communities. With support from organizations like these, successful and sustainable programs abroad may be able to house indigenous brain-power poised to bolster activities and supporting structures that apply their own set of “recognized” ethics.

#### *Conclusion*

To responsibly and comprehensively analyze the social, ethical, and legal aspects of S&T and remain in tune with the global nature of science and technology, more ethicists in the developed world should increasingly consider S&T's international impacts and relevancy to different cultures. Social barriers to achieve ethical conduct with regard to science and technology must not deter, but encourage ethicists to increase their scope beyond “hot-button” issues. It remains important to talk proactively about issues like embryonic stem cell concerns and nanotechnology, but such concerns should not overwhelm discussions on the ethics of S&T. In addition, privileged nations must not remain focused on what they know in terms of ethical standards, and expect that others will follow suit once they are ready to acknowledge the need for more ethical frameworks. Conversely,

developing nations should not surrender their ideals and submit to Western standards merely to become recognized in the scientific and ethics communities. Much reflection needs to occur to reconcile the ethical standards of developed and developing nations, and more original research from developing nations is needed for this to happen. However, for the voices of the developing world to be heard in the global science ethics community, more support and reflection from funding organizations in industrialized nations, international bodies, academic institutions, knowledgeable actors of the developed world, local participants, and peer-reviewed journals is also required.

[1] U.S. President Barack Obama's 2009 Inaugural Address, January 21, 2009, <http://www.whitehouse.gov/blog/inaugural-address/> (Accessed 4/16/09).

[2] Chen, S., Ravallion, M. (2008), “The Developing World is Poorer than We Thought, but No Less Successful in the Fight against Poverty,” *World Bank*.

[3] See [http://www.globalhealth.org/infectious\\_diseases/global\\_view/](http://www.globalhealth.org/infectious_diseases/global_view/) (Accessed 4/16/09).

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[7] Borry, P., Schotsmans, P., Dierrickx, K. (2005), “Developing Countries and Bioethical Research,” *The New England Journal of Medicine*, 353:8.

[8] See <http://rocketics.psu.edu/climate/policy/edcc.shtml> (Accessed 4/17/09).

[9] Ministry of Health of the People's Republic of China (2007), “Regulations on ethical review of biomedical research involving human subjects,” <http://61.49.18.91/publicfiles/business/htmlfiles/mohkjjys/s3581/200804/18816.htm> (Accessed 4/4/09).

[10] Renzong, Q., “Capacity Building: Training for Research Ethics in China,” Presentation at the Global Forum Plenary Session on Building an Infrastructure through Training: Best Practices and Lessons, Vilnius, Lithuania, June 28, 2007.

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[13] Rosenthal, E., (2009), "Third-World Stove Soot is Target in Climate Fight," *The New York Times*, April 15, 2009.

[14] See <http://stglobal.org> (Accessed 4/4/09).

[15] Guo, F., "The Absence of Engineering Ethics in China and its Solutions: An STS Perspective," Presentation at *Science and Technology in Society Conference*, Washington, DC, March 28, 2009.

[16] Smart, A., Lampton, C., Veerabhadrappa, V., Guo, F., Kurdegelashvili, L., "Policies for Achieving Energy Justice in Society: A Case Study on Solar Energy Technologies in Low-Income Housing," Presentation at *Science and Technology in Society Conference*, Washington, DC, March 28, 2009.

[17] Addom, B., "ICTs for Synergy: A Case Study of Scientific Knowledge and Local Farmers' Innovative Activities in Ghana," Presentation at *Science and Technology in Society Conference*, Washington, DC, March 28, 2009.

[18] Green-Barber, L., "Indigenous Peoples, Technological Globalization, and Social Mobilization," Presentation at *Science and Technology in Society Conference*, Washington, DC, March 28, 2009.

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## In the News

### NEXT WORD ON GINA

In 2008, Congress passed the Genetic Information Nondiscrimination Act (GINA). Title II of this act is designed to protect employees, applicants, and former employees from discrimination based on personal genetic information. Prior to taking effect, Article II requires that the Equal Employment Opportunity Commission (EEOC) issue implementing regulations to provide all those who fall under the jurisdiction of Title II further guidance. The EEOC's proposed rules, released in March, offer a section by section analysis of Title II, and invite written comments from members of the public regarding these regulations.

The EEOC's proposed rules begin by outlining and clarifying the definition of key terms found in Title II. Significant terms include "employee," specifying

that GINA covers job applicants, current and former employees, members of labor unions, apprentices, and trainees, and the term "covered entity," clarifying that those subject to GINA include employers, employment agencies, labor organizations, and training and apprenticeship programs on federal, state, and local levels. The proposed rules define genetic tests as "analysis of human DNA, RNA, chromosomes, proteins, or metabolites, which detects genotypes, mutations, or chromosomal changes." Public comments are being sought, however, as to whether to broaden the scope of the term 'genetic test' to include tests that are not specifically genetic, such as a test for drug or alcohol abuse or a test for communicable or infectious diseases that are transmitted through food handling. The regulation also specifies definitions for "family member," "family medical history," "genetic information, monitoring, and services," and "manifestation or manifested."

The proposed rules outline activities prohibited by Title II of GINA. Title II prohibits employment agencies, labor organizations, and any apprenticeship or training program from causing or requiring an employer to act discriminately. Title II also forbids retaliation by an employer against any employee who seeks redress for an act made unlawful by GINA. The regulation describes Title II's prohibition of an employer's unlawful acquisition of genetic information. Title II disallows employers from requesting genetic information from applicants or employees or from purchasing genetic information about an applicant or employee.

The EEOC then addresses certain exemptions to the regulations. The first area of exemption pertains to the rule barring employees from obtaining genetic information about employees or applicants. Certain circumstances exist in which an employer would not be held accountable for obtaining genetic information. For example, if they unintentionally obtained genetic information, such as through "commercially and public available" sources, such as books or newspapers, or through overhearing an employee talk about a hereditary genetic disorder. The acquisition of genetic information would

also be permissible if it were for law enforcement or for the monitoring of the biological effects of toxic substances in the workplace. Title II mandates strict confidentiality regarding any information taken or shared under these circumstances.

Exceptions to Title II also exist with respect to confidentiality. There are certain instances in which it would be lawful for an employer, employment agency, or other labor organization to divulge genetic information of employees or applicants. These organizations may release information to researchers conducting research in compliance with regulations under 45 CFR part 46. Genetic information may also be disclosed to government officials investigating compliance with the statute or to investigators in compliance with a court order. Genetic information may also be released as required by the Family and Medical Leave Act (FMLA), or to any federal, state, or local official in connection with a contagious disease that poses an immediate hazard of death or life-threatening illness.

The EEOC invites public comments on the proposed rules and Title II in its entirety. They can be accessed through the *Federal Register* at <http://frwebgate1.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=320170354770+0+2+0&WAIAction=retrieve>. Comments are due by May 1, 2009.

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### RESEARCHERS AND IRBS RECEIVE NEW GUIDANCE ON COMPLIANCE WITH GINA

Biomedical researchers and institutional review boards (IRB) now have a new tool to assist them in adhering to the requirements of the recently passed Genetic Non-Discrimination Act (GINA). The Office for Human Research Protections (OHRP) has produced a guidance document for investigators and institutional review boards to assist in compliance with GINA. The guidance document discusses the implications of GINA for investigators who conduct, and IRBs that review, genetic research, primarily with respect to the criteria for IRB approval of research and requirements for obtaining informed

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consent. The document also includes suggestions on how researchers and IRBs could incorporate GINA's requirements into their own policies.

The guidance document suggests that IRBs carefully consider the protections provided by GINA in determining whether proposed research projects satisfy the criteria for IRB approval. In approving research, an IRB must verify that a proposed project meets a number of requirements outlined by GINA. These requirements include assuring that the risks to human subjects are minimized, guaranteeing that risks to human subjects are reasonable in relation to the benefits, and providing adequate provisions to protect the privacy of the subject and maintain the confidentiality of genetic data. OHRP points out that GINA will cover research begun before the act was made law, and thus researchers and IRBs should immediately begin to consider the above mentioned guidance. The document points out that GINA will significantly reduce the risks of insurers or employers obtaining genetic information, favorably affecting the risk-benefit assessment for genetic testing.

ORHP also recommends that IRBs and investigators take into account the protections offered by GINA when developing and reviewing consent processes and documents. GINA requires researchers to provide a description of any reasonable foreseeable risks or discomforts posed to the subjects and a statement describing the extent to which the confidentiality of the subjects' medical records will be maintained. Investigators and IRBs should consider including a description of the above stated protections provided by GINA in their consent processes and documents. If such a description is included, investigators and IRBs must ensure that these descriptions do not overstate the protections offered by GINA. Some important details that should be included in such a description include the fact that many provisions do not enter into force until late 2009 or early 2010, that GINA addresses employment and health coverage only, not life insurance, disability insurance, or long-term care insurance, and that GINA generally does not apply to employers with fewer than

fifteen employees. Investigators and IRBs should also understand that regardless of when genetic information was obtained, the use of this information is restricted as soon as GINA takes effect.

OHRP's complete guidance document can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html>

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### **FDA RELEASES NEW GUIDELINES ON ADVERSE EVENTS REPORTING**

In January 2009, the Food and Drug Administration (FDA) announced the availability of new guidelines for adverse event (AE) reporting to Institutional Review Boards (IRBs). These guidelines are designed to assist sponsors and investigators of clinical trials in differentiating between unanticipated problems that need to be reported to their IRB and those that do not, and to assist them in communicating with their IRB more efficiently. The guidelines are a response to the recent increase of vague and unnecessary AE reports.

FDA regulations state that all clinical studies involving human subjects must be submitted to and subsequently overseen by an IRB, whose purpose is to assess continuously the degree of risk the experimental treatments pose to human subjects. Information about unanticipated adverse effects during the trials is critical for an IRB to carry out its duties. The review boards have recently reported increasing volumes of individual, unanalyzed adverse events reports. These reports, designed to provide specific and thorough analyses of unanticipated problems, are intended to assist IRBs in improving human subject protection. However, the mass amounts of vague reports are inhibiting, rather than improving, the IRB's ability to protect human subjects.

The FDA recommends a number of steps the IRBs, researchers, and sponsors, could take to streamline the process of AE reporting. For example, the guidelines suggest an AE should fit into one of several outlined categories before being reported to the IRB. These categories include single occurrences that are uncommon, but related to drug exposure, multiple occurrences that have

not been previously observed, or multiple occurrences that occur at a frequency or

severity not previously observed. Another FDA suggestion is that in multicenter studies, the creation and/or reporting of AEs should be left to the sponsor, and not to the individual investigators.

The ultimate goal of the FDA guidelines is to decrease the quantity while increasing the quality of AE reports, thus assisting IRBs in more effectively protecting the rights and safety of human test subjects.

The full text of the FDA guidelines can be accessed at <http://www.fda.gov/cder/guidance/OC2008150fnl.htm>.

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### **OIG: NSF NEEDS TO IMPROVE METHODS FOR DETERMINING CONFLICTS OF INTEREST**

It is a regular occurrence for the Office of the Inspector General (OIG) to receive complaints about conflict of interest violations in the National Science Foundation's (NSF) merit review process. The OIG has recently identified an inconsistency in how NSF handles conflict of interest (COI) disclosures – that measures NSF uses to determine conflicts of interests for panelists conducting on-site reviews are much more extensive than those for ad hoc reviewers. Panelists are given an extensive COI lecture before discussing the proposal. Additionally, they are asked to review a list of examples of COIs and to certify that they have no such conflicting affiliations or relationships.

NSF has not, however, taken these steps when assessing conflicts of interest in ad hoc or remote reviews. Ad hoc reviewers are asked to use FastLane, an NSF website, to conduct their proposal reviews. Instead of being given a COI briefing or a list of potential COIs to review and report, FastLane simply asks ad hoc reviewers to describe any connections they may have with the particular proposal. This lack of guidance

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for ad hoc reviewers regarding COIs creates a situation in which NSF may not be informed of possible COIs, thus tainting NSF's merit review.

As a result, the OIG has issued a series of recommendations to improve NSF's COI disclosure process. The OIG recommended that NSF change its COI form so as to include "certification language that reviewers have disclosed all COIs" along with incorporating a legal warning of the consequences of violating the certification. A second recommendation is that NSF improve FastLane to include more helpful information regarding COIs, along with adding a check box requiring ad hoc reviewers to verify their certification before being given proposals. Lastly, the OIG recommended that NSF better inform its grantees and reviewers about COIs through the creation of a COI FAQ website, along with internet training programs for both PIs and NSF program officials.

After asking for and being granted an extension of the deadline for its response, NSF has since provided a full response to all of the recommendations provided by the OIG. This response will be discussed in the next OIG semi-annual report, due out in the Spring 2009.

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## **OBAMA TAKES FIRST STEPS TO RESTORE SCIENTIFIC INTEGRITY**

Since his inauguration, President Obama has made no attempts to hide his desire to make science an essential part of his policymaking process. As part of his commitment to "restore scientific integrity in decision making," Obama released a memorandum in March discussing the significant role of science in policy making. The memorandum also stressed the importance of creating an environment in which the American public can trust the science underlying Obama's policies.

The memorandum highlights the vitality of science and its important role in achieving a broad range of national goals. It states that scientific progress should be considered in all areas of decision

making, including public health, the environment, energy, climate change, and national security. The public must be able to trust the quality and integrity of scientific information behind these policies. To address these concerns, the President Obama has asked the Director of the Office of Science and Technology Policy (OSTP) to develop recommendations that will ensure scientific integrity throughout the executive branch. Such recommendations must ensure that officials neither suppress nor change scientific findings, and that such findings are made available to the public. The recommendations are to guarantee transparency in the "preparation, identification, and use of scientific and technological findings in policymaking." Finally, the recommendations should ensure that science professionals in the executive branch are hired based on knowledge, credentials, experience, and integrity. The OSTP will have 120 days to develop these recommendations. The full memorandum can be accessed at [http://www.whitehouse.gov/the\\_press\\_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/](http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/)

In concert with the President's memorandum, the Bipartisan Policy Center's Science for Policy Project released a report on how OSTP could implement the memorandum on scientific integrity. It can be accessed at <http://www.bipartisanpolicy.org/ht/a/GetDocumentAction/i/9982>.

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## **NSF RELEASES PLANS TO IMPROVE RCR TRAINING**

Ethical and responsible research practices are essential for excellence and public trust in science. Consequently, quality education about the responsible conduct of research (RCR) is considered an essential part of preparing America's future scientists. With that in mind, the National Science Foundation (NSF) recently proposed an implementation plan for Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act. Section 7009 mandates that institutions applying for NSF funding provide an RCR training program for their research staff.

The first step of NSF's proposed implementation policy is to increase the opportunities for RCR training by grantees' researchers. This step requires that a proposing institution's Authorized Organizational Representative certify that the proposed research project offers a program through which each researcher/staff member participating in the NSF funded project is educated and appropriately trained on the responsible and ethical conduct of research. NSF funding requirements will be changed to include these training programs as a prerequisite for support. While the proposing institution will not have to present details of its planned RCR training, they will be subject to NSF review upon request.

The second step to NSF's proposed implementation aspires to increase the quality of the training that is given through the establishment of an online database of training materials. This online digital library will be comprised of "findings, pedagogical materials, and promising findings regarding the ethical and responsible conduct of research in science and engineering." The database will be compiled by the research communities the NSF supports. It is hoped that the database will become a valuable resource in training future scientists and engineers.

Public comments regarding the proposed implementation plan were due March 31, 2009. The NSF identified some areas in which it was particularly interested in the public's opinion. Those areas included challenges the institution might face in complying with the regulations, the role Principal Investigators should play in this compliance, the pros and cons of different compliance plans, and how online resources might be helpful in training students and postdoctoral researchers. NSF also requested public comment on possible approaches to verifying that the proposing institutions are providing requisite training.

The NSF's proposed implementation procedures can be found in the *Federal Register* at <http://edocket.access.gpo.gov/2009/pdf/E9-4100.pdf>

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## BRINGING UNIVERSITIES TO THE FOREFRONT OF ACADEMIC DISSEMINATION

Among the purposes of a university, the creation and dissemination of new knowledge through research and scholarship is one of the most important. Without effective dissemination of this new knowledge, however, its benefit is negated and the original thinking of university faculty is wasted. Thus, the diffusion of this information is as important as the information itself. The recent shift to the widespread use of digital technologies is changing how universities must approach the dissemination of new scholarship. Universities have customarily relied on formal publication systems for distribution of scholarship, but new digital technologies have opened the door to additional and broader dissemination possibilities and entirely new content.

In response to the growing importance of the university's role in dissemination of scholarly information, a study group formed by the AAU, ARL, CNI, and NASULGC recently proposed a set of recommendations for actions to be taken by the university community to enhance its ability to distribute new academic work. The study group stated that recent developments in information technologies have created an extraordinary opportunity for scholars to express and transmit their knowledge more widely than before. The same developments are allowing much more extensive access to this information around the globe. Unfortunately, these opportunities have been impeded by the universities' outdated publishing methods.

Traditional university publishing methods are based on the outsourcing of academic information through the sale of their copyrights. Universities have assumed that wide dissemination of academic information required the total concession of copyrights to the publishing journal. Alternative digital technologies, such as audio, video, and internet resources, provide substantial means through which universities could distribute their information while maintaining substantial rights to their own work. Universities must begin to

promote circulation processes that maintain copyrights, while pushing for maximum utilization of the diverse ranges of dissemination.

The study group recommended that universities, along with retaining rights to their work, seek to replace their tenure and promotion practices. These practices rely heavily on rewarding faculty members based solely on publication through traditional journals. This outdated basis for promotion and tenure forces faculty to focus primarily on publication through journals instead of utilizing alternative dissemination methods. Focusing on journal publications strengthens the ability of outside institutions to control dissemination and hinders academic innovation. Universities need to develop more effective publishing and promotion models, ideally ones that maintain some critical features of traditional publishing methods, while creating incentive for innovation in academia and dissemination methods.

The study group suggested several means through which universities could modify their publishing methods and seek broader means of dissemination. The group emphasized the need for universities to seek assistance from scholarly societies and university presses. Additionally, the group also accentuated the benefits of integrating new dissemination models into existing university technology environments. With appropriate dissemination and rights managements strategies, existing resources could be utilized and developed to maximize a university's ability to distribute its scholarly work. Such a strategy would also maximize a university's past investments in technology.

The study group's primary recommendation to universities is to "initiate discussion involving administration and faculty about modifying current practices and/or intellectual property policies such that the university retains a set of rights sufficient to ensure that broad dissemination of the research and scholarly work produced by its faculty occurs." The group hopes that by adhering to the aforementioned suggestions, and also a number of other related actions detailed in its report, universities will be able to update their

current policies to provide the best dissemination methods, making future academic innovation possible and ensuring wider access to this knowledge.

The full report can be accessed at <http://www.arl.org/bm~doc/disseminating-research-feb09.pdf>

\*MB

## ATSDR CAUSES MORE PROBLEMS THAN IT SOLVES

The Agency for Toxic Substances and Disease Registry (ATSDR) was created in 1980 to protect American citizens from harmful exposure and diseases related to toxic substances. After recent studies, however, it seems that ATSDR has caused more harm than it has prevented. Last September, the House of Representative's Subcommittee on Investigations and Oversight released a detailed staff report highlighting ATSDR's gross errors and the harm that these errors have caused to the American people. The report criticizes ATSDR's faulty leadership for a complete lack of effective public protection against toxic hazards.

The report highlights that ATSDR leaders are often unwilling to confront the most obvious health hazards and their effects on American citizens. Instead, it seems the main goal of the ATSDR is to prove that the community's claims of toxic hazards are false, rather than attempting to substantiate such claims. The report states that even in cases where ATSDR does initiate research into a possible threat, its leaders often downplay these threats, which are often later found by other investigators to pose serious risks to the public.

The Subcommittee highlights ten examples of events where the public has been exposed to a toxic hazard and ATSDR's response has been insufficient. One example criticizes ATSDR leadership for failing to address formaldehyde spills after hurricane Katrina. Another criticizes how ATSDR downplayed the threat of lead levels in Washington D.C.'s water in 2002. Both cases were dismissed by ATSDR leadership. Yet, both were subsequently studied by independent groups and found

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to pose significant health risks to the public.

ATSDR's Office of Science is in charge of creating and releasing public health reports, the main source for public health information regarding potential toxic hazards. The investigation found that the Office of Science is severely understaffed to handle its enormous volumes of documents. Additionally, the Subcommittee found that it frequently engaged in "wordsmithing," changing the words of reports to downplay threats or achieve certain objectives.

The investigation was severely hampered in its review of Office of Science employees. Interviews were almost always in groups, constraining participants in offering their frank opinions. The Subcommittee has received numerous complaints from ATSDR employees in the past, yet only one employee attended an open comment session held during the Subcommittee's investigation, suggesting that a large percentage of employees remain fearful of raising critical concerns with the agency's leadership.

The Subcommittee investigation cast serious doubt on the agency's effectiveness under current leadership and protocol. The Subcommittee states that legislative actions may be necessary to address long-standing structural issues, but that no fundamental changes will occur until the employees, the majority of whom remain dedicated to protecting public health, have leaders they can follow. As long as the agency's leaders refuse to address serious public health problems, and continue to produce deeply flawed public health reports, ATSDR will continue to harm the communities it was designed to protect.

The report by the Subcommittee on Investigations and Oversight on Science and Technology can be accessed at [http://democrats.science.house.gov/Media/file/Commdocs/hearings/2009/Oversight/12mar/ATSDR\\_Staff\\_Report\\_no%20photos.pdf](http://democrats.science.house.gov/Media/file/Commdocs/hearings/2009/Oversight/12mar/ATSDR_Staff_Report_no%20photos.pdf)

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## Announcements

**Conference** - UNESCO Chair in Bioethics, Israel National Commission for UNESCO, the International Center for Health, Law and Ethics, and the Zefat Academic College are hosting the International Conference on Ethics Committees in Zefat, Israel on May 17-20, 2009. The conference will be an international platform for exchange on topics such as establishing bioethics committees, programs for continuing bioethics education, and different kinds of bioethics committees. Visit: <http://www.isas.co.il/bioethics2009/>.

**Conference** - PRIM&R is hosting its *May Regional Programs* for IRB members, chairs, administrators, and research staff in San Diego, CA on May 6-8, 2009. Visit: [http://www.primr.org/Conferences.aspx?id=6485&ekmense=297ded8b\\_363\\_0\\_6485\\_2](http://www.primr.org/Conferences.aspx?id=6485&ekmense=297ded8b_363_0_6485_2).

**Conference** - The International Society for Bioethics (SIBI) is organizing the 4<sup>th</sup> World Conference on Bioethics in Gijón, Spain from May 18-21, 2009. The conference will discuss themes of hunger, poverty, bioethics, biotechnology, and informed consent. Visit: <http://www.sibi.org/ingles/act/6Congreso/pinf.htm>.

**Conference** - AAAS and the Food and Drug Law Institute are convening the first of three colloquia on personalized medicine on June 1-2, 2009 in Washington, DC. The colloquium will address scientific discoveries, business models, and regulatory changes, as well as electronic health records, reimbursement, education, and ethical, legal, and policy issues. Visit: <http://www.aaas.org/spp/PM/colloquia>.

**Conference** - On August 26-28, 2009, the Nanoethics Research Group, the Center for Innovative Nanotechnology, and the Center for Ethics of Science and Technology at Chulalongkorn University will host *Nanoethics Asia*, a workshop to discuss the ethical, social, cultural, and legal implications of nanotechnology in the context of Asia and other non-Western regions. Visit: <http://www.stc.arts.chula.ac.th/NEA2009/>.

**Conference** - The Sixteenth Session of the International Bioethics Committee of UNESCO will be held in Mexico City on May 4-6, 2009. Main topics of the meeting include the principle of social responsibility and health as set forth in the Universal Declaration on Bioethics and Human Rights, and human cloning with respects to international governance. Register at [www.unesco.org/bioethics](http://www.unesco.org/bioethics) before April 25, 2009.

**Competition** - The Fuqua/Coah K. Center on Leadership and Ethics at Duke University's Fuqua School of Business is having a Doctorate Dissertation Proposal Competition. Doctorate candidates whose research contributes to the understanding of leadership and ethical issues facing the community should send their applications to [coledissertation@duke.edu](mailto:coledissertation@duke.edu) by May 15, 2009. Winners will receive \$1,000. Visit: <http://www.fuqua.duke.edu/centers/cole/competitions/dissertation/index.html>.

**Event** - On April 30, 2009, federal agencies, including the Smithsonian and the Uniformed Services University, will host "The Caring that is Health: the Gift of Nursing and Nursing Research in American Society" at the National Museum of Art, Washington, DC. Visit: <http://www.thechiefinformationgroup.com/conference/smithsonian/index.php?cid=6>.

**Grant** - PRIM&R is awarding small grants to professionals in the early stages of their career who are studying, teaching, and/or writing about research ethics. Application deadline is June 30, 2009. Visit: <http://www.primr.org/AboutUs.aspx?id=6625>.

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