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THE HUMAN RIGHT TO ENJOY THE BENETFITS OF SCIENTIFIC PROGRESS

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In 1966, the United Nations (UN) General Assembly adopted the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 15 of the ICESCR recognizes the right of everyone to "enjoy the benefits of scientific progress and its applications." Article 15 also requires governments to:

1. take the steps necessary for the "conservation, the development and the diffusion of science"
2. "respect the freedom indispensable for scientific research" and
3. "recognize the benefits to be derived from the encouragement and development of international contacts and cooperation" in science.

Almost forty-five years later, this provision remains one of the least well known and least clearly understood of the international human rights framework.

While other human rights are the subject of legal interpretation, rigorous academic debate, and focused international attention, the right to the benefits of scientific progress has been neglected. Hence, many questions remain to be answered about the precise meaning of the right. Are governments required to ensure equal access to Viagra as to antiretroviral drugs? What are the implications of this right for research and development into weaponry? What about research that has the potential to be misused for malicious purposes? These are just some of the questions that need to be answered if the 160 governments that have voluntarily agreed to be legally bound by the ICESCR are to be held accountable for their obligations.

Points of consensus

In 2007, the United Nations Educational, Scientific and Cultural Organization (UNESCO) initiated a process to give meaning to the right to enjoy the benefits of scientific progress and its applications. Over the course of three meetings, approximately thirty experts met to consider the relationship of Article 15 to other rights, and to start to define in concrete terms the specific meaning of Article 15. Participants were drawn principally from academia and the human rights community. AAAS was the only participating science organization, represented by the author.

At the end of the UNESCO process, participants adopted the *Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications* [1]. The Statement reflects four principal points of consensus. First, realization of the right to the benefits of scientific progress is necessary for the fulfillment of several other rights. Second, the right also has meaning and value independent of other human rights. Third, the right requires governments to implement special measures necessary to address the needs of disadvantaged and marginalized groups. Finally, scientific freedom is an essential element of the right.

***Access to science is key to many human rights*:** Human rights share several common characteristics: they are universal, inalienable, and they are indivisible, interdependent and interrelated; that is, they come as a package. The limited literature existing about the right to the benefits of scientific progress has principally focused on the relationship and interdependence of this right with other rights, particularly the rights to food, health, energy, a clean environment, reproduction, and information technology [2].

***Science has a value in its own right*:** It is incumbent on governments to establish the legal, policy and institutional frameworks necessary to promote the development and diffusion of science and technology, and to do so in a manner consistent with fundamental human rights. Governments also have a duty to institute effective science curricula at all levels, and to ensure minority participation in science education. Finally, opportunities must be provided for pubic engagement in decision-making about science and technology, for example, through consensus conferences, and official Requests For Information.

Focus on disadvantaged and marginalized groups: The right to the benefits of scientific progress does not entitle everyone to receive free cosmetic surgery, or hybrid cars. Rather, the focus of the right, at minimum and at its core, is on ensuring access to the basic science and technology required to live life with dignity (e.g., essential medicines, potable water, and basic sanitation). One example would be by implementing exceptions to intellectual property laws to allow access to essential medicines for the poor. When the basic science and technology do not exist, then governments must provide the funding, or create incentives, to encourage research in these areas.

Protect scientific freedom: Scientific freedom represents the juncture at which the scientific community and human rights have most frequently met. Freedom of thought, freedom to hold opinions without interference, and the freedoms to travel and to seek, receive and impart information and ideas, have for decades been championed by scientists and scientific associations, particularly when colleagues have faced threats and persecution. Other relevant rights include the right to form and join professional societies, and the freedom to collaborate with others, both within and across international borders. Respect for these rights is fundamental to the protection of scientific freedom, and a vital component of a government's responsibility to develop, conserve and diffuse science.

Conceptual challenges

While a growing consensus exists around the preceding four elements of the right to the benefits of scientific progress, several conceptual challenges remain.

1. Scientific freedom is not absolute, but must be balanced by the rights of individuals and interests of the community. At what point does legitimate government regulation become an unjustified infringement on scientific freedom?
2. Scientific research is increasingly funded and carried out by private actors with profit margins, rather than public benefit, as their primary motivation. What are the implications of this for how governments can meet their responsibility to implement the right to the benefits of scientific progress?
3. In practice, tensions can exist between intellectual property rights and ensuring access to the benefits of scientific progress. How can this tension be reconciled?
4. Disparities are increasing between governments with the resources, capability, and infrastructure necessary to engage in research and development, and those without. The international human rights framework requires the 'haves' to help the 'have nots', but how this can be achieved remains unclear.
5. Heightened national security concerns and increased sensitivity to potential biological, chemical and nuclear threats pose particular challenges for international cooperation. The question is how to balance these concerns with the legitimate need of scientists to engage in international exchanges, attend foreign meetings, and communicate across borders.
6. Some applications of science and technology are, by their nature, destructive. Weapons, missiles and bombs, for example, are destructive and, arguably, violations of human rights *per se*. How, then, do these examples of "scientific progress" fit into the human rights framework as provided by Article 15?

Where to from here?

The UNESCO process and the adoption of the *Venice Statement* were the first steps toward giving meaning to the right to the benefits of scientific progress, and ensuring governments are held accountable for fulfilling it. What is required now is for the right to be placed firmly on the scientific community's agenda, for without the input of scientists, conceptualization of the right may fail to take into account the realities of the scientific endeavor and standards of good scientific practice.

Individual scientists from all walks of life – universities, professional associations, business and government – can contribute. At the cutting edge of scientific discoveries, scientists can give priority to research into areas of particular relevance to disadvantaged and marginalized groups and keep governments abreast of new scientific applications of particular societal benefit. They can also use the right to the benefits of scientific progress to inform their educational curricula, develop business plans, and design foreign aid initiatives.

Scientific associations also have a crucial role to play in supporting the implementation of the right. Through their advocacy and outreach programs, training and research activities, scientific associations can use their influential voices to demand that governments realize the right to the benefits of scientific progress. They can also reflect on how this right applies to their own discipline, identifying barriers to realizing the right and developing ways to remove them.

Indeed, the AAAS Science and Human Rights Program is currently working with the 42 scientific organizations that comprise the AAAS Science and Human Rights Coalition on a Joint Initiative specifically dedicated to the right to the benefits of scientific progress. One aim of the initiative is to inform the scientific community of the right, and engage the community in helping realize it. Options being pursued by the Coalition include the development of indicators necessary to measure progress in the implementation of the right, and cataloging of the many and varied ways in which scientific freedom is restricted at home and around the world.

Almost forty-five years ago the right to the benefits of scientific progress was incorporated into the International Covenant on Economic, Social and Cultural Rights. A movement is now underway to determine the precise meaning and practical implications of the right, and to ensure its implementation. The outcome of this process will be

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

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important for governments that are legally bound to respect, protect and fulfill this right and for the broader society that would be served by the realization of this right. For the scientific community, the interests of which are intrinsically tied to the provisions of this right, the door is open to become engaged in this process.

[1] Available at: http://shr.aaas.org/article15/Reference_Materials/VeniceStatement_July2009.pdf.

[2] See, for example, Cook, Rebecca, J (1993) "International Human Rights and Women's Reproductive Health," *24 Studies in Family Planning* 73; Haugen, Hans Morten (2005), "The Right to Food, the Right to Benefit from Science and the TRIPS Agreement," in Eide, W. B. and Kracht, U. (eds), *Food and Human Rights in Development*, Intersentia, pp. 425-460; Claude, Richard Pierre and Issel, Bernardo W. (1998), "Health, Medicine and Science in the Universal Declaration of Human Rights," *Health and Human Rights*, 3(2): 127-142.

Letter to the Editor

Response to letter by Tee L. Guidotti

My essay "Troubled Waters, Part I" [see PER, vol. 22(2), Spring 2009] describes ethical concerns, including factual mistakes, conflict of interest issues, and questionable data related to a 2007 Environmental Health Perspectives (EHP) paper written by Tee L. Guidotti and colleagues. Guidotti, *et al.*, found "no identifiable public health impact," after several years of record lead contamination in Washington, DC's drinking water [1], whereas a follow-up study by Marc Edwards and colleagues in 2009, determined that hundreds (and perhaps thousands) of infants and young children were adversely affected [2]. Congressional and DC Inspector General staff are investigating this and other discrepancies [3].

Guidotti responded to my essay [see PER, vol. 22(3), Summer 2009] by accusing me of incorrect and irresponsible allegations about his study, which are addressed in sequence in the following paragraphs. Guidotti writes that Edwards, *et al.*, 2009, which I cite, "erroneously suggested that [Guidotti, *et al.*,] was wrong on several points."

Response: Edwards, *et al.*, does criticize Guidotti for specific factual errors. My reporting indicates that these criticisms are accurate. Most important among them are: the duration of unwitting exposure to contaminated drinking water and the timing of public health interventions. Guidotti, *et al.*, state that lead levels rose suddenly in 2003 and health authorities intervened in the same year. Edwards, *et al.*, state that lead levels rose in 2001 and the key public health interventions occurred after a 2004 front page *Washington Post* article alerted the public [5]. Who's right? An EPA report and DC WASA's own data back up Edwards, *et al.*, regarding the duration of the high lead levels [4]. Numerous press reports also back up his contention that public health interventions effectively started in 2004 [6, 7].

Guidotti claims that I failed to tell readers about the June 16, 2009 *Washington Post* article, "Lead study not tainted by utility, panel says," which he says presented a "more balanced and accurate view of the story."

Response: Right from the start and throughout my essay, I clearly state that the EHP panel found the relationship between Guidotti and the District of Columbia Water and Sewer Authority (WASA) not to have violated EHP policy. I also cite the June 16, 2009 *Washington Post* story. The very subtitle to my essay is, "First author cleared of some ethics allegations, but further questions remain.

Guidotti takes issue with my description of him as a "paid consultant."

Response: In sworn written testimony given in 2008 to a House of Representatives subcommittee, Guidotti himself stated that he was, "a consultant in public health and risk management to water and public health agencies, most notably the District of Columbia Water and Sewer Authority" [8]. And he was paid -- from 2004 to 2006 WASA paid over $750,000 to George Washington University (GWU) for the salaries and services of Guidotti and his colleagues that were mainly related to lead in drinking water. Guidotti has himself agreed to this in public. At a DC Council meeting on May 26, 2004, the then-chair of the Council's Public Works and Environment Committee, Carol Schwartz, introduced Guidotti saying, "Dr Guidotti is an employee, via a consultancy, of WASA. Is that correct?" Guidotti replied in the affirmative [9]. Guidotti is correct that WASA's payments to him and his group were made through a university contract. I have never claimed or implied otherwise. What I have written and continue to stand by is that he was a WASA consultant and was well-paid for it, albeit through his former employer.

Guidotti criticizes me for repeating allegations about his EHP paper that were subsequently rejected by EHP's review panel.

Response: In my essay, I described an apparent contractual restraint on Guidotti's freedom to publish and the EHP panel's determination that the contract did not restrain him. I also described how the panel found that the paper had been published without deleting a "key sentence" as the report's main conclusion -- a change Guidotti had agreed to make. Guidotti has followed the panel's recommendations and submitted an erratum and an apology [10]. But he subsequently took back this apology in a letter to *The Washington Post*, writing, "our study concluded that the data we analyzed showed no identifiable correlation between increased lead in D.C. drinking water and elevated blood lead levels. The suggestion that our conclusion was published by mistake does a great disservice to me and risks creating panic in the community where none is warranted." [11].

My essay also describes some of the other scientific concerns about Guidotti, *et al.*, that were raised by Edwards in a March 2009 letter to EHP [12]. These include the number of children identified by DC's expanded lead screening program in 2004 as having elevated blood lead levels and the sources of their lead exposure. On this topic, I stand by my original account. My essay also describes the case of a severely lead poisoned young boy mentioned in Edwards' letter. The boy's family sued WASA and the DC Department of Health. Guidotti, *et al.*, mentions this child but do not mention the law suit nor the lead water pipe or elevated lead levels in the family's tap water, as uncovered by

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Edwards. Guidotti does not address my points about this boy.

The Washington, DC lead crisis from 2001 to 2004 is a unique modern case study of the consequences of massive lead contamination in drinking water. The people who lived through the crisis, the public health community, and parents everywhere deserve to know the full health consequences and circumstances surrounding this event. Although Guidotti disagrees, my reporting indicates that his 2007 paper fails to represent accurately those events.

Rebecca Renner
Science Writer
December 2009

[1] Guidotti, T.L. et al. 2007. "Elevated Lead in Drinking Water in Washington, DC, 2003–2004: The Public Health Response," *Environmental Health Perspectives*, 115, 695-701. http://www.ehponline.org/docs/2007/8722/abstract.html

[2] Edwards, M., et. al., 2009. "Elevated Blood Lead in Young Children Due to Lead-Contaminated Drinking Water: Washington, DC, 2001-2004," *Environmental Science & Technology*, 43, 1618–1623. http://pubs.acs.org/doi/abs/10.1021/es802789w?cookieSet=1&journalCode=esthag

[3] Stewart, N. "Officials Want Probe of Lead-Study Paper," *The Washington Post*, February 14, 2009; B01. http://www.washingtonpost.com/wp-dyn/content/article/2009/02/13/AR2009021302501.html

[4] United Sates Environmental Protection Agency, *Elevated Lead in D.C. Drinking Water – A Study of Potential Causative Events, Final Summary Report*, EPA-815-R-07-021, August 2007. http://www.epa.gov/ogwdw/lcrmr/lead_review.html

[5] Nakamura, D. "Water in D.C. Exceeds EPA Lead Limit; Random Tests Last Summer Found High Levels in 4,000 Homes Throughout City," *The Washington Post*, January 31, 2004, p. A1. http://www.ewatertek.ca/htm%20files/washingtonpost_com%20Water%20in%20D_C_%20Exceeds%20EPA%20Lead%20Limit.htm

[6] McElhatton, J. "WASA head concedes agency failing," *The Washington Times*, February, 12, 2004.

[7] Nakamura, D. "Davis Assails Water Agency On Lead Risk," *The Washington Post*, February 3, 2004. http://www.washingtonpost.com/wp-dyn/articles/A6956-2004Feb2.html

[8] House Transportation and Infrastructure Committee, Subcommittee on Water Resources and Environment, "Emerging Contaminants in US Waters." September 18, 2008. Testimony of Tee Guidotti. http://transportation.house.gov/Media/File/water/20080918/Guidotti%20Testimony.pdf

[9] District of Columbia Office of Cable Television on demand video of 5/26/2004 Public Oversight Hearing (Continuation), Committee on Public Works and the Environment, Carol Schwartz, Chairperson. http://octt.dc.gov/services/on_demand_video/channel13/May2004/05_26_04_PUBLIC_WORKS_9.asx

[10] Guidotti, et al., 2007, erratum. http://www.ehponline.org/docs/2009/117-8/errata2.html

[11] Guidotti, TL. "Setting the Record Straight," *The Washington Post*, Letter to the Editor, August 14, 2009. http://www.washingtonpost.com/wp-dyn/content/article/2009/08/13/AR2009081303395.html

[12] "Read about conflict of interest concerns in WASA-sponsored paper about lead in DC's water." WASA Watch. http://dcwasawatch.blogspot.com/

In the News

~~CANCELLED~~: NO BABOONS WANTED HERE

In October, Oklahoma State University (OSU) president, Burns Hargis, notified faculty that he was canceling the university's participation in a proposed study that would have tested anthrax treatments and vaccines in baboons, which would then be euthanized as a safety measure. The NIH-funded study, which was to be carried out by the university Center for Veterinary Health Sciences in its Animal Biosecurity Level (ABSL) 3 facility, had received the go-ahead following a year-long review by OSU's Institutional Animal Care and Use Committee (IACUC).

Although one reason for President Hargis' decision was to avoid controversy, the decision, made without input from research faculty involved in the project, garnered international attention, earning a rebuke from FASEB [1], an accusation of "administrative cowardice" from the American Association of University Professors [2], and a shout out by the Animal Liberation Front [3]. Communicating through a spokesman, President Hargis said the research was "not in the best interest of the university," would be a "new area…outside [our] current research programs," and would have "distracted" the school from its "ongoing programs in bioterrorism research" [4]. Ironically, the university's ABSL 3 facility was completed in 2006 with the express purpose of attracting federal dollars to conduct studies on biodefense and infectious disease, presumably like the planned anthrax study.

If, indeed, the facility was built with just this sort of study in mind, why did President Hargis cancel it? The answer depends on who you talk to. University officials indicated that it was the euthanization of the animals that made the study troublesome. And everyone agrees that fear of extreme animal rightists played a role, although OSU received no threats. But the agreement stops there.

OSU faculty report that in the past, President Hargis has shown unhealthy deference to a very large donor, Madeleine Pickens, the wife of multi-billionaire T. Boone Pickens. Because Mrs. Pickens is an animal rights supporter, they believe this decision may be linked to pressure from her. The president vehemently denies he was "influenced" by any donor or that he spoke with Mrs. Pickens about this issue, but Dr. Stephen McKeever, Vice-President for Research and Technology Transfer, admits that Mr. Hargis worried about unmerited and distorted criticisms of the study. Recently, for example, Mrs. Pickens was critical of the vet school based on sensationalized and untrue charges of inhumane practices in its training programs. The administration refuted the charges to select members of the media only, but Dr. Richard Eberle, co-PI on the study, claims that Mr. Hargis ordered his faculty not to "embarrass" Mrs. Pickens. And a spokesman for President Hargis acknowledges that although Hargis is "proud of the work the vet school does, he has larger issues to consider," including donors.

In an interview with this writer, McKeever said that "confidential" information was a major factor in Hargis' decision, despite the study's scientific

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merit. If everyone knew what President Hargis had learned, according to McKeever, they would understand his course of action. It was this information, coupled with concerns about animal rights violence and misrepresentation of the research, that caused the plug to be pulled on the anthrax study.

On December 8, both the head of the IACUC and President Hargis spoke at a meeting of the faculty council, where the president repeated that he was in possession of "lurid" confidential information [5]. The IACUC asked Hargis to rescind his edict, and presented a resolution critical of the decision-making process. President Hargis stuck to his initial ruling, but acknowledged that he made "rookie mistakes" in failing to consult the IACUC and Dr. Eberle before reaching and announcing his decision. He apologized to faculty and expressed his commitment to "shared governance."

Going forward, the administration insists that it is open to allowing experiments with non-human primates, even if euthanization is necessary. However, it is fair to ask why their current fear of violent animal rightists would disappear, especially after they have drawn nationwide attention to themselves. Indeed, in a comment posted to an article in *ScienceInsider*, a reader opined that now that the animal rights community sees that OSU is a "soft touch" on this issue, the university has put itself at elevated risk [6]. And with Madeleine Pickens weighing in on the president's decision with a hearty "Kudos for a Great Decision!," the issue of undue influence on the part of donors lingers.

Another concern for OSU is the reaction of the NIH, whose Office of Extramural Research answered queries about OSU's actions with the following statement: "NIH fully expects institutions to honor … assurances and commitment[s] to complete NIH supported projects as requested, approved, and funded…." [7]. It would be a final, sad irony if OSU's attempt to attract NIH-funded projects and raise the research profile of the university results in a tattered reputation in the eyes of the NIH and the scientific and academic communities, and with its only support coming from the animal rights extremists it fears.

[1]http://www.faseb.org/pdf/OSU_anthrax_12_2_09.pdf
[2] Jaschik, Scott, "Euthanized Research Project,"http://www.insidehighered.com/layout/set/print/news/2009/12/09/okstate
[3]http://www.animalliberationpressoffice.org/press_releases/2009/pr_09_12-02_osuprimatesnot.htm
[4] Simpson, Susan, "Anthrax Study Rejected by OSU," http://www.newsok.com/anthrax-study-rejected-by-osu/article/3421451?custon_click
[5]http://dailyme.com/story/2009120900002619/osu-chief-discusses-research-decision-burn.html
[6]http://blogs.sciencemag.org/scienceinsider/2009/12/threat-of-anima.html
[7] http://newsok.com/osu-chief-discusses-research-decision/article/3423662?custom_click=headlines_widget

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IMPLEMENTING THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

On October, 1, 2009, the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services issued interim final rules to implement Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA). Title I of GINA prohibits insurers from requesting, requiring, or purchasing genetic information from an individual (or their family members) to determine one's eligibility for enrollment, group premiums, or any other underwriting purpose.

The interim regulations provide definitions for several terms used in the GINA legislation. "Genetic information," is defined as "information about the genetic tests of family members, the manifestation of disease or disorder in family members, or any request of or receipt by the individual or family members of genetic services." Additionally, the regulations clarify that the term "family member" can be applied to an individual's extended family, up to one's fourth-degree relatives. The regulations also distinguish between manifestation of a disease and genetic predisposition, as GINA only bars insurers from using the latter for underwriting purposes.

Insurers will not be penalized for incidental collection of genetic information. Furthermore, there is a provision allowing insurers to collect genetic information for research, if the request is made under specific conditions (the request must be made in writing, the subjects must participate voluntarily, and the information cannot be used for underwriting purposes). The regulations also permit insurers to request the minimum amount of information needed in order to determine whether payment of a claim for benefits will be made. The regulations took effect December 7, 2009, but the departments will accept public comments on the interim final rules until January 5, 2010.

Title I of GINA also requires that that the Social Security Act be amended to extend the protection offered by the "Standards for Privacy of Individually Identifiable Health Information" (Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPPA) to genetic information. While the Privacy Rule of HIPPA prohibits group health plans and insurers from using or disclosing health information for under-writing purposes, it does not explicitly state that health information includes genetic information.

That is why HHS's Office for Civil Rights (OCR) also issued a proposed rule to modify the HIPPA Privacy Rule. The new rule would state clearly that genetic information is health information, and make corresponding changes to definitions and provisions of the Rule to be in accordance with GINA. When implemented, these amendments will prohibit group health plans and insurers from using or disclosing genetic information for underwriting purposes [1]. On October 1, 2009, OCR opened the proposed rule to a 60-day period of public comment.

As the effective date of the interim final regulations approached, controversy arose as both the National Business Group of Health and DMAA: The Care Continuum Alliance expressed concerns about the impact of the regulation's overly broad definition of underwriting on employer-sponsored wellness programs as well as the interim regulation's potential effect on disease

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management programs. Both groups asked for a delay in the implementation of the new regulations to assess their impact.

In response, the AARP, the Center for Medical Consumers, NAACP, and more than 50 other organizations stressed the urgency of implementing the provisions in December, stating that a delay would weaken the protections that the law aims to offer the American people. The effective date of the interim regulations was not postponed.

Title II of GINA prohibits employers from using genetic information to discriminate against employees. Title II of GINA became effective November 21, 2009, but the Equal Employment Opportunity Commission (EEOC) has not yet implemented any regulations [2].

[1] HHS News Release, 10/1/2009, "New Rules Protect Patients' Genetic Information": http://www.hhs.gov/news/press/2009pres/10/20091001b.html

[2] Background Information for EEOC Notice of Proposed Rulemaking on Title II of the Genetic Information Nondiscrimination Act of 2008: http://www.eeoc.gov/policy/docs/qanda_geneticinfo.html

To view the interim GINA regulations, go to: http://edocket.access.gpo.gov/2009/pdf/E9-22504.pdf

To view the Department of Human and Health and Services Proposed Rule, visit: http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/genetic/ginanprm.pdf

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IOM RELEASES RECOMMENDATIONS FOR ENHANCING PRIVACY IN RESEARCH

On January 27, 2009, the Institute of Medicine (IOM) Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule released the report, *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*. The committee was charged with evaluating the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, which ensures individuals' health information is protected and sets requirements for conducting health research. The committee concluded that the Privacy Rule is often subject to misinterpretation and does not adequately protect privacy, therefore hindering health research.

The committee recommended that Congress authorize the Department of Health and Human Services (HHS), along with other relevant agencies, to develop a new approach to protecting privacy, to be applied uniformly to all health research. All interventional human subjects research should comply with the Common Rule, regulations adopted by 18 federal agencies to protect human subjects. For information-based research, the HHS and other relevant agencies should develop a uniform approach toward establishing best practices in privacy, security, and transparency. The report draws comparisons between HIPAA and Ontario's Personal Health Information Protection Act (PHIPA), emphasizing that PHIPA applies to any entity that receives personally identifiable health information from a health information custodian (e.g., hospitals or pharmacists), and not just to the health care sector, as with the HIPAA Privacy Rule. Drawing from PHIPA and a report commissioned by the United Kingdom's Prime Minister, the committee recommended creating safe harbors in order to expand research opportunities.

To protect privacy, laws should prohibit unauthorized reidentification of health information. For research that requires identifiable health information, approval and oversight of an ethics oversight board is necessary. The committee further recommended that the board be established specifically to review information-based research, rather than using institutional review boards (IRB) created to review interventional research. The committee proposed forgoing the universal requirement for informed consent, suggesting that, in certain situations, disclosure to a certified entity and/or a waiver of informed consent by the review board may be more effective and efficient. Furthermore, the committee recommended that with the implementation of this new approach, health research should then be exempt from the HIPAA Privacy Rule.

If the recommendation for the new approach is not put into practice, the committee recommended that HHS revise the Privacy Rule, creating guidelines for best practices and simplifying provisions regarding the use of health information in research. HHS should develop materials to facilitate the effective use of already-existing data and materials. These materials should include a single consent form that permits individuals to authorize use and disclosure of health information for interrelated research activities. HHS should also clarify the conditions under which DNA information is considered health information. Furthermore, guidelines should simplify the criteria used by IRBs and Privacy Boards for making decisions involving health research.

The report emphasizes that HHS should support all institutions in the health research community in safe-guarding the security of health data, regardless of each institution's approach in this effort. HHS or Congress should provide those IRB and Privacy Board members who act in good faith with protection against civil suits. Finally, the committee recommended that both HHS and researchers educate the public about health research.

To view the Privacy Rule regulations, visit: http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/adminsimpregtext.pdf

To view the Ontario Personal Health Information Protection Act, visit: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm

To view the United Kingdom report, visit: http://www.justice.gov.uk/reviews/docs/data-sharing-review-report.pdf

To view the committee report, visit: http://www.nap.edu/catalog.php?record_id=12458

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NEW PhRMA GUIDELINES ON CONDUCT OF CLINICAL TRIALS AND COMMUNICATION OF RESULTS

On October 1, 2009, the Pharmaceutical Research and Manufacturers of America's (PhRMA) "Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results" went into effect. The Principles are intended to protect research participants, address appropriate conduct of clinical trials, ensure

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objectivity in research, and provide adequate information of clinical trial results in a timely manner.

PhRMA follows the standards from the Guideline for Good Clinical Practice of the International Conference on Harmonization (ICH), with oversight by institutional review boards (IRBs), ethics committees (EC), and national health authorities. Investigators are required to obtain informed consent from all participants, and inform them of any changes relevant to the trial, updating their consent when necessary. All trials, including those conducted in the developing world, must be followed up and monitored for safety and quality assurance.

To ensure objectivity in research, the Principles note that it may be necessary for a data safety monitoring board (DSMB) to monitor interim trial results in order to protect the well-being of participants. To avoid conflict of interest or loss of objectivity, investigators should not serve on a DSMB monitoring their own trial, nor should they investigate a pharmaceutical product in which they, or their families, have direct ownership. Possible conflicts of interest should be disclosed prior to the start of a trial.

In the past, some pharmaceutical companies have used professional writers to contribute to articles under the names of clinical trial investigators or physicians, a practice known as "ghost-writing." The new Principles, in line with the standards of the International Committee of Medical Journal Editors, require that any major contributors be listed as authors. In the case of large, multi-center groups that have conducted the study, the individuals accepting responsibility for the manuscript should be identified. Those who contributed to a lesser degree should be noted in the acknowledgments or listed as "participating investigators" or "scientific advisors."

The Principles also emphasize that summary results of all clinical trials for market-approved drugs, as well as drugs that have been discontinued, should be made available in a timely manner. PhRMA defines "timely" as within 30 days of drug approval or 12 months after completion of the trial. For drugs that have been discontinued, companies should provide results within 12 months of the discontinuation. Clinical trials should also be registered in a government clinical trial database, such as www.ClinicalTrials.gov, within 21 days of the first patient's enrollment.

Antitrust regulations prevent PhRMA from mandating the Principles, but the trade group expects companies and their investigators to follow them.

To read the full report, visit: http://www.phrma.org/files/attachments/042009_Clinical%20Trial%20Principles_FINAL.pdf

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OBAMA CREATES COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

On November 24, 2009, President Obama signed an Executive Order establishing the Presidential Commission for the Study of Bioethical Issues. The Commission will be based in the Department of Health and Human Services, and will advise the President on bioethical, social, and legal issues relating to science, healthcare, and technology.

The Commission is charged with identifying and examining issues, recommending regulatory or policy actions needed to address the issues, and considering multiple perspectives and possibilities for collaboration. The Executive Order explicitly states that the Commission is not responsible for reviewing or approving specific projects, but may accept appropriate suggestions of issues from departments, agencies, and the public. The Commission is permitted to conduct research and hearings, commission papers, and establish committees and subcommittees as needed.

The Commission's membership will be limited to 13 members appointed by the President. Members will serve a two-year term and will be eligible for reappointment. Upon signing the Executive Order, Obama announced that he has appointed Amy Gutmann, the president of the University of Pennsylvania, as Chair. James Wagner, the president of Emory University, will serve as Vice Chair. The remaining members will be selected from a variety of backgrounds, with no more than 3 appointed from the Executive Branch.

To view the Executive Order, visit: http://edocket.access.gpo.gov/2009/E9-28805.htm

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NIH UPDATES REQUIREMENT FOR INSTRUCTION IN RESPONSIBLE CONDUCT OF RESEARCH

On November 24, 2009, the National Institutes of Health (NIH) issued updated requirements for instruction in responsible conduct of research (RCR). All new and renewal applications submitted after January 24, 2010 must include plans for instruction in RCR that follow the new guidelines, which also apply to continuation applications with deadlines on or after January 1, 2011.

According to NIH, the new guidelines are necessary to address issues that have arisen in recent years regarding instruction in RCR and to provide standards for the scientific research community. The guidelines focus on formal instruction.

In terms of instruction format, the guidelines state that courses taught solely through online instruction would not be considered adequate to fulfilling the requirement of RCR instruction, as substantial face-to-face time and group discussions are required for optimum participation. NIH also listed several topics, including conflict of interests, human subject policies, and peer review, that should be included in RCR instruction. The guidelines provide specific recommendations on the appropriate level of faculty participation in RCR instruction, as well as the duration and frequency of instruction.

Plans for RCR instruction will be peer reviewed to ensure they are meeting the NIH's standards. According to the update, "the review panel's evaluation of the plan will not be a factor in the determination of the impact/priority score…. The results of the review of the plan for instruction in responsible conduct of research and the past record of instruction in responsible conduct of research, where applicable, will be reported as an administrative note in the summary statement and will explain how

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the review panel determined its rating. Regardless of the impact/policy score, applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan." Although NIH will not require institutions to certify their compliance with their instruction plans, institutions are expected to keep adequate records and to be able to demonstrate that NIH-sponsored researchers have received RCR education.

NIH has made supplemental information on RCR instruction available at the NIH Research Training website, including examples of programs that meet NIH's best practice standards for RCR instruction [1].

[1] The NIH Research Training website: http://grants.nih.gov/training/extramural.htm

To view the NIH guidelines, go to: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

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BEST PRACTICES FOR SYNTHETIC BIOLOGY

Synthetic biology combines biology with engineering to manufacture biological organisms and structures. In the future, researchers may be able to develop better vaccines, drugs, renewable energy sources, and more by enhancing organisms. Because of biosecurity and other implications, these future benefits must be balanced against risks of exploitation or ill intent.

Several synthetic biology companies formed the International Gene Synthesis Consortium (IGSC) to develop best practices to keep gene synthesis technologies from misuse. IGSC has created five core practices that will be adopted by each company to promote biosecurity. According to IGSC's practices, synthetic gene orders and amino acids will be screened using a Regulated Pathogen Database, with potential customers evaluated and cleared before delivery of their orders. IGSC companies will retain customer, screening, and order records for a minimum of eight years. If any problem orders are identified, companies have the right to refuse to fill any order and will notify the appropriate authorities.

Concurrently, a workshop held on November 3, 2009 by the International Association of Synthetic Biology (IASB), in collaboration with UC Berkeley's Goldman School of Public Policy, finalized a Code of Conduct for gene synthesis. The Code focuses on screening DNA sequences to determine whether they are associated with pathogenic organisms. Any associations must be evaluated by an expert, and customers must demonstrate benevolent uses for that sequence. If no demonstration can be made, the request for the sequence will be denied. Participants at the workshop also agreed to form a Technical Expert Group on Biosecurity to develop benchmarks and guidelines for gene synthesis best practices and promote biosafety and biosecurity.

On November 27, 2009, the Department of Health and Human Services (HHS) released *Screening Framework Guidance for Synthetic Double-Stranded DNA Providers*. These recommendations propose screening the providers of synthetic double-stranded DNA 200 base pairs or more in length. Upon receiving an order, HHS recommends that the company perform customer screening, sequence screening, and follow-up screening, as needed. If the company has reason to believe that a customer may violate any U.S. laws or regulations, it should contact the appropriate government authorities. The guidelines include specific recommendations for proper screening methods and software. HHS advises companies to retain screening records for at least eight years.

To view the IGSC core practices, visit: http://www.genesynthesisconsortium.org/Harmonized_Screening_Protocol.html

To view the IASB Code of Conduct, visit: http://www.ia-sb.eu/tasks/sites/synthetic-biology/assets/File/pdf/iasb_code_of_conduct_final.pdf

The HHS recommendations can be found at: http://edocket.access.gpo.gov/2009/e9-28328.htm

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Announcements

Call for Applications – The European Neuroscience and Society Network invites applications for Short Visit and Exchange Grants for work on the ethical, legal, and social implications of neuroscience. Deadline: January 12, 2010. For more information, visit: http://www.neurosocieties.eu/.

Call for Papers – Papers are invited for inclusion in the *International Journal of Technoethics*. Topics may include bio, computer, and engineering ethics; education, information, communication, and organizational technoethics; technoethics and cognition; and technoethics and society, among others. Submission Guidelines: http://www.igi-global.com/development/author_info/guide.asp.

Call for Syllabi – The Online Ethics Center of the National Academy of Engineering and the Center for the Study of Ethics in the Professions at Illinois Institute of Technology are collecting course syllabi, workshop schedules, and other materials from areas of professional and applied ethics for inclusion in an Ethics Education Library and an Online Ethics Center collection. Contact: Kelly Laas, laas@iit.edu. Visit: http://ethics.iit.edu/eelibrary/?q=node/2395.

Conference – The 5th International Conference on the Ethics of National Security Intelligence will be held on March 11-12, 2010 at Georgetown University. Visit: http://intelligence-ethics.org.

Conference – The 2010 OHRP Research Community Forum, "Protecting Research Participants: Ethical Challenges within a Regulatory Framework," will be held on February 4, 2010 at the Bar Harbor Conference Center in Seattle, Washington. Visit: http://nwabr.org/takepart/irb.html.

Fellowship – The Stockdale Center, in collaboration with the Carnegie Council for Ethics in International Affairs, invites applications for its 2010-2011 Resident Fellowship Program in Ethics. Up to three residential fellows will conduct research projects and participate in weekly seminars on national defense, war, military professions, and ethics. Deadline: February 15, 2010. Send cover letter and CV to Dr. Edward T. Barrett, ebarrett@usna.edu.

Meeting – The 19th Annual Meeting of the Association for Practical and Professional Ethics will be held on March 4-7, 2010 at the Hilton Cincinnati Netherland Plaza. For meeting and registration information, see: http://www.indiana.edu/~appe/annualmeeting.html.

Workshop – The 17th annual "Teaching Research Ethics" workshop will be held from May 18-21, 2010 on the Indiana University Bloomington campus. Topics will include ethical theory, trainee and authorship issues, conflict of interest, human subject use in clinical and non-clinical research, and responsible data management. For more information and registration information, see: http://poynter.indiana.edu/tre.

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