Professional Ethics Report

AAAS
ADVANCING SCIENCE, SERVING SOCIETY

Publication of the American Association for the Advancement of Science (AAAS), Scientific Responsibility, Human Rights & Law Program, in collaboration with the AAAS Committee on Scientific Freedom & Responsibility

VOLUME XXV NUMBER 2 SPRING 2012

FROM THE EDITOR

In December 2011, the Woods Hole Oceanographic Institute (WHOI) was subpoenaed by British Petroleum (BP) as part of its defense of lawsuits brought against the company as a result of the Deepwater Horizon oil spill in April 2010. WHOI is not a party to any of the lawsuits, but BP's attorneys argued that the scientific data collected by WHOI scientists were important to its defense. WHOI challenged the subpoena, but on April 20 a federal magistrate judge ordered the Institute to turn over the materials requested by BP.

The subpoena of research data from scientists uninvolved in ongoing litigation is not a new phenomenon; it's been happening for decades as scientific and technical matters have increasingly become more embedded in litigation.* Yet, the WHOI case is the most recent, and it raises serious questions about the relationship between law and science. To spur greater visibility and understanding of those issues, *PER* has reprinted, with permission, a Statement on the case and its implications for science by the WHOI that appears on the Institute's website (see http://www.whoi.edu/main/president-director/statement/scientific-deliberative-process). Additional insights into this matter can be found at http://bostonglobe.com/opinion/2012/06/02/reddy/Gt82ZS7yoi5sHTgDG5SLkN/story.html and http://www.sciencemag.org/content/336/6086/1219.full.pdf.

We welcome responses from our readers.

--Editor.

*Mark S. Frankel, "Private Interests Count Too," *Science and Engineering Ethics*, 15:367-373, 2009.

STATEMENT ON THE NEED TO PROTECT THE SCIENTIFIC DELIBERATIVE PROCESS

Dr. Susan K. Avery and Dr. Laurence P. Madin

Dr. Susan K. Avery *is the President and Director of the Woods Hole Oceanographic Institution. .* ***Dr. Laurence P. Madin*** *is Director of Research at the Woods Hole Oceanographic Institution*

A situation has arisen involving scientists at the Woods Hole Oceanographic Institution (WHOI) that should concern all those who value the principles of academic freedom and responsibility, and believe these principles to be essential to the integrity of the deliberative scientific process.

Today, Sunday June 3, the *Boston Globe* published an opinion piece by Drs. Christopher Reddy and Richard Camilli about WHOI's court-ordered production of documents in the *Deepwater Horizon* litigation. We offer here a fuller account of these events, and our view of what is at stake for WHOI, scientists in the United States, and society at large. What concerns us is the erosion of the academic freedom to "…remain free to inquire, to study and to evaluate…" without being subject to subpoena or investigation as recognized and protected by the law going back to the 1957 Supreme Court decision, *Sweezy vs New Hampshire*. In *Sweezy*, the Supreme Court stood up to protect the freedoms of academic debate, thought, and lecture in holding, "Freedom to reason and freedom for disputation on the basis of observation and experiment are the necessary conditions for the advancement of scientific knowledge." Unlike *Sweezy*, we are not facing the challenges of academics during the Communist red scare; however, the threat of litigation stifling scientific deliberation is real and troubling.

The *Deepwater Horizon* disaster, which began on April 20, 2010, killed 11 people and spilled oil at a depth of nearly a mile under the Gulf of Mexico. WHOI scientists and engineers have expertise and technology developed from their research that was applicable to this emergency. Over the course of the spill, nearly 100 WHOI researchers, marine crew, and staff provided technical support and conducted measurements and research at the site of the spill and in the affected areas of the Gulf. Their work included measuring the flow rate and sampling the oil from the well's failed blowout preventer, searching for and mapping a large underwater oil plume, tracking the ocean currents in the affected areas, examining the distribution and fate of dispersants underwater, and assessing the effects of the spill on coastal and deep-water ecosystems. WHOI scientists and engineers continue to do important research in the Gulf in the aftermath of this spill. The Institution is immensely proud of our staff for their dedication, skill, and willingness to assist in a time of national crisis.

At the request of the U.S. Coast Guard, WHOI scientists Camilli and Reddy led operations using WHOI-developed technology to measure the rate at which fluids flowed out of the damaged well and to obtain a direct sample of the well's fluids. Subsequently, these researchers and their colleagues, largely on their own time, analyzed the data they collected and published two peer-reviewed studies in *Proceedings of the National Academy of Sciences [1] [2]*. They determined a flow rate of 57,000 barrels of oil per day, which was used to calculate a total release of approximately 4.9 million barrels.

In December 2011, WHOI was subpoenaed by lawyers representing BP in response to lawsuits brought against the oil company by the U.S. government, fishermen, workers, and residents injured by the *Deepwater Horizon* disaster. It is important to note that WHOI is not a party to the lawsuit. BP claimed in its subpoena that it needed information to better understand scientific findings by Camilli, Reddy, and others related to the flow rate measurements they made at the Macondo well. Cleanwater Act violation fines that will be levied on BP may be based in great measure on the amount of oil released; therefore, billions of dollars are at stake.

As was stated in the *Globe* op-ed, WHOI turned over everything BP would need to analyze and confirm or refute the findings. However, BP demanded more—the scientists' email communications, notes, and manuscript drafts: "…any transmission or exchange of any information, whether orally or in writing, including without limitation any conversation or discussion…" concerning the research. WHOI, through our lawyers at Goodwin Procter, challenged this demand, but on April 20, the magistrate judge ordered the institution to produce the vast majority of its deliberative work. On June 1, WHOI turned over the last of more than 3,500 emails and associated documents to BP.

This case raises issues that go far beyond our institution and BP. Despite earlier Supreme Court recognition of the importance of the deliberative scientific process, there remains inadequate legislation and legal precedent to shield researchers and institutions who are not parties to litigation from having to surrender pre-publication materials, including deliberative emails and notes, manuscript drafts, reviewers' comments, and other private correspondence. This situation leaves scientists and institutions vulnerable to litigants who could disregard context and use the material inappropriately and inaccurately in an effort to discredit their work. In addition, there is no guarantee that the costs, both time and material, incurred by an institution in response to court-mandated requests will be reimbursed by the litigants.

While transparency to provide adequate information to reproduce scientific results is an important principle, this situation poses a serious danger to the scientific process. It threatens to facilitate misinterpretation of scientific findings by highlighting preliminary evaluations and opinions, conflating facts with assumptions, and implying conclusions without a valid scientific process or review. Even worse, pulling academics and researchers into litigation they are not a party to will have a chilling effect on how science is conducted. The essence of the scientific process is rigorous deliberation in which scientists examine, question, test, reject, and modify ideas as they work toward a verifiable conclusion. Without adequate legal protection, researchers and their institutions may reasonably fear that their deliberative process can be attacked and their intellectual property exposed, or that they will become entrained in litigation to which they are not parties and where they are unlikely to derive any benefit. As a consequence, scientists may feel forced to curtail, censor or avoid the normal deliberative process. In future emergencies, particularly those that might give rise to litigation, researchers may be more reluctant to volunteer expertise and technology.

The materials that BP demanded may include intellectual property, hard won by the researchers. While there are protections that can be placed by the court and through confidentiality orders, experts in the litigant parties receiving these materials may obtain insight into the creation of this intellectual property and be able to replicate it for their own programs even if they do not directly take it. It is unlikely that institutions such as WHOI would be able to identify or prosecute this infringement of intellectual property rights.

Academic research catalyzes innovation that stimulates our economy and enhances our quality of life. But history has proven time and again that academic institutions also supply invaluable qualities in responding to crises ranging from national security to public health. These qualities include capabilities based on knowledge and technology derived from decades of innovative research, together with a willingness to bring these skills to bear rapidly in emergency situations. Standards of academic research also include a commitment to unbiased and objective research, and both thoroughness in the collection and analysis of data, and prudence in observing strict standards of quality and peer review. Ironically, some of these very qualities that drew scientists into the response effort will suffer as the deliberative process is eroded.

We urge professional scientific and higher education organizations, legal advocates, legislators, citizens, and businesses to examine these issues and support the establishment of adequate protections for researchers and their institutions. Such safeguards will help ensure the freedom of the nation's scientific enterprise, thus assuring its continued success in fostering innovation and economic growth and in responding to societal needs and crises.

To view this statement, go to: http://www.whoi.edu/main/president-director/statement/scientific-deliberative-process

[1] Camilli R, D Di Iorio, A Bowen, CM Reddy, AH Techet, DR Yoerger, LL Whitcomb, JS Seewald, SP Sylva and J Fenwick, "Acoustic measurement of the Deepwater Horizon Macondo well flow rate," *PNAS*, published online September 8, 2011. doi: 10.1073/pnas.1100385108

[2] Reddy CM, JS Arey, JS Seewald, SP Sylva, KL Lemkau, RK Nelson, CA Carmichael, CP McIntyre, J Fenwick, GT Ventura, BAS Van Mooy and R Camilli, "Composition and fate of gas and oil released to the water column during the Deepwater Horizon oil spill," *PNAS*, published online July 18, 2011. doi: 10.1073/pnas.1101242108

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The *Professional Ethics Report (PER)* is published quarterly by the Scientific Responsibility, Human Rights & Law Program in collaboration with the Committee on Scientific Freedom and Responsibility.

Issues of *PER* are available online at: http://srhrl.aaas.org/newsletter/per/index.shtml

Back issues of *PER* are available online at: http://srhrl.aaas.org/newsletter/per/archives.shtml

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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.

In the News

THREE DNA DONORS, TWO PARENTS, ONE ETHICS REPORT

It is estimated that every thirty minutes, a child around the world is born who will develop a mitochondrial disease by 10 years of age [1]. The diseases are progressive and have no cure. However, with the emergence of mitochondrial DNA transfer techniques, there may be less of a need to develop one.

The Nuffield Council on Bioethics has published a report concluding that techniques to prevent the transmission of mitochondrial DNA diseases are ethical. The procedures are done during in vitro fertilization (IVF) and treatment options involve replacing defective mitochondria from the mother's egg with healthy mitochondria from a donor egg. The techniques for the pronuclear transfer and maternal spinal transfer have been developed by UK scientists, and were recently evaluated by the Nuffield Council [2].

The idea behind mitochondrial DNA therapy is to develop methods by which women with mitochondrial disease could bear children who would not develop the same disease yet remain genetically related to them. Frances Flinter, a member of the six-person Working Group that contributed to the report noted that "only 0.1% of [the children's] DNA would come from the donor and 99.9% of their DNA from their parents." As such, children's physical resemblance to relatives would come from the nuclear DNA of their parents [2].

Whereas nuclear DNA has around 3 billion base pairs, mitochondrial DNA only contains around 16,500 [3, 4]. Located outside the cell nucleus, mitochondria are small structures which produce ATP, the energy source which powers the cell. Defects in the mitochondrial DNA can inhibit the cell from delivering sufficient energy to organs and muscles [4]. Mitochondrial DNA mutations can lead to kidney disease, liver disease, blindness, deafness, heart malfunction, stroke, and dementia [2].

Mitochondrial DNA is inherited maternally, whereas nuclear DNA is inherited from both parents. This property of mitochondrial DNA testing allows for the creation of a direct lineage pathway of females. Because donated mitochondria will be passed along to subsequent descendents of female children who have undergone the donation, these techniques are a form of germline therapy. The Chair of the Council's inquiry, Dr. Geoff Watts, acknowledged the 'slippery slope' fear that may arise from the action. He responded, however, by noting that the techniques approved were only in "the clearly-defined situation of otherwise incurable mitochondrial disorders, under strict regulation" [2]. Currently, UK law prohibits techniques which alter any part of the DNA of an egg before it has been implanted into the mother. Accordingly, these techniques are not yet legal in the UK [5].

The summary of the Nuffield Council on Bioethics report states that "As only part of the donated egg is used and not its nuclear DNA, it is not legally or biologically accurate to refer to the mitochondrial donor as a mother or 'third parent' of the resulting child." This conclusion reflects the Council's findings that by and large mitochondrial DNA has little social or cultural emphasis attached to it. As such, the donors of the mitochondrial DNA are exempt from certain aspects of regulation, such as the requirement to be identifiable to adults who carry their DNA [6].

The report examined the ethical considerations for affected families, potential donors, researchers and medical professionals if these newly developed techniques were to be used in treatment. Dr. Watts, said, "If further research shows these techniques to be sufficiently safe and effective, we think it would be ethical for families to use them if they wished to, provided they receive an appropriate level of information and support." He added that the Council would recommend that these families agree to long-term follow-up inquiries for the affected children [2].

[1] Global Mitochondrial Disease Awareness Week Website. http://www.gmdaw.org/about-mito.htm
[2] Novel techniques to prevent mitochondrial DNA disorders would be an ethical treatment option. Nuffield Council on Bioethics Press release. http://www.nuffieldbioethics.org/news/novel-techniques-prevent-mitochondrial-dna-disorders-would-be-ethical-treatment-option
[3] National Human Genome Research Institute. http://www.genome.gov/25520880
[4] William Gahl, M.D., Ph.D. NIH National Human Genome Research Institute. http://www.genome.gov/glossary/?id=129
[5] Therapy for Mitochondrial Disease is Ethical, Says Nuffield Council. 11 June 2012. Gretchen Vogel, ScienceInsider.
[6] Summary of report Novel Techniques for the Prevention of Mitochondrial DNA Disorders: An Ethical Review. 12 June 2012. Nuffield Council on Bioethics

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POLITICS OF SEA LEVEL RISE IN NORTH CAROLINA

A controversial bill legislating sea level rise is under consideration by the North Carolina (NC) State Legislature. It sanctions the Coastal Resource Commission (CRC) as the only state agency authorized to define the rate of sea level rise for regulatory purposes. While county and local governments are free to define their own rates, it can only be for non-regulatory purposes. The bill also states that rates can only be determined using historical data and that the CRC "shall not include scenarios of accelerated rate of sea-level rise unless…consistent with historic trends" [1]. Dr. Robert B. Jackson, Chair of Global Environment Change at Duke University, argued against this mandate. At a panel hearing on June 7, he testified that "it's already clear from the data that the rates of sea level rise are accelerating" [2]. Dr. Jackson was the sole climatologist at the hearing.

The debate started in 2010 when the Science Panel on Coastal Hazards issued its report on a target for sea level rise through 2100. The members, all scientists holding various academic positions, were critical of the notion of simply using historical data to extrapolate future sea-level rise trends and agreed to use models that included the effects of global warming, thus an accelerated rate. It considered a 1-meter rise by 2100 as a realistic planning measure, a calculation intended to help the state plan for rising water that could threaten 2,000 sq miles.

This report was criticized by NC-20, a nonprofit and pro-business advocacy group comprised of representatives from 20 coastal counties, businesses and private citizens. NC-20 feared that planning and retrofitting infrastructure with a 1-meter sea level rise baseline would be a tremendous waste of money and argued that the research was flawed. Tom Thompson of

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NC-20 commented that "you can't mandate for an entire region of the state based on hypothetical data" [3]. According to Senator David Rouzer, the bill's main backer, more severe predictions of sea level rise would sink property values, reduce taxes, and inflate insurance rates. However, the N.C Coastal Federation views it differently. By allowing infrastructure to be built without higher sea level rise calculations in mind, local governments could lose federal planning grants and insurance rates can increase.

As a result of this legislation, when considering coastal development, local governments could only assume the sea level will rise 8 inches by 2100, as opposed to the 39 inches predicted by the Science Panel on Coastal Hazards. It seems that NC is standing alone in its stance. Other states have in fact prepared for a greater sea level rise. Delaware, for instance, is adopting a plan for sea-level rise of up to 60 inches by the end of the century. Southeast Florida is projecting a 9- to 24-inch rise by 2060, and California is preparing for a 55-inch rise by 2100.

If drafted into law, the legislation would be choosing a path that runs counter to "every major science organization in the world," [4] says Dr. Rob Young, a geology professor at Western Carolina University. Though the legislation will give the CRC the chance to include accelerated rates in the future, there won't be an immediate feedback. Dr. Jackson of Duke expressed concern for this at the same panel hearing. "Why push this bill now. Why take planning away from the people…if in 10 years, if it's not as fast, you can go backwards."

Currently, the bill has passed the NC Senate and has had a conference committee appointed for further review. Before this bill can become law, it must pass the NC legislature and be signed by the Governor.

To hear the joint State Senate's Agriculture/Environment Committee Panel on House Bill 819, visit: http://www.wral.com/news/state/nccapitol/video/11180522/#/vid11180522

To keep track of North Carolina House Bill 819, visit: http://www.ncleg.net/gascripts/BillLookUp/BillLookUp.pl?Session=2011&BillID=H819

To read Bill 819 in full, visit: http://www.ncleg.net/Sessions/2011/Bills/House/PDF/H819v4.pdf

[1]http://www.ncleg.net/Sessions/2011/Bills/House/PDF/H819v4.pdf
[2]http://www.wral.com/news/state/nccapitol/video/11180522/#/vid11180522
[3]http://news.sciencemag.org/scienceinsider/2012/06/legislating-sea-level-rise.html
[4]http://www.nccoast.org/Article.aspx?k=b965eb03-1d87-4284-9bfb-46d8b3eb67fb
[5]http://www.wral.com/news/state/nccapitol/video/11180522/#/vid11180522

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10 RECOMMENDATIONS TO ADDRESS CONFLICT OF INTEREST IN REPORTING INDUSTRY-SPONSORED RESEARCH

The May 2012 issue of the *Mayo Clinic Proceedings* presented ten recommendations for reporting industry-sponsored clinical research, the outcome of the 2010 Medical Publishing Insights and Practices (MPIP) roundtable discussions. The MPIP roundtable consisted of 23 representatives from the pharmaceutical industry and academic journals who came together to discuss the "persistent and perceived credibility gap" in industry-sponsored clinical research [1]. The roundtable's recommendations address both the industry and academic roles in producing such reports, and respond to the perception of a conflict of interest in the pharmaceutical companies' participation in research in which they have so much to gain from successful results.

The MPIP was founded in 2008 as a joint effort of members of the pharmaceutical industry and the International Society for Medical Publication Professionals (ISMPP). The MPIP has sought to meet its goals of "mutual respect, understanding and trust" between these two groups through joint meetings and research sessions, the production of resource materials, and now, these ten recommendations for publishing [2].

The "credibility gap" stems from a perception of a bias towards presenting positive outcomes and generally concealing the motives or sponsorship of authors who contribute to research reports. The ten recommendations from MPIP accordingly focus on increasing transparency throughout the writing and publication process. Specifically, this means reporting all results, including those that are negative or indeterminate, acknowledging all authors and contributing writers, fully disclosing all authors' potential conflict of interest, and explaining the statistical methods used to perform the analyses in the report.

In terms of authorship, ghostwriting and guest authorship, respectively the practices of not acknowledging a contributing author or failing to disclose the name of an author who does not meet journal requirements, provide a loophole to the understood academic expectation of fully disclosing all contributing authors. The recommendations explicitly advocate a joint effort by sponsors, authors, and publishers to end these misleading practices.

The recommendations also acknowledge that some weak practices come from a lack of clarity and codification of professional behavior on the part of academic writers and editors. In this respect, there are recommendations that address education of authors and editors to encourage high standards in manuscript production and publishing. As in other recommendations, collaborative efforts are emphasized. "Editors, sponsors, and clinicians would benefit from consensus on more uniform reporting guidelines that clearly specify the type and format of adverse event data," write the authors of the Mayo report [1].

The ten recommendations are listed in the Mayo report as follows:

1. Ensure clinical studies and publications address clinically important questions;
2. Make public all results, including negative or unfavorable ones, in a timely fashion, while avoiding redundancy;
3. Improve understanding and disclosure of authors' potential conflicts of interest;
4. Educate authors on how to develop quality manuscripts and meet journal expectations;
5. Improve disclosure of authorship contributions and writing assistance and continue education on best publication practices to end ghostwriting and guest authorship;
6. Report adverse event data more transparently and in a more clinically meaningful manner;
7. Provide access to more complete protocol information;

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8. Transparently report statistical methods used in analysis;
9. Ensure authors can access complete study data, know how to do so, and can attest to this;
10. Support the sharing of prior reviews from other journals.

For the full report, see [1].

[1]http://www.sciencedirect.com/science/article/pii/S0025619612002984
[2] http://www.mpip-initiative.org/about-mpip

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GLOBAL RESEARCH COUNCIL: PRINCIPLES FOR MERIT REVIEW

On May 15, 2012 after two-years of international and regional meetings and a two-day Global Summit on Merit Review, a newly minted Global Research Council (GRC) emerged. The summit, the first of its kind, was attended by leading officials in research funding organizations from G20/OECD countries, those that are most research intensive, and produced a statement of principles for scientific merit review. According to NSF Director Subra Suresh, the GRC will be a "voluntary…virtual organization [1]," governed by a board comprised equally of representatives from the developing and developed world.

The process of merit review, practiced by the NSF and other research funding organizations, is essential for evaluating scientific research. It ensures that only the most deserving research is funded. Additionally, the merit review process separates funding decisions from political bias. Currently there are a variety of merit review processes and principles, as a study on peer review by the European Science Foundation discovered [2]. While a variety is "to be expected, cherished and celebrated [3]," says Suresh, disparate review standards are one of the largest barriers to global collaborative research.

It was with this reality that leaders of funding agencies met in Arlington, VA at the global summit. By releasing a common set of principles regarding scientific merit review, participants recognized best practices that can cultivate global research cooperation. The principles include:

1. Expert Assessment
2. Transparency
3. Impartiality
4. Appropriateness
5. Confidentiality
6. Integrity and Ethical Consideration

There has been some skepticism, however, particularly in terms of the breadth of the current discussions and the lack of representation by researchers. Kieron Flanagan of the University of Manchester contends that the GRC should not just remain a talk shop for standards, and that "if statements stay at this general level they're not going to be Earth-shattering [4]." Granted, the GRC is a nascent organization, and while it is voluntary and its statement of principles has not been codified into international law, it is a step in the right direction toward a "more unified approach to the scientific process" said Suresh. However, how unified it will be remains unknown until researchers, those who use the merit review process, are included in discussions.

A global consensus on merit review principles would serve the dual role of promoting cooperation among funders, while at the same time increasing fair competition for resources. Additionally, with science gradually being seen as a promoter for economic growth, nations with emerging R&D funders can look to the GRC's recommended principles. But the ultimate potential of the GRC lies in the utility of funder cooperation. In a world where global issues require globally concerted efforts, a standard set of merit review principles can foster collaborative research to tackle these issues.

The GRC will not provide funding for research projects, as each member agency will cover its own costs. Now that the GRC has discussed merit review principles, it will turn to developing common views on research integrity and expanding open access. According to Matthias Kleiner, head of the German Research Foundation, the basic tenants of research integrity will be easier to define, while finding a consensus for open access will be more difficult, as it can range from "database sharing to journal pricing [6]." The GRC will meet again at the 2nd Global Summit for Merit Review in 2013 in Berlin.

To learn more about the merit review principles agreed upon, visit: http://www.nsf.gov/news/newsmedia/globalsummit/gs_principles.pdf

[1]http://news.sciencemag.org/scienceinsider/2012/05/new-global-research-council-take.html
[2]http://www.nature.com/news/2011/110504/full/473017a.html
[3]http://blogs.nature.com/news/2012/05/worlds-science-funders-announce-global-research-council.html
[4] http://www.nature.com/news/global-council-aims-to-coordinate-science-1.10680
[5]http://www.nsf.gov/news/news_images.jsp?cntn_id=124178&org=NSF
[6]http://news.sciencemag.org/scienceinsider/2012/05/new-global-research-council-take.html

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NEW US GOVERNMENT POLICY FOR DUAL USE RESEARCH

On March 29, the United States Government issued its new Policy for Oversight of Life Sciences Dual Use Research of Concern [1]. The four-page policy requires government agencies that fund life sciences research to regularly review and report research that could be misapplied to pose a significant threat to public health and safety. In addition, agencies must work with investigators to develop risk mitigation plans for any proposed or ongoing research that falls under the policy.

The policy applies to all life sciences research that is conducted by or funded by federal agencies, and each funding agency is responsible for monitoring the research it funds. Reporting is limited to potential dual use research on 15 select agents of concern, including some types of avian influenza virus, *Bacillus anthracis* and the Ebola virus.

Within 90 days of the policy's issuance, all agencies must conduct an initial review of proposed and current projects, identifying which projects meet the criteria for dual use research of concern (DURC) described in the policy and reporting on the identified risks and mitigation strategies that have been proposed or implemented. Agencies will need to submit updated reports to the Assistant to the President for Homeland Security and Counterterrorism every two years.

The Association of American Universities (AAU) has expressed concerns about the lack of details for implementation and the

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overlapping jurisdiction of multiple funding agencies, which could increase confusion and regulatory burden on researchers [2].

The policy's release coincided with the National Science Advisory Board for Biosecurity's (NSABB) March 29-30 meeting on the publication of two research papers on H5N1 bird flu transmissibility. Whether to publish key experimental details of those papers has drawn attention from scientists and policy makers around the world (see "Influenza Research Sparks Debate over Publication," *PER*, Spring 2012). In closed sessions, NSABB members heard testimony from the authors and other influenza researchers, public health experts, and the intelligence community. NSABB members were convinced that the laboratory-created influenza strains were not as lethal to ferrets as they had initially been perceived, and that publishing the research results could positively impact future research on surveillance for naturally-occurring pandemic flu.

In light of this additional information, the NSABB unanimously recommended the revised version of the paper by Yoshihiro Kawaoka's group at the University of Wisconsin be published in full [3]. It was published in *Nature* online on May 2 [4]. The paper describes the mutations that enabled the H5N1 virus to attach more strongly to host cells in the acidic environment of the mammalian respiratory tract. According to WHO flu experts, the benefit of this new information will be in understanding the type of changes that increase transmissibility, not simply monitoring a specified set of mutations. The second paper was submitted to *Science* by Ron Fouchier of Erasmus MC in the Netherlands. In a split decision, the NSABB recommended the data, methods and conclusions be published pending further revisions. Fouchier cleared yet another hurdle by securing an export license from the Dutch government in late April [5]. His paper was published in *Science* in late June [6].

Even as the journals are moving forward, discussions continue about ongoing concerns over the research and its publication. H5N1 transmissibility studies have been on hold since the initial NSABB review of the two papers in late 2011. In a letter to the NIH, NSABB member Michael Osterholm described the March NSABB meeting agenda as biased toward full publication [7]. Senator Joe Lieberman presided over a hearing where NIH and NSABB representatives explained the NSABB process and the basis for the recommendations [8]. At a National Academies workshop on May 1, experts discussed lessons learned from this and previous influenza research, and how to move forward with governance and oversight [9]. NIH and NSABB agree studies should be closely monitored for dual use risks from the beginning, so that similar controversies over publication can be averted.

[1]http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf
[2]www.aau.edu/WorkArea/DownloadAsset.aspx?id=13280
[3]http://www.nih.gov/about/director/03302012_NSABB_Recommendations.pdf
[4]http://www.nature.com/nature/journal/vaop/ncurrent/full/nature10831.html
[5]http://news.sciencemag.org/scienceinsider/2012/04/dutch-government-oks-publication.html
[6] S. Herfst *et al.*, *Science* **336**, 1534 (2012).http://www.sciencemag.org/content/336/6088/1534.full
[7]http://news.sciencemag.org/scienceinsider/NSABB%20letter%20final%2041212_3.pdf
[8]http://news.sciencemag.org/scienceinsider/2012/04/secret-briefing-helped-sway-h5n1.html
[9]http://sites.nationalacademies.org/PGA/stl/H5N1/index.htm

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PATENTS FOR HUMANITY

In February, the U.S. Patent and Trademark Office (USPTO) announced a 12 month pilot program titled *Patents for Humanity*. The program aims to provide a business incentive for technological progress to be applied to humanitarian needs. Until August 31, USPTO will be accepting applications that describe how patent owners have applied their patented technologies to humanitarian needs [1].

The applications will be judged by a combination of experts from academia and federal laboratories. Up to fifty winners will be selected across the following categories: Medical, Food and Nutrition, Clean Technology, and Information Technology. Each winner will be awarded a certificate that can be used to accelerate the patent application process by: (a) moving a "patent re-examination proceeding" to the front of the queue; (b) moving an appeal before the Board of Patent Appeals and Interferences (BPAI) to the front of the queue; or (c) ensuring a final decision on an application within 12 months [2].

[1]http://www.uspto.gov/patents/init_events/patents_for_humanity.jsp
[2] http://www.uspto.gov/news/pr/2012/12-10.jsp

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In the Societies

AAUP RELEASES 56 GUIDELINES FOR ACADEMIC-INDUSTRY RELATIONSHIPS

On June 13, 2012, the American Association of University Professors (AAUP) released a draft report titled *Recommended Principles and Practices to Guide Academic-Industry Relationships*. The nearly 300-page report recommends 56 principles that address means of preserving academic integrity amidst the ever-complicating connections between academic research and industry interests. The AAUP stressed in its press release that the report was still in a draft form and they plan to revise it after receiving public comments [1]. Common understanding of IP rights in academic research has recently undergone a considerable shift with the 2011 U.S. Supreme Court decision in *Stanford vs. Roche.* Previously, the Bayh-Dole Act of 1980 was generally interpreted to give automatic ownership of IP rights to the university where research took place, even if the research was federally funded. In *Stanford vs. Roche*, the Supreme Court decided that IP rights originated with researchers until they chose to sign them over to the university or another party. In response to this shift, many universities now require that faculty sign over their patent rights for future research as a condition of employment or in exchange for the use of university's facilities for outside research [2].

In the report, the AAUP argues for the restoration of patent rights to researchers. Principle 11 states that faculty rights "extend to decisions involving invention management, intellectual property (IP), licensing, commercialization,

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dissemination, and public use" [3, p. 137]. It goes on to specify that faculty should not be coerced into signing over these rights as a part of their contract with the university.

As with most of the recommendations in the report, this principle is framed in the context of broader goals such as academic freedom and research integrity. The report contends that when the university owns faculty patent rights "it tends to create institutional conflicts of interest between the university's governance role and its potential financial and competitive interests in exploiting those patented inventions for its own benefit" [3, p. 133].

Despite the arguments for greater academic integrity, other academic associations have criticized the AAUP's presentation of IP rights. Andrew Cohn, vice president of the Association of University Technology Managers, said in a statement that the recommendations "oversimplify the incredibly complex, nuanced process of academic technology transfer" [2]. John Vaughn, the executive vice president of the Association of American Universities, similarly criticized the report, stating that it "essentially ignores the role that universities play in providing the facilities and research support that make it possible for faculty members to conduct their groundbreaking research" [2].

The report also makes recommendations on topics that come up less frequently in similar guidelines. One notable example is the section on strategic corporate alliances (SCA). The concern with these long-term research arrangements with outside company sponsors is their possible adverse effects on "university governance." Specifically, the report cautions against letting such relationships color decisions about graduate student and medical resident admissions and appointments. The report draws on case studies from existing and past SCAs at American universities to illustrate how the conflicting interests of such a relationship can play out in various aspects of academic oversight and administration, such as hiring, funding, and even research direction.

Other sections of the report focus on such issues as financial conflict of interest, clinical research and industry sponsorship, and managing conflict of interest in the context of clinical care and human subjects research.

For the full report, which begins with a summary of all 56 principles, see [3].

[1] AAUP Press Release. http://www.aaup.org/AAUP/newsroom/2012PRs/industry.htm
[2] http://chronicle.com/article/AAUP-Meets-Resistance-as-It/132241/
[3] http://www.aaup.org/industryall.pdf

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BETTER LATE THAN NEVER: GERMAN MEDICAL ASSOCIATION APOLOGIZES FOR DOCTORS' INVOLVEMENT IN NAZI ATROCITIES

In a display of acknowledgment and responsibility, the German Medical Association has issued a Declaration of apology for the atrocities committed by Nazi doctors in World War II [1]. The statement, which has been well-received for its honesty and straightforwardness, asks for forgiveness from the victims and their families for the actions of the German doctors who the German Medical Association recognizes as having been "guilty of scores of human rights violations" during the Holocaust.

German doctors in WWII conducted numerous horrific experiments on prisoners in concentration camps. Seeking to identify the limits of the human body to improve military personnel survival, doctors put prisoners in low pressure chambers and exposed them to freezing temperatures in order to assess how long a human could survive with minimal oxygen and to test warming techniques for hypothermia victims. Other experiments included forced infection with contagious disease and involuntary sterilization for those deemed "unworthy of life."

A striking aspect of the declaration is the revelation that "leading members of the medical community" became involved in the work because they personally were Nazi supporters, not because they had been forced to by a higher authority. The declaration considers this example as a "warning for the future" that even "outstanding representatives of renowned academic medical and research institutions" could willingly be involved in such egregious human rights abuses.

Art Caplan, a professor at the University of Pennsylvania, commented on the importance of such a blunt apology. In an MSNBC editorial, he wrote, "In the history of apologies for crimes and abuses carried out in the name of medicine this is the most important ever made. It does nothing to soften the horror of the Holocaust but it both ascribes responsibility where it belongs and ends any further efforts to deny or obfuscate what actually happened." He further noted that "The world must still grapple with the Holocaust as genocide carried out in the name of science and medicine. But it no longer needs to try and push those involved in German medicine to speak out about their role. They have done so and they deserve full credit for it" [2].

[1] May 28, 2012. German Medical Society Apologies for Nazi-era Atrocities by Doctors.http://www.ahrp.org/cms/content/view/852/9/
[2] May 24. German Doctors Apologize For Holocaust Horrors. http://vitals.msnbc.msn.com/_nv/more/section/archive?author=ArtC2445701

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Announcements

Award - A call for nominations is now open for the 2012 Manuel Velasco Suárez Award for Excellence in Bioethics. The award is presented by the Pan American Health Organization (PAHO) and the Pan American Health and Education Foundation (PAHEF). The award is given to a scholar in Latin America or the Caribbean whose work demonstrates achievement in bioethics and who submits a sound research proposal for scholarly activities to be carried out in the field of basic or applied bioethics. The Manuel Velasco Suárez Award for Excellence in Bioethics is part of the Awards for Excellence in Inter-American Public Health Program, a joint initiative of PAHO and PAHEF. Each award includes a cash prize or research grant, certificate of honor and, a symbolic representation of the award. The deadline for submissions is July 20, 2012. More information may be found at: www.pahef.org.

Award - The American Association for the Advancement of Science is currently accepting nominations for the Award for Scientific Freedom and Responsibility. The award is presented annually by AAAS to honor scientists and engineers whose exemplary actions have served to foster scientific freedom and responsibility. The award recognizes scientists and engineers

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who have acted to protect the public's health, safety, or welfare, focused public attention on important potential impacts of science and technology on society by their responsible participation in public policy debates, or established important new precedents in carrying out the social responsibilities or in defending the professional freedom of scientists and engineers. This annual award consists of a prize of $5,000, a commemorative plaque, complimentary registration, and reimbursement for travel and hotel expenses to attend the AAAS Annual Meeting. The deadline for nominations is September 3, 2012. For more information, see:http://www.aaas.org/aboutaaas/awards/freedom/. Contact Deborah Runkle with questions at drunkle@aaas.org.

Call for Abstracts - The seventh International Congress on Peer Review and Biomedical Publication invites abstract submissions for the meeting on September 8-10, 2013 in Chicago. The Congress is organized by JAMA and the BMJ. Suggested topics include: bias and efforts to eliminate biased reporting, research and publication ethics, mechanisms for improving quality of reporting, models for peer review and scientific publication, dissemination of scientific information. The deadline for abstract submission is March 1, 2013. Contact Annette Flanagin with questions at jama-peer@jama-archives.org.

Call for Abstracts - International Neuroethics Society is now accepting abstracts for its 2012 meeting in New Orleans. The Society welcomes abstracts reporting recent developments and results in the field of neuroethics. This meeting is a satellite of the Society for Neuroscience meeting, and presentations will take place October 11-12, 2012. The deadline for submission is July 2. Additional information is available at: http://www.neuroethicssociety.org/2012-meeting-call-for-abstracts.

Call for Papers - The Poynter Center for the Study of Ethics and American Institutions seeks paper submission on the topic of "Humanitarianism and Human Rights in the 21st Century" for the 40th Anniversary symposium that will be held October 10-12, 2012 at Indiana University. The Center invites proposals for papers that examine normative and practical issues bearing on international human rights in politics, economics, education, policy, and/or religion. Submissions are due by July 1, 2012. For more information, contact Emma Young at eayoung@indiana.edu.

Call for Papers - The journal *Ethics and Information Technology* invites article submissions for a special issue on "Ethics of Social Networks for Special Needs Users." The journal is particularly interested in contributions that identify ethical issues and their resolution by devising policies and proposing design solutions to the problems identified. Some possible themes include: minimum age and protection of minors, effect of a daily use of social networks on kids development including school performance, cyber-bullying, harassment and violence arising from SN usage amongst children, accessibility of elderly or disabled persons to SN, digital divide and e-inclusion, ethical issues such as: identity, agency and autonomy for special needs users, and generational gaps and solidarities arising from SN usage. The closing date for submission is September 30, 2012. Submit articles on the online system found at: www.editorialmanager.com/etin. For more information, contact Caroline Rizza at Caroline.rizza@jrc.ec.europa.eu.

Conference - The 8th International Conference on Bioethics Education: Contents, Methods, Trends will take place in Tiberias, Israel, September 2-5, 2012. The conference will cover such topics bioethics, ethics and religion, ethics and law, scientific ethics and medical ethics in the context of teaching methodology and teaching evaluation, among others. For more information and to register for the meeting, go to: http://www.isas.co.il/bioethics2012/price.php.

Conference - ETHICOMP Latin America invites participation in the Second Argentine Working Conference on Information and Communication Technology Ethics. The meeting will be held October 8-12, 2012. Topics discussed at the meeting will include ICT ethical concepts, ethical issues particular to South America such as privacy and surveillance, e-government, e-voting, open source initiatives and robotics, implications of these issues for professional practices, and ideas for incorporating these issues into education curricula. To find out more about the meeting, visit: http://cs.uns.edu.ar/cacic2012/index.php/en/component/content/article/13/20-ii-ethicomp .

Funding Opportunity - The National Human Genome Research Institute is soliciting grant applications for the support of Specialized and Exploratory Centers of Excellence in ELSI Research (CEERs). The CEER program is designed to develop and support trans-disciplinary research teams that have the expertise and flexibility to anticipate, conduct research on, and respond quickly to a range of ELSI issues related to the rapidly increasing availability and use of genomic approaches and information. For additional information, contact Joy T. Boyer at jb40m@nih.gov.

Meeting - The AAAS Science and Human Rights Coalition will hold its eighth meeting July 16-17, 2012 at AAAS headquarters in DC. The meeting will begin with an opening plenary with Assistant Secretary of State Michael Posner on the topic of internet freedom and human rights. The meeting will continue on July 17 with working group meetings, training workshops, and panel discussions on human rights issues central to the mission of the Coalition, including: Advancing the Right to Development through Science and Technology, Building the Next Generation of Socially Responsible Innovators: Integrating Human Rights in Technology and Engineering Curricula, and The Human Right to Clean Water and Sanitation. The Coalition meeting will conclude with a panel on Technology, Human Rights and Professional Responsibility. To register and view the agenda, go to: https://www.signup4.net/Public/ap.aspx?EID=SHRC10E.

Publication - In July, the Council of Graduate Schools (CGS) will release a book documenting the results of the Project for Scholarly Integrity, a multi-year, multi-institutional project funded by the U.S. Office of Research Integrity (ORI) to identify promising practices in embedding research and scholarly integrity into graduate education. A companion, beta version of an online interactive Dashboard will provide users with the opportunity to generate customizable analyses of baseline data gathered through two research activities: a Research Integrity Inventory Survey used to collect data on activities and resources from 240 graduate programs, and the Survey of Organizational Research Climate (SORC). For information contact Daniel Denecke at ddenecke@cgs.nche.edu or Julia Kent at jkent@cgs.nche.edu. For additional background on the Project for Scholarly Integrity, visit: www.scholarlyintegrity.org.