Professional Ethics Report

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ADVANCING SCIENCE, SERVING SOCIETY

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ENGAGING SCIENTISTS AND APPLYING SCIENCE TO ADVANCE HUMAN RIGHTS

Mona Younis

Mona Younis, Ph.D., joined AAAS in 2007 as Director of the Science and Human Rights Program. Prior to joining the Association, she was human rights Program Officer at the Mertz Gilmore Foundation, overseeing funding programs for human rights in the U.S. and internationally as well as immigrant rights.

Scientists, like most people, are not necessarily aware that governments have a range of obligations to meet in the area of human rights. Once they know, they will be eager to contribute their expertise to the important work being undertaken to realize human rights, and will develop many new ways of doing so. The AAAS Science and Human Rights Program (SHRP) has set out to test those propositions through two program areas devoted to engaging scientists and applying science to human rights ends.

Why Scientists?

From a set of principles first articulated in the Universal Declaration of Human Rights, and adopted by the UN General Assembly in 1948, human rights has evolved into an elaborate system of international laws, institutions, and mechanisms focused on what governments must do to ensure the wellbeing of people – all people, everywhere. The ethical standards embodied in international human rights law establish governments' obligations to "respect, protect, and fulfill" the rights that provide for the minimum that people require to live fully human lives. The realization of even minimum standards, however, requires considerably more concerted effort.

Scientists have much to contribute to that endeavor. Substantively, science and scientific expertise are fundamental to many of the recognized human rights, such as health, receiving and imparting information, a healthy environment, and adequate food, to name but a few. Technically, scientists have ample tools, techniques, and technologies to contribute to enhance the work of human rights practitioners in monitoring human rights, preventing violations, assessing governments' progress in meeting their human rights obligations, and more.

The legal community, with its rich tradition of *pro bono* service and human rights advocacy, is considerably ahead of most professions in its engagement in human rights. Indeed, until very recently human rights work was viewed as synonymous with legal work. As human rights organizations developed their capacities to address the full spectrum of human rights – civil, cultural, economic, political, and social – and as governments have sought guidance on how to meet their obligations in these areas, human rights work has taken on a variety of forms. SHRP believes scientists are essential to these efforts and has designed two program areas to expand the mobilization of science and scientists for human rights.

Science for Human Rights

Many times over the course of the evolution of the human rights system, science has provided timely and vital contributions. SHRP's first such contribution came soon after its establishment in 1977 when, in the wake of Argentina's "Dirty War," it responded to a request by the new civilian President, Raúl Alfonsín, and the human rights group Mothers of the Plaza de Mayo for help in exhuming mass graves. In 1984, SHRP dispatched forensic and genetic scientists to Argentina to help identify the victims and document the crimes, and to identify children who had been forcibly taken from former dissidents for adoption by supporters of the previous regime. Two decades later, SHRP is using satellite imagery to document human rights violations involving destruction of housing and infrastructure, which it has applied in Zimbabwe, Chad, Lebanon, and elsewhere. In addition to expanding the application of geospatial technologies to expose a range of human rights violations that have already occurred, SHRP is working with human rights partners to determine how the technology can be used in prevention. One such partnership with Amnesty International-USA (AIUSA) produced the recently launched campaign, "Eyes on Darfur," which is using satellite imagery to monitor the fate of 12 villages under threat of attack, in the hope of providing them with a measure of protection.

Between SHRP's application of forensic and genetic sciences in the 1980s and geospatial technologies in the 2000s, it pioneered other applications, such as statistical and information management techniques and electronic encryption technologies, for human rights work. Recognizing both the potential and the need for additional human rights appropriate scientific tools and technologies, SHRP is devoting a program area to the identification and application of new discoveries and adaptations of science.

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Some technologies that SHRP is currently exploring for potential human rights uses are wireless communications technologies, structure mapping, and budget analysis.

Accompanying SHRP's pursuit of science for human rights ends is a commitment to transfer the skills to and build the capacity of human rights organizations to use the science and technology themselves. The model is SHRP's early work in establishing, training, and supporting local teams of forensic anthropologists in Latin America, which resulted in the formation of two internationally renowned organizations – Equipo Argentino de Antropología Forense (Argentina) and Fundación de Antropología Forense de Guatemala (Guatemala) – that today conduct forensic work throughout the world. Similarly, in the area of geospatial technologies, SHRP's training and technical assistance enabled AIUSA and other human rights organizations to begin to incorporate remote sensing, geographic information systems, and other geospatial technologies into their work. Such a transfer of skills is intended not only to strengthen human rights organizations' scientific capacity and appreciation of science, but also to ensure the use of the technology where it is most needed – in the field – and, in the long run, will enable SHRP to move on to identifying and cultivating other scientific inputs and applications.

These creative and practical applications of science to real and immediate human rights problems grew out of communication between scientists and human rights practitioners. To increase such contributions, SHRP will invest in creating a variety of opportunities that link the science and human rights communities together to enable scientists to learn about emerging human rights needs and human rights advocates to consider science-based solutions.

Scientists for Human Rights

SHRP is ideally positioned to reach and engage scientists through its access to the 262 societies and 130,000 individual members that are affiliated with AAAS, which make it the largest multi-disciplinary scientific membership organization in the world. SHRP will enlist scientific societies in human rights efforts through the Science and Human Rights Coalition – a network of AAAS-affiliated scientific societies and professional associations with human rights sections or working groups – and will engage individual scientists through a variety of activities designed to bring their expertise to human rights work.

Through the Science and Human Rights Coalition, SHRP will create opportunities for scientific and professional associations to hear directly from human rights advocates to consider the relevance of international human rights law and norms for their respective fields and the potential of their fields to enhance the work being undertaken to uphold those laws and norms. By bringing scientists together across fields – the life, physical, social, and behavioral sciences – the Coalition has the potential of becoming an important venue for the generation of new cross-disciplinary initiatives in the service of human rights.

Ongoing communication between the two communities also will serve to expand human rights practitioners' knowledge of how, by improving measurement, indicators, and the collection of evidence, for example, science-based methods can strengthen their work and help remedy problems encountered in the field. Additionally, by combining the voices of hundreds of thousands of its members, the Coalition will augment the impact of those societies' efforts on behalf of colleagues whose human rights are at risk and on human rights issues more broadly.

To tap the expertise of individual scientists for the human rights work being carried out, SHRP is developing an array of formats and activities to engage scientists from a variety of disciplines. Inspired by the legal community's tradition of *pro bono* consulting, SHRP will be developing a network of "on call" scientists to advise and assist human rights organizations, national human rights commissions, and field offices of the UN Office of the High Commissioner for Human Rights. These *pro bono* consultancies will provide human rights practitioners the opportunity to avail of the wealth of expertise available through AAAS, both in-house and through the Association's members.

With an eye to the future, SHRP will establish other means, such as a fellows program and graduate fellowships, to support young scientists in researching human rights-specific problems in their graduate work, in the process contributing to recognition of the human rights field as a rich and rewarding terrain for scientific inquiry and contribution.

SHRP will collect and compile the know-how that emerges from these various applications to create an online resource for the human rights community. Ultimately, the objective is to develop an extensive repertoire of scientific applications and contributions that can be shared, transferred, developed, adapted, and refined globally.

Together, these programs will provide scientists a range of opportunities to contribute their expertise to the human rights work being carried out to realize

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Editor: Mark S. Frankel
Deputy Editor: Caitlin E. Gamble
Contributing Authors: Diana Calla, Celia Smith, and Jennifer Sta. Ana

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the world envisioned by the framers of the Universal Declaration of Human Rights. We hope you will join us in that endeavor!

For more information about these and other activities sponsored by SHRP, please visit http://shr.aaas.org/.

IN THE NEWS

THE "DON'TS" TO HANDLING RESEARCH MISCONDUCT

The U.S. Office of Research Integrity (ORI) offers technical assistance to institutions managing research misconduct charges. On May 1, 2007, ORI's Division of Investigative Oversight (DIO) posted on its website thirteen problem areas of which institutions must be wary when handling misconduct allegations. Below are the thirteen problem areas, each followed by a brief description (to see the full notification go to: http://ori.hhs.gov/misconduct/Problemareas.shtml):

1) **The initial allegations are handled by the laboratory director rather than immediately informing the Research Integrity Officer (RIO)** - This could be a serious problem, since it typically results in improper sequestration [of research data and materials].

2) **Sequestration of research records is not conducted in a timely way or is inadequate -** Prompt notification of the RIO of allegations is vital…[T]he RIO must act in a careful way to assess the allegations, and, if they warrant action…promptly sequester the relevant records. Taking too long to do this, or talking to witnesses, including the probable respondent, prior to sequestration, can allow guilty parties to alter or destroy critical raw data and other records.

3) **Inquiry and investigation committees lack appropriate expertise** - …[T]he lack of appropriate expertise can lead to a failure to adequately identify and review the raw data, so that conclusions are based on an incomplete analysis.

4) **Interviews are poorly conducted and annotated when discussing exhibits. Many are not recorded or transcribed** - The new regulation, 42 C.F.R. part 93, recommends that inter views be recorded during the inquiry and requires that this be done for the investigation.

5) **Committees and institutions are intimidated by aggressive outside counsel -** Although it is obviously important to provide due process to the respondent and other witnesses, a well written institutional policy and procedure, if carefully followed, can help enormously in dealing with a constant stream of letters from the respondent's attorney.

6) **Institutions often intentionally do not follow up on new allegations that are uncovered during the inquiry or investigation -** This is contrary to the requirements of the regulation and compromises the ability of the institution to identify the duration and scope of the possible misconduct.

7) **Institutions often provide little or no support to whistleblowers -** Institutions should provide a support mechanism for complainants so they do not feel as isolated as they often do at present…

8) **Inquiry and investigation reports are poorly documented, failing to provide either a meaningful summary of the evidence or a rationale for the findings –** …[Institutional] committees and officials expect DIO's oversight to be perfunctory, and their reports frequently do not meet the guidelines in the regulation or those routinely transmitted to the RIO when acknowledging the institution's notification of ORI of its progressing to an investigation.

9) **Institutions do not handle admissions well** - Many are legally insufficient, lack specificity and fail to admit to falsification or fabrication of data. Others are insufficient because they were either not written, or were not signed in the presence of witnesses, and thus are easily retracted. Lastly, many are made by respondents anxious to limit the scope of the findings made against them, and institutions often wish to minimize their effort and wish to accept the admission…and do not independently review the rest of the respondent's research for evidence of a broader set of misconduct issues.

10) **Many institutions are lax in following NIH guidelines on retaining research records** - Historically, one of ORI's most enduring problems is the lack of primary data.

11) **Institutions could do a better job of providing guidelines to senior staff on their mentoring skills and responsibilities** - DIO believes that the single most effective tool in reducing the level of research misconduct by junior scientists is through better mentoring and monitoring of students and fellows.

12) **Many institutions have inadequate and out-of-date policies and procedures; student disciplinary procedures are often inappropriately applied when students are accused of research misconduct in PHS funded research** - Institutional policies and procedures vary widely in terms of their adequacy in how to properly deal with allegations of research misconduct and in their adherence to the appropriate Federal regulations. Most have not yet been updated to take into account the significant changes made in the June 2005 regulation (42 C.F.R. § 93).

13) **IRB committees are often given inadequate guidance and training in recognizing research misconduct issues, in contrast to protocol violations and other matters they are expected to handle** – [I]t is important that IRB members be both trained to recognize the difference between

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research misconduct and the issues they normally deal with, and to refer such matters immediately to appropriate institutional officials, rather than trying to handle the misconduct matters directly.

*JS

PROMOTING INTEGRITY OR MEDIOCRITY? FDA PROPOSES NEW GUIDELINES ON CONFLICTS OF INTEREST

On March 15, 2007, the U.S. Food and Drug Administration proposed guidelines to better assess conflicts of interest for appointment to FDA Advisory Committees. The draft is intended to restrain industry influence over committee members and safeguard public health during FDA's approval process. Previous endeavors, such as the "FDA Waiver Criteria 2000," did not sufficiently curb conflicts because, according to the Draft Guidance, the document's efforts to consolidate the FDA's incongruous laws made it challenging for "Centers and offices…to achieve consistent results that the public could readily understand."

The draft seeks to offer a simpler approach in the form of a six-step flowchart (See: http://www.fda.gov/oc/advisory/waiver/ACAlgorithm.pdf). Upon navigating the algorithm, if FDA staff determine committee members have a financial interest over $50K, participation in the advisory meeting is prohibited. Under special circumstances, those with financial interests under or equal to $50K could receive a waiver for non-voting participation only. The proposed cutoff of $50K is half the existing threshold of $100K.

The new guidance has received both praise and criticism. U.S. Rep. Maurice Hinchey (D-N.Y.) was quoted in the *Chicago Tribune* stating, "By ending the practice of allowing FDA advisory boards to be filled with voting members who have financial conflicts of interest the agency is taking an important step toward ensuring that the only interest advisory board members have when voting to approve a drug or device is that of the health and safety of American consumers." A very different point of view is expressed in the editorial, "Probity gone nuts," in the May 2007 issue of *Nature Biotechnology,* which characterizes the guidelines as an effort to promote public relations and appease political strategies, while "mak[ing] expert recruitment more difficult, resulting in delayed committee meetings and ultimately lengthened drug approval times. Worse still, it will encourage scientific mediocrity on panels." The editorial also claims that the FDA guidelines are misdirected, referring to a study published in *JAMA* (295:1921-1928, 2006), which found that advisory committee members are swayed more so by competitor conflicts than financial ties with companies connected with deliberated products.

To see the draft guidelines, go to: http://www.fda.gov/oc/advisory/waiver/COIguidedft.html. The deadline for public comment was May 21, 2007.

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SCIENCE WITH HONOR: THE SCIENCE COUNCIL OF JAPAN'S CODE OF CONDUCT

Following a disturbing number of scientific misconduct issues, both in Japan and elsewhere, the Science Council of Japan has expressed concern with loss of public trust. "Even misconduct by one scientist can compromise public trust in the scientific community at large, as well as the intellectual activities of science in general," the Council wrote in a statement approved last October. The statement delineates a Code of Conduct for Scientists and includes a document entitled, "Toward Autonomous Implementation of the Code of Conduct for Scientists." Both documents can be viewed at: http://www.scj.go.jp/ja/info/kohyo/pdf/kohyo-20-s3e-1.pdf.

The Council noted the changing dynamics of the research environment, with intense funding competition and an increase in non-tenured employment, placing greater pressure on individual research scientists to produce results quickly. Yet, as outlined in the Code of Conduct, science has a responsibility to improve people's health and welfare, the safety of society, and the sustainability of the global environment. "[F]or science to contribute to realizing a more affluent human society through its own sound growth and development, scientists must establish ethical norms to strictly control their own conduct, while fulfilling their obligation of accountability to society…."

According to the Code, scientists should work to assure the quality of expert knowledge, act with honesty and integrity at all stages of the research process, observe all laws, give proper consideration to the welfare of research subjects (including due respect for animals), engage in respectful relations with others, and manage conflicts of interest. However, the Code goes even a step further. It charges scientists to strive in understanding the relationships between science and society and to evaluate the potential implications of their work. In doing so, they should "neutrally and objectively disclose the results" of such an evaluation and build a "constructive dialog with society."

The supplementary document requests that universities, colleges, research institutions, academic associations, and funding agencies act independently to establish codes that will facilitate open environments and prevent misconduct. The Council's Code outlines broad guidelines applicable to all academic fields, and given the spirit of these guidelines, the document asks individual research groups to establish codes salient to their specific disciplines. Such codes would speak specifically to the creation of a self-monitoring system overseeing ethics, the education of young scientists on ethical issues, as well as a means for handling misconduct accusations.

The Council's document notes that groups need to establish proper channels for consultation on misconduct issues. Anyone reporting a suspicion of misconduct should not suffer as a result. Relevant facts should be investigated promptly, with impartiality, and the final result should be made public.

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DOD GRANT AND FACULTY OPPOSITION IGNITES CONTROVERSY OVER STANFORD RESEARCH

After rejection of a proposed ban on tobacco company funding (http://daily.stanford.edu/article/2007/5/18/tobaccoFundingBanFails), Stanford's research policies have taken center stage in yet another controversy- this time over a Department of Defense (DOD) grant, which allots $105 million for a multi-institution U.S. Army High-Performance Computing Research Center (AHPCRC). The project focuses on development of nanotechnologies, lighter materials for military equipment, wireless communications, and improved supercomputing. While DOD funding is nothing new to the university research community, the size and scale of this grant has compounded concern among Stanford faculty.

On June 1, 65 faculty members submitted a letter to University leadership expressing concerns with the proposal's transparency, the ethical implications of supporting research with direct military applications, and possible violations of University rules. "While we wholly endorse fundamental principles of academic freedom," the letter states, "it seems reasonable to draw attention to an ethical regime that imposes careful strictures on even very innocuous forms of human-subject research … but which applies no scrutiny to a huge, long-term project aimed at enhancing the destructive capacities of the military." Much of the letter's concern arises from language in the government Program Announcement (PA) soliciting proposals. The faculty letter advocates public release of Stanford's successful proposal as well as open debate concerning its ethical implications.

The letter questions the honesty with which the Center's research endeavors have been represented to the public. According to faculty, while Stanford press releases have focused on basic research and spin off-technologies, PA document language states that system designs from the Center should enable "a significant increase in combat effectiveness." The structure of the Center's leadership suggests a high degree of Army collaboration for applied research. Of similar concern, is how an "outreach provision" of the grant to promote math, engineering, and computing in nearby schools "may in fact be envisioned as a feeder system, designed to use Stanford's name, prestige and resources to channel gifted students toward interest and experience in military applications."

Augmenting transparency concerns is PA language referring to a requirement that the Center's 11 staff scientists be "U.S. citizens… capable of acquiring secret clearances." University policy forbids non-disclosable research. Furthermore, its policies restrict "agreements which permit discrimination on the basis of citizenship." Without a fuller discloser of the successful proposal, it is unclear whether it stands in conflict with these policies. Also unclear is the power held by the Army's manager (CAM) with regard to the research agenda. To faculty expressing concern, the CAM's authority "appears to constitute a form of veto power that seems to contradict the University's own guidelines concerning faculty independence" and concepts of academic freedom.

The Center's lead scientist from Stanford, Prof. Charbel Farhat, expressed surprise with the letter. He told the *Stanford Daily* that the Center's research is not classified. He supports making the proposal public, and he emphasized that the 17 faculty authors of the proposal care as much about academic freedom as their peers. The letter's authors await response from University administration and the Faculty Senate's Committee on Research, which will address whether university policies have been violated.
http://daily.stanford.edu/article/2007/6/1/opedTroublingDefenseGrantMayHaveStrings

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THE RIGHT TO EXPERIMENTAL TREATMENTS

On May 19, 2007, a little girl from New York died of a rare and virulent form of cancer, leaving people to wonder: what if four-year old Penelope London had been granted permission to undergo treatment with experimental cancer drugs? Would they have saved her life, or would they have made her even more ill? These are the kinds of questions that currently face the FDA, pharmaceutical companies, doctors and patients.

The freedom to make choices about disease treatments conflicts with drug companies' obligations to place new products under rigorous—and time-consuming—testing and analysis before they are marketed. Organizations such as the Abigail Alliance are calling for legislation allowing patients to buy experimental drugs directly from pharmaceutical companies, once an illness outweighs the possible dangers of taking a medicine that has not been fully approved by the FDA.[1] Such transactions pose risks for drug companies as well as patients, since tests could be delayed for months if a patient taking the drug suffers adverse effects or dies.

Penelope suffered from neuroblastoma since she was 16 months old, and doctors estimated her chances of being cured were just 25%.[2] Traditional forms of therapy could not hold off the cancer, and the London family, in desperation, turned to experimental treatments. One of these was a virus, currently undergoing tests at Neotropix, Inc. Despite assurances from the FDA that, in this case, his company would suffer no delays if the treatment caused harm, Neotropix CEO Peter Lanciano refused the Londons' request. He feared the consequences of using an unapproved drug on a child, both for Penelope's sake and for that of his company. Penelope's father, John London, argued that the risk of harm was irrelevant, since his daughter was already suffering.

Following Lanciano's refusal, the Londons heard of a similar treatment, this time from Jennerex Biotherapeutics. Oncologist William Carroll of the NYU Medical Center agreed to treat Penelope with the drug, but only after he had obtained special permission to administer a live virus. Despite efforts to significantly speed up this process, the decision wasn't made fast enough, and Penelope passed away a few weeks later. Perhaps her life could not have been saved with

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the unapproved drugs, but it is a chance that many other patients are willing to take, and an issue that pharmaceutical companies and the FDA will have to reconcile, as they question how best to apply their resources for the greater good.

[1] *The Abigail Alliance for Better Access to Experimental Drugs Home Page*. http://abigail-alliance.org/
[2] "Saying No To Penelope." *The Wall Street Journal Online*. 1 May 2007. http://online.wsj.com/article/SB117798196751887629.html

*CS

NEUROTECH GETS IN UNCLE SAM'S HEAD

Within the past three months, two organizations in the field of neurotechnology have announced support for a National Neurotechnology Initiative (NNTI). Both the Center for Neurotechnology Studies (CNS: http://www.potomacinstitute.org/academiccen/cns.htm) at the Potomac Institute for Policy Studies and the Neurotechnology Industry Organization (NIO: http://www.neurotechindustry.org/publicpolicy/nationalneurotechinit.html) have met with representatives from Congress and other agencies to discuss the need for such a program, as well as what it might look like once implemented.

Supporters of the program envision that it would mirror the National Nanotechnology Initiative, which is a multiagency, multidisciplinary program coordinated by NSF to facilitate responsible research and development in the field of nanotechnology.

NNTI goals include the development of supporting infrastructure and tools needed to advance neurotechnology, development of an advanced interdisciplinary research and development program, facilitation of the transfer of new technologies into medicine, education and other areas that will benefit the public good, and support for responsible development by considering ethical, legal and social issues that might arise.

The NNTI would likely be administered by NSF, though the NIH is another possibility for that role. At a recent CNS event, Dr. Rita Colwell, former director of NSF, explained her belief that NSF would be better-suited for coordinating NNTI, predominantly because its focus is much wider than NIH's, and NSF could thus better facilitate the interdisciplinary approach. Dr. Colwell also described the ideal make-up for an Advisory Board to the Coordinating Office that would consist of people from business, community representatives, bioethicists, leading neurologists, and scientists from other disciplines. The inclusion of bioethicists in the above list is particularly important: the NNTI would look very carefully at ethical, legal, and social issues (ELSI) of neurotechnology, and would aim to do so in an anticipatory fashion as well as whenever new research requires new considerations.

One important policy implication for neurotechnology is its potential to dramatically transform education. Classrooms in 1900, 1950, and today look very similar to each other, indicating that up until this point we have done a great disservice to all students by failing to implement new knowledge about how people learn. The assumption that most classroom designs and curriculum plans are based on is that all kids learn in the same way, which is something that most people know intuitively (and some researchers are beginning to demonstrate scientifically) is not true. Thus, there is a hope that as neuroscience advances, neurotechnology can be applied to help people learn better. Perhaps kids who today are diagnosed with 'learning disabilities' are not so much disabled as they are ill-suited for the rigid structure of the current educational environment.

At the aforementioned CNS event, Dr. Colwell and Dr. Dennis McBride of the Potomac Institute both emphasized the need for creativity in research, something that they hope a NNTI can be structured to reward. They identified an early and ongoing focus on ethics and the interdisciplinary nature as the two most important elements the NNTI must have. The effort must be federally coordinated, because the requirements and goals of science and industry, especially at this juncture, are different, and without federal help, the contributions that science could make to the field will not be realized.

*DC

NAS ADDRESSES DATA INTEGRITY

In April, the National Academies' Committee on Assuring the Integrity of Research Data convened a meeting of experts from academia, journals, and government to discuss the difficulties of and recommendations for maintaining good data. The Committee is preparing a report on preserving data in light of new scientific and technological advancements. Comments from the meeting's speakers addressed key issues in several fields, guided by case studies of research in climate change, the life sciences, and the pharmaceutical and biotechnology industries.

Climatologists asked for more clarification of issues such as ownership, public availability, archival maintenance, and investigator responsibility. Codes, programs and models are essential to confirm reproducibility in addition to inputted data. Yet, key questions regarding these data remain unanswered: Are permission and compensation to use these codes and programs necessary, or should they be open for public use? And in terms of archiving data, should federal agencies, sponsors, or investigators be responsible for what information is archived, developing standards, updating the archive, and establishing infrastructure? Furthermore, in reference to the "Hockey Stick" controversy, a disputed graph published by Mann, *et al*.[1], which restructured temperatures from the last 1,000 years and was thrust into the national spotlight by the 2001 Intergovernmental Panel on Climate Change (IPCC) report, climate scientists found themselves harassed by lawmakers and by angry demands for data from "controversial bloggers." What are the investigators' duties for sharing information in these situations? Current problems with climatology data lie in the fact that these are new fields and that scientist are conducting themselves in an *ad hoc* manner in the absence of clear rules and guidelines.

Other case studies illustrated that standards for data sharing vary throughout different disciplines. Thomas Cech, President of the Howard Hughes Medical Institute, described understanding among

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researchers in the life sciences. According to the National Academies report, *Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences*, investigators follow a "commonly-held principle" known as "UPSIDE" (Uniform Principle for Sharing Integral Data and Materials Expeditiously). Public databases have also been accepted throughout the community, such as GenBank and PDB. Investigators know that in order to get published, data must also be submitted to a database to ensure credibility and potential reproducibility. Dr. Cech also highlighted some uncertainties. For instance, no consistent community standard exists for the sharing of software, and with greater overlap between academic and commercial interests, it is unclear if uniform principles should apply to both sectors.

Journal editors echoed the need for clearer standards. Editors for *The Journal of Cell Biology, Nature, Science,* and *Proceedings of the National Academy of Sciences* (PNAS), made recommendations for ensuring honest data in a "culture of image manipulation." In an age of electronic submission and PhotoShop, images can be easily processed and altered, like in the case of Hwang Woo-Suk, who adjusted the tonal range of his images to seemingly illustrate patient-specific embryonic stem cells from human SCNT blastocysts.[2] Journals need to routinely screen submitted images and develop software for detecting image manipulation. However, limited resources and the sheer quantity of papers have limited their ability to do so. As of April 2007, only *The Journal of Cell Biology* and *Science* are implementing routine screenings. Also, the editors expressed the need to impose effective sanctions. For example, PNAS had a case where a departmental chair refuted PNAS' conclusions and its rejection of a colleague's work. Although the journal can decline an investigator's future publications, it cannot enforce sanctions in his or her local departments.

From the academic institutions' perspective, data migration is a significant issue. Although library science has well documented data by keeping multiple copies, it has been increasingly harder to manage this task in a digital age. As technology advances, the medium for storing information becomes more fragile and unreliable. In the process of mining through data and transferring information to secure media, how can one discern what is important and accessible? Furthermore, who will pay for the transfer and provide accessibility? One speaker stressed that the university or funder should be responsible for data upkeep. Faculty members cannot be made responsible for "long-term stewardship" because researchers tend to move on once projects have concluded.

Government representatives also expressed funding concerns. A speaker from the White House Office of Science and Technology Policy (OSTP) pointed out that "no one wants to fund caretaking of research. Everyone wants to fund new research." If federal agencies are mandated to fund additional public access and maintain data, this could mean a significant decrease in new projects. Yet, as an executive body that coordinates projects among federal agencies, OSTP needs to promote preservation of both physical and digital data in dispersed, scientific collections.

However, before data are shared, they must be legitimate. One speaker observed that the real problem with data integrity first lies in research practices. Mentoring within the lab is important to produce quality science. Dishonest data would not be contrived if a lab had "a PI committed to integrity," and "a structure that supports that integrity, such as regular lab meetings, review of raw data before publication, and proper training."

Whatever the Committee report's final details, the two-day meeting demonstrated that communication and interaction among researchers, journals, academic institutions, funders, federal agencies, and government are vital to assure data integrity. In the spirit of fostering such communication, the Committee expressed strong interest in further communicating with the newly formed government Interagency Working Group on Digital Data. "You may have given this Committee a reason for its existence," stated one of the members to the Working Group's chair. The Committee hopes to provide a useful framework for addressing the data issues raised in a variety of fields, fully acknowledging respective fields' grievances and recognizing the commonalities and needed association among scientific communities.

For more information on the Committee on Assuring the Integrity of Research Data, visit:
http://www7.nationalacademies.org/data/

[1] Mann, M.E., R.S. Bradley, and M.K. Hughes (1999). "Northern Hemisphere Temperatures During the Past Millennium: Inferences, Uncertainties, and Limitations." *Geophysical Research Letters* 26 (6): 759-762.
[2] W. S. Hwang, *et al*.(2005). "Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts". *Science* 308: 1777-1783.

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PRIVATE SECTOR NANO GUIDELINES

Nanotechnology is a multidisciplinary field encompassing the manipulation of matter smaller than 1 micrometer. With advancements in a wide-range of fields, nanotechnology has many beneficial uses, such as rapidly delivering medication and eradicating pollutants. Conversely, it also carries potential risks.

In June 2007, DuPont and Environmental Defense released the "Nano Risk Framework" to evaluate the risks of developing nanomaterials. The guidelines are referred to by *The New York Times* as "the most extensive effort yet to address…the lack of information about whether materials in such minute sizes can pose novel or unexpected hazards." The Framework recommends that organizations evaluate potential nano research and technology as follows: 1) characterize nanomaterials and their applications; 2) identify properties, hazards, and potential human/environmental exposures; 3) assess risks; 4) determine management options and responses to risks; 5) decide and document how to continue production, and act accordingly; and 6) review risk assessment and adapt in light of needed changes. The Guidelines are

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accompanied by three case studies illustrating how they could be applied.

Critics cited in *The New York Times* dub the guidelines as unsound, complex for small businesses, and an obstruction to federal regulation and open discussion.

To see the "Nano Risk Framework," go to: http://www.environmentaldefense.org/documents/6496_Nano%20Risk%20Framework.pdf

To see *The New York Times* article on the guidelines, go to: http://nytimes.com/2007/06/21/technology/21nanotech.html?pagewanted=print

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RESOURCES

RESPONDING TO RESEARCH MISCONDUCT: SAMPLE POLICY AND PROCEDURES UPDATE FROM ORI

On May 17, 2005 the Public Health Service (PHS) issued a new final rule, Policies on Research Misconduct (42 CFR Part 93), that was published at 70 *Federal Register* 28379 and became effective June 16, 2005. The final rule sets forth a template for institutional compliance with detailed research misconduct proceedings, and it requires institutional written policies and procedures. To assist institutions in drafting these documents, the Office of Research Integrity (ORI) has provided new "Sample Policy and Procedures for Responding to Allegations of Research Misconduct," posted at: http://ori.dhhs.gov/policies/documents/SamplePolicyandProcedures-5-07.pdf. The Sample Policy and Procedures includes definitions, rights and responsibilities, general policies and principles, guidance for conducting assessment and inquiry, the inquiry report, conduct of the investigation, the investigation report, and institutional administrative actions. It also provides citations to relevant sections of the regulations.

Spurred by comments and questions from affected parties, the new document is a revision of an earlier version entitled "Model Policy for Responding to Allegations of Research Misconduct." The document's title has been changed to clarify that while it is intended to meet all of the regulatory requirements, it does not necessarily represent the best model for doing so. Institutions are free to use the Sample document as much or as little as they wish.

Sample Policy and Procedures, while drafted to comply with all regulations in the final rule, does not carry weight as a legal document. Ultimately, ORI compliance judgments will be based on regulations as set forth in the PHS Policies.

For more information, visit the ORI website at: http://ori.dhhs.gov/policies/PolicyPreamble.shtml

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American Anthropological Association
American Political Science Association
American Psychological Association
Association for Psychological Science
American Society for Engineering Education
American Sociological Association

ANNOUNCEMENTS

Call for Papers- The 8th International Conference on Ethics Across the Curriculum, to be held November 15-17, 2007 at the National University of Ireland, is calling for papers. Entries may be considered for publication in *Teaching Ethics*. Submissions should be sent by September 15. For more information and submission instructions, visit: http://www.rit.edu/~692awww/seac/Dublin07.pdf

Call for Papers - Surveillance and Society will be publishing a special issue on the future and effects of medical surveillance, and is seeking papers. (Nontraditional submissions, including art, poetry, opinion and reviews are also welcome.) Submissions should be sent in to Emily Smith (smithea@post.queensu.ca) by January 1, 2008. Inquiries regarding content of submissions should be directed to Sarah Earle (s.earle@open.ac.uk) or Carol Komaromy (c.komaromy@open.ac.uk).

Conference- The Computer Ethics Philosophical Enquiry (CEPE) will hold the Seventh International Computer Ethics Conference at the University of San Diego on July 12-14, 2007. For more information and to register, visit: http://cepe2007.sandiego.edu/.

Conference- The Pacific Institute for Ethics & Social Policy and the National Institutes of Health will hold an ELSI conference entitled, "Challenging Assumptions: Religious Faith, Genetic Science, and Human Dignity" October 12-14, 2007 in Portland, Oregon. For more information, visit: http://www.pacificinstitute.net/challengingAssumptionsConference/info.html.

Educational Event- On September 17-19, 2007, Public Responsibility in Medicine and Research (PRIM&R) will host three educational programs in Towson, MD: IRB Administrator 101, IBC Basics, and Essentials of IACUC Administration. These offerings are tailored specifically to the educational needs of Institutional Review Board (IRB)/Human Research Protections Program (HRPP), Institutional Animal Care and Use Committee (IACUC), and Institutional Biosafety Committee (IBC) members, administrators, and staff. Information can be obtained online at: www.primr.org, or please contact Mariellen Diemand (mdiemand@primr.org) with questions.

Grant- The National Postdoctoral Association, with support from the Office of Research Integrity, is offering seed grants up to $1000 to postdoctoral offices and associations for the support of responsible conduct of research (RCR) programming directed at postdocs. Applications are available at http://www.nationalpostdoc.org/RCR_SeedGrants. The submission deadline is July 27, 2007.

Nominations- AAAS is accepting nominations for the Scientific Freedom and Responsibility Award. The award is given to scientists or engineers or their associations whose exemplary actions have served to foster scientific freedom and responsibility. Such achievements can include: acting to protect the public's health, safety or welfare; focusing public attention on important potential impacts of science and technology on society by their responsible participation in public policy debates; or establishing important new precedents in carrying out the social responsibilities or in defending the professional freedom of scientists and engineers. For more information visit: http://www.aaas.org/aboutaaas/awards/freedom/index.shtml. Nominations are due August 1, 2007.