Professional Ethics Report

AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE • SCIENTIFIC RESPONSIBILITY, HUMAN RIGHTS, & LAW PROGRAM

VOLUME 27 **NUMBER 2** **SPRING 2014**

SOCIAL RESPONSIBILITY AND RESEARCH ETHICS: NOT EITHER/OR BUT BOTH

*By **Stephanie J. Bird***

***Stephanie J. Bird** is co-Editor of Science and Engineering Ethics and an independent consultant. She is a laboratory-trained neuroscientist and former Special Assistant to both the Provost and the Vice President for Research of the Massachusetts Institute of Technology (MIT), where she was responsible for developing educational programs on the responsible conduct of research, engineering ethics, and professional ethics more generally.*

The general view has been that science education should emphasize scientific concepts and principles. To the extent that it was given any thought within the science community, it was assumed that students would learn about responsible research conduct and other ethical concerns by observing good examples and through courses and education outside the core of science itself. It has become apparent that this approach is inadequate and serves neither the needs of the research community, nor those of society as a whole.

Professional Ethics Report (PER) is a quarterly 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.

AAAS

ADVANCING SCIENCE, SERVING SOCIETY

Presently, the focus of US ethics education in science and engineering tends to be on the individual and the responsible conduct of research (Kline 2013), or microethics [i]. In Europe, ethics education in science and engineering is grounded firmly in the concept of social responsibilities of scientists and engineers (Zandvoort, et al. 2013; Bird et al. 2013), or macroethics [ii]. The US focus on microethics rather than macroethics has led to some criticism (Kline 2013; Zandvoort et al. 2013). However, this difference is not only understandable, but appropriate because it reflects the different circumstances that have led to current efforts to introduce and integrate an awareness and examination of ethical values and conflicts into the education of scientists and engineers. Neither of these two approaches is sufficient on its own, but together they are complementary, and each makes important contributions to the education of scientists and engineers in a global and technological society.

Scientific Research: Misconduct and the Responsible Conduct of Research

Members of the scientific community rely on their colleagues to provide accurate, dependable, reproducible research that can be relied on to serve as a solid foundation upon which other researchers can build. In general, scientists are intensely curious about the nature of the universe. They expect that their work will contribute to "a common fund of knowledge" and that, in the aggregate, this knowledge will make the world a better place. Research in basic science investigates topics like how nerve cells communicate with each other and what a memory is. Research in applied science builds on basic science, for example, investigating how the memory process might be enhanced. While basic science and applied science are different, like most things, the difference is most apparent from a distance and much less distinct at the interface.

In the 1980s, the highly publicized examples of research misconduct were of fabrication, falsification, plagiarism, sexual misconduct/ harassment of graduate students by US investigators doing research outside of the US, and similar serious deviations from accepted, and acceptable, research practice. Although not uniform in their views, members of the scientific community generally recognized that research misconduct represented a significant internal threat to the research enterprise because of the real possibility that it could undermine not only public trust, but also confidence in the research process within the community as well (National Academy of Sciences 1992).

It is readily apparent that egregious misconduct undermines the fundamental assumptions that one can rely on the work of colleagues and build on it, and that one will receive fair credit for one's contribution to a project. These microethical issues are ones that can be addressed within the everyday context of research through education, explicit policies developed by laboratory and department heads, university administrators, disciplinary societies, and in the relationships between individuals. The elements of the responsible conduct of research are part of the research environment with which researchers are (or become) familiar and over which they have some control.

On the other hand, macroethical issues arise out of the use and potential misuse and abuse of research findings. These include their use in the development or support of public policy, and in the design and diffusion of technologies. Generally, the uses of scientific research are determined not by the researchers themselves but by employers, commercial private sector entities, government agencies, including the military, healthcare workers, the media, other members of the public, or in any case, individuals or groups that are only

indirectly, or even completely, unrelated to the researchers. Basic science researchers have little, if any, control of the uses or misuse of their research. The general perspective within and even beyond the research community has long been that it is the user *not* the researchers who should be held responsible for how research findings are used, a view that remains widely held (Kline 2013). But, again, all research is not the same. As a college student a few decades ago, I remember a philosophy professor emphatically explaining that it was the military and the politicians, not Robert Oppenheimer and his fellow scientists, who should be held responsible for the death and destruction wrought by the atomic bomb. Yet it is one thing to investigate the secrets of the atom which may lead to applications beyond the wildest imaginings of the researcher; it is another to specifically work to apply those findings to develop a bomb with only one obvious use. The nature of the connection between research and its product is an important and substantial difference between basic and applied research.

It is not surprising that research ethics in the US emphasizes responsible conduct of research both because the elements of research conduct are immediately relevant to the day-to-day research environment,

EDITOR: Mark S. Frankel
DEPUTY EDITOR: Rebecca Carlson

Issues are available online at:
http://www.aaas.org/4w4

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.

AAAS
1200 New York Avenue NW
Washington, DC 20005
Tel: 202-326-6217
Email: srhrl@aaas.org
Website: http://www.aaas.org/

ISSN: 1045-8808

and because they are within the sphere of influence of the researcher. A fundamental tenet of adult education is that it needs to start where people are. The potential applications of much of basic science are beyond the ken of the average researcher, never mind the possible economic, legal, cultural and ethical implications of those applications.

Social Responsibility

However necessary the microethics approach, it is not sufficient. The research community is a part of, not apart from, the larger society. Like other professionals, scientists contribute to society through their work in a manner that reflects their interests, talents and expertise. Some benefits and privileges accompany their professional role, as well as some responsibilities. The social responsibilities of researchers arise not simply because research is funded (directly or indirectly) by the public. Research is carried out in the name of society as an expression and reflection of the society's needs, interests, priorities and expected impacts. Like anyone claiming to act in the name or interests of society, there is a largely unwritten, unexpressed contract. While researchers are compensated financially, with intellectual rewards and social status, society expects more than a high quality product. This expectation is expressed to some degree in the "broader impacts" criterion for evaluation and funding of National Science Foundation grant proposals, the inclusion of "significance" as a criterion for evaluating National Institutes of Health applications, and in the various formulations of the America COMPETES Act (2007).

Social responsibility has been identified as the responsibility embodied in the Paramountcy principle, the fundamental and primary ethical principle of engineering included in the professional engineers code of ethics: “Engineers, in the fulfillment of their professional duties shall hold paramount the safety, health and welfare of the public” (NSPE 2003). The social responsibility of scientists requires that they also attend to the foreseeable societal impacts of their work, particularly as these impacts affect the safety, health or welfare of the society. In part that responsibility flows from privileged status. For example, researchers are allowed to carry out experiments as they deem appropriate with relatively little oversight. An exception is research that involves research subjects whose humane treatment, whether laboratory animals or humans, is a responsibility that goes with the privilege and is explicitly expected under the rubric of the responsible conduct of research as well as spelled out in regulations that codify the principles of bioethics. But the social responsibilities of researchers extend beyond upholding the ethical standards of society. The Uppsala Code of Ethics for Scientists highlights the responsibility of scientists to refrain from, and speak out against, weapons research and other scientific research with the potential for detrimental consequences for the environment, and for present and future generations (Gustafsson et al. 1984). Furthermore, researchers' special knowledge that comes from their work, education and expertise enables them to understand the limits of the science and when its application (e.g., in the development or support of public policy) is a misuse or even abuse of the science. Researchers have a responsibility to oppose the misuse of their work.

Moreover, because of their special knowledge researchers are in a position to contribute substantially to public understanding of science and technology, and thereby to a democratic society, by promoting an informed citizenry. It seems plausible that these larger notions of responsibility underlie the relatively recent addition of discussions of "the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research"(NIH 2009) as appropriate elements of education in the responsible conduct of research.

The European Perspective

While research scandals have been receiving increasing attention in the US, in Europe there has been growing awareness and concern regarding the intended and unintended environmental and societal impacts of technological and scientific advances (of which the Uppsala Code is an example). The European macroethical approach to science ethics

***Bird** continued on page 3*

***Bird** continued from page 2*

education arises from a full-throated declaration of the goals and role of higher education in society. In the last 10 years, as part of an effort to harmonize educational requirements at institutions of higher learning across Europe, an overarching educational framework has been adopted that highlights the widespread and strongly-held European view of social responsibility (Bologna Process 2005). The framework of qualifications for European Higher Education (EHEA) includes the expectation that *all* graduates, including those in science and engineering, "have the ability to gather and interpret relevant data (... within their field of study) to inform judgments that include reflection on relevant social, scientific or ethical issues" (at the bachelor's level) and "have the ability to integrate knowledge... and formulate judgments ... that include reflecting on social and ethical responsibilities linked to the application of their knowledge and judgments" (at the master's level).

Consistent with the idea that part of the social responsibility of researchers is to contribute to the development of an informed citizenry, the EHEA framework indicates that all graduates are expected to be able to "communicate information, ideas, problems and solutions to both specialist and non-specialist audiences" (at the bachelor's level), "communicate their conclusions, and the knowledge and rationale underpinning these [conclusions], to specialist and non-specialist audiences clearly and unambiguously" (at the master's level), and "communicate with their peers ... and society in general about their areas of expertise" (at the doctoral level).

Ethics Education in Science: Recommendations

Educational programs in science ethics in Europe and the US approach the topic from different directions for understandable reasons. In Europe, the macroethical approach is primary. However, providing "the big picture" is not enough. Trainees need to understand what is expected of them by peers in their field and what they themselves can expect as members of the global research community. At a minimum, this is responsible research conduct: the research integrity that all researchers around the globe rely on and require of their colleagues. It is noteworthy that the EHEA framework expects that graduates at the doctoral level "have demonstrated the ability to conceive, design, [and] implement... research with scholarly integrity." This is an important first step but more is needed, including in-depth discussions of the standards of the research community and responsible research conduct, potential for miscommunication, reasonable and unreasonable expectations, the potential for self-deception, and long-held, unconscious and possibly invalid assumptions or bias.

The microethical approach in the US is an essential beginning because it fulfills the fundamental educational criterion of starting where people are, in their own environment, acknowledging and validating the foundational ethical principles that underlie the research process. But it is insufficient because it does not adequately recognize the larger societal context of which research (and engineering) are a part. James Rest (1986, 1988), Muriel Bebeau (1991) and others have shown that moral development can and, with attention and nurturing, does continue throughout formal education as individuals learn about and appreciate their personal and professional role in society as members, professionals, contributors, and citizens. Yet, as employers, students and their families have called for an increasingly specialized education to meet the needs of the modern, technological world, US higher education has moved toward specialization at the expense of "breadth requirements" - that is, the very courses outside the core of science where students might learn about responsible research conduct and other ethical concerns. These are the elements of higher education, analogous to the multidisciplinary/cross-disciplinary/interdisciplinary components of ethics education in science and engineering in many European programs, that equip specialists to see and understand the societal context of their work. At the same time, while it is clear that science and engineering curricula should include stand-alone courses examining the ethical, legal and social policy implications of science and technology, along with responsible research conduct these issues must also be integrated into core courses in the form of modules, problem sets, exam questions and as elements of graduate theses.

Social responsibility and responsible research conduct are the two essential sides of ethical science. Both are necessary for an adequate education in science and engineering.

Notes

[i] In the US, it is not entirely true that science and engineering ethics education deals purely with microethical issues since programs and courses in science, technology and society (STS) are available at many universities and have been for decades, but they are not usually required for students majoring in science and engineering.

[ii] John Ladd (1980) is the source of this useful nomenclature that has been expanded and enhanced by Joseph Herkert (2005). It should be noted that macroethics includes not only collective professional responsibility, but also the decisions made by society about technology.

References

America COMPETES Act of 2007 (2007). https://www.govtrack.us/congress/bills/110/hr2272#summary (see Sections 7008 and 7009 [Accessed 30 June 2014]).

Bebeau, Muriel (1991) Can Ethics be Taught? A Look at the Evidence. *Journal of the American College of Dentists* **58** (1): 100-115.

Bird, Stephanie J., Zandvoort, Henk, Børsen, Tom & Deneke, Michael (2013). European Perspectives on Teaching Social Responsibility in Science and Engineering *Science and Engineering Ethics* 19 (4): 1413-1594.

Bologna Process (2005). Bologna Qualifications Framework http://www.nqai.ie/documents/bolognasummary.pdf (Accessed 27 June 2014) and http://www.ond.vlaanderen.be/hogeronderwijs/bologna/qf/overarching.asp (Accessed 27 June 2014).

***Bird** continued on page 4*

***Bird** continued from page 3*

Gustafsson, Bengt, Wallensteen, Peter, Ryden, Lars, and Tibell, Gunnar (1984). The Uppsala Code of Ethics for Scientists. *Journal of Peace Research* 21 (4): 311-316. (see also http://www.codex.uu.se/en/texts/Uppsala%20codex.pdf [Accessed 27 June 2014]).

Herkert, Joseph R. (2005). Ways of thinking about and teaching ethical problem solving: Microethics and macroethics in engineering. *Science and Engineering Ethics* 11(3): 373–385.

Kline, Ronald (2013). Teaching Social Responsibility for the Conduct of Research, *IEEE Technology and Society Magazine* Summer 2013, 52-58.

Ladd, John (1980). The quest for a code of professional ethics: An intellectual and moral confusion. In Rosemary Chalk, Mark S. Frankel and S.B. Chafer (eds) *AAAS Professional Ethics Project: Professional Ethics Activities in the Scientific and Engineering Societies.* AAAS, Washington DC, pp. 154-159.

National Academy of Sciences (NAS) (1992). *Responsible Science: Ensuring the Integrity of the Research Process,* Vol. I. Washington, DC: National Academies Press.

National Institutes of Health (NIH) (2009). "Update on the Requirement for Instruction in the Responsible Conduct of Research." *NIH Guide for Grants and Contracts* November 24. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html [Accessed 27 June 2014].

National Society of Professional Engineers (2003). Code of Ethics for Engineers. http://www.mtengineers.org/pd/NSPECodeofEthics.pdf (Accessed 27 June 2014).

Rest, James R. (1986). Moral Development in Young Adults, in R.A. Mines and K.S. Kitchener, (eds), *Adult Cognitive Development.* Praeger, New York.

Rest, James R. (1988) Can Ethics Be Taught in Professional Schools? The Psychological Research, *Easier Said Than Done*, pp. 22-26.

Zandvoort, Henk, Børsen, Tom, Deneke, Michael & Bird, Stephanie J. (2013). Editors' Overview - Perspectives on Teaching Social Responsibility to Students in Science and Engineering. *Science and Engineering Ethics* 19 (4): 1413-1438.

In the News

Bioethics Commission Releases Neuroscience Ethics Report

*By **Josh Ettinger***

In response to President Obama's request to "identify proactively a set of core ethical standards" for neuroscience research and applications, the Presidential Commission for the Study of Bioethical Issues released its report "Gray Matters: Integrative Approaches for Neuroscience, Ethics, and Society" in May 2014 [1]. The President's call for ethical considerations is linked to the Administration's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative, announced in April 2013.

According to the report, ethics need to be made relevant and pragmatic in order to play a meaningful role in scientific research. As the report notes, "ethics education has a better chance of informing action when it is continually reinforced and connected to practical experience." [1] The report provides several recommendations for institutions to build an ethical infrastructure that enhances best practices at all stages of research.

First, institutions should work to integrate ethical standards at all stages of research; ethics should play a key role in the earliest conception of a study to the final stages of results and impacts. Second, institutions should build an effective infrastructure that systematically evaluates its own ethical standards and considers innovative approaches towards better integration. The report lauds the Defense Advanced Research Project Agency (DARPA) for its innovative ethics program for the BRAIN initiative, which includes an independent review panel of leading bioethicists from outside the organization. Third, institutions should incorporate routine ethics educational programs for researchers at all levels. Lastly, they should ensure that advisory and review boards include individuals with an expertise in ethical practices. Research teams should include researchers with an experience in ethics as well.

The report recommends several strategies for better integration of ethics into the scientific community. Ethics education should start early—ideally before students enter college—and continue through advanced degrees and professional research environments. In fact, the inclusion of ethics in high school classes engages students and sparks greater interest in science. The report also emphasizes that proper implementation of ethics into scientific research and education demands adequate funding. It commends an emerging model of independent ethics consultation services offered to research teams, and the positive impact of engagement with stakeholders in the community and public.

The field of neuroscience is an ideal field to inculcate stronger ethics into science because it is highly multidisciplinary, linking fields such as biology, computer science and physics, and bearing significant impacts on society. The report notes that if ethicists are not fluent in the hard science, they will be unable to have a meaningful impact on neuroscience research. Likewise, scientists must be fluent in ethics in order to understand fully all the dimensions of their research. The report suggests that inclusion of professional activities related to ethics integration in career reward structures like tenure may offer further incentives to scientists. Additionally, research funders can apply pressure by requiring an ethics component as part of grant proposals. The report mentions several ethical issues specific to neuroscience. For example, what are the ethical guidelines for health decision preferences made by individuals with dementia and other degenerative diseases? What are the best practices for the use of neuroscience in the courtroom? How should researchers protect the privacy of study participants who undergo neuroimaging? What are the ethics of

***News** continued on page 5*

***News** continued from page 4*

using deep brain stimulation for mental health, especially given the moral condemnation of similar procedures in the past, such as frontal lobe lobotomy?

These issues are likely to become increasingly complex and ubiquitous as the field of neuroscience progresses. It is essential that the scientific community build an effective ethics infrastructure now, proactively, in anticipation of these mounting challenges. As the report notes, "fulfillment of these obligations supports scientific quality and is crucial to maintaining public trust essential for scientific progress." [1] An upcoming second report from the Commission will examine these ethical and societal implications specific to neuroscience in greater detail.

[1]http://www.bioethics.gov/sites/default/files/Gray%20Matters%20Vol%201.pdf

Minnesota Law Reauthorizes Collection of Newborn Blood Samples

*By **Josh Ettinger***

In early May, Minnesota Governor Mark Dayton signed a bill into law reauthorizing the collection of newborn blood samples [1]. The bill's passage reverses a 2011 ruling by the Minnesota State Supreme Court that collecting blood samples of newborns violated the state's genetic privacy regulations.

The blood is collected in order to analyze infant DNA for congenital and genetic diseases; supporters argue that it enables researchers to create new tests and provide early diagnosis for a variety of disorders. However, critics argue that it violates privacy rights, particularly when the samples are collected without parental consent. "It's clearly valuable to the government, but they couldn't do that with your coat or your cat," said Twila Brase, President of the Citizens' Council for Health Freedom in St Paul, Minnesota [1].

In 2009, several families sued the state, claiming that they never consented for the collection of their babies' blood. In 2011, the Minnesota Supreme Court ruled that the state could not collect such samples without consent, and all previously collected blood samples were destroyed. The new law will go into effect on August 1, 2014 and will permit scientists to rebuild their DNA sample databases.

In an attempt to assuage privacy concerns, the law allows parents to opt-out and refuse the collection of their children's genetic information. "This very welcome bill is all about giving freedom back to parents to make decisions for their child," said Dr. Mark Schleiss, a virologist at the University of Minnesota [1]. "This bill positions Minnesota to save as many lives as possible while upholding parents' rights to refuse testing, request destruction of test results, or both," said Dr. Robert M. Jacobson, president of the Minnesota Chapter of the American Academy of Pediatrics [2].

Yet others, such as Chuck Samuelson, Executive Director of the Minnesota American Civil Liberties Union, argue that the practice should be opt-in rather than opt-out [3]. Additionally, Brase states that parents may not be adequately informed about the procedure, and may object to particular kinds of research for which their infant's blood will be used [1].

[1]http://www.nature.com/news/minnesota-to-resume-storing-newborn-blood-samples-1.15161

[2]http://www.washingtontimes.com/news/2014/may/1/minn-house-passes-newborn-blood-sample-bill/

[3]http://blogs.citypages.com/blotter/2014/05/aclu_opposes_new_law_allowing_state_to_keep_newborn_blood_samples.php

U.K. Organizations Agree to Greater Transparency on Animal Research

*By **Josh Ettinger***

In May 2014, over 70 scientific research organizations in the U.K. launched an agreement to improve transparency about their usage of animals for research [1]. Organizations that signed the agreement include large pharmaceutical companies such as Bayer and GlaxoSmithKline, universities such as Cambridge and Oxford, and other scientific organizations. The agreement resulted from the 2012 "Declaration of Openness on Animal Research," in which organizations involved in the life sciences pledged to create a plan towards improving communication about their use of animals for scientific, medical and veterinary research.

The resulting agreement, "Concordat on Openness on Animal Research," entails four commitments: that signatories will be "clear about when, how and why" they use animals in research; improve communications with the media and public; "be proactive in providing opportunities for the public to find out about research using animals"; and annually report on progress [2]. Each commitment contains specific steps on how the organizations can put the declarations into practice.

Animal rights organizations are dissatisfied with the agreement. They claim that the concordant will accomplish little towards protecting animal research subjects and only serves as a public relations maneuver. "This concordat presents a veneer of openness but it's actually just another platform for obscuring the unpalatable truth about animal experiments," said Wendy Higgins, communications director of the Humane Society International [3]. "It is simply transparency on their terms with researchers having complete control over what the public gets to see," writes Michelle Thew, Chief Executive of the British Union for the Abolition of Vivisection (BUAV) [4].

The concordat argues that though scientists are actively developing alternatives, animals still play a vital role in research. The signatories hope to educate the public on the reality of animal research so individuals can build informed opinions on whether or not they support the practice. "We believe that the Concordat will give its signatories the opportunity to come together to share and promote good practice in being open about animal research and in providing the public with better insights into the reasons for, methods of, and progress resulting from, the use of animals in research."

***News** continued on page 6*

***News** continued from page 5*

Animal research in the U.K. is regulated by the Animals in Science Regulation Unit of the Home Office (ASRU). Organizations using animals for research are required to follow the three "R"s, namely, replacing animals with alternatives when possible, reducing the number of animals used, and refining techniques to mitigate both physical and psychological suffering. This concordant is part of an ongoing conflict between science organizations and animal rights activists over the ethics of the use of animals for research.

[1]http://www.the-scientist.com/?articles.view/articleNo/39999/title/More-Openness-on-Lab-Animals/

[2]http://www.understandinganimalresearch.org.uk/assets/document/F50071CB-EA9F-3B85-F2849E78AE6DDE7C/concordat-on-opennes.pdf

[3]http://www.bbc.com/news/science-environment-27411472

[4]http://www.huffingtonpost.co.uk/michelle-thew/buav-calls-concordat-open_b_5321630.html

Canadian Legal Ruling Raises Concerns About Mandated Genetic Testing

*By **Josh Ettinger***

After being severely injured in a house fire that killed three others, Tammy Adacsi, a Canadian woman in her mid-thirties, decided to sue the landlords of the house for negligence [1]. Ms. Adacsi claimed that she suffers from carbon monoxide poisoning, pneumonia and post-traumatic stress disorder from the fire, preventing her from returning to work. In court, the defendants argued that because Adacsi has a strong family history of Huntington's disease (HD), many of the symptoms she claimed are associated with the incident may be a result of the onset of the disease. The court then ordered her to undergo genetic testing for HD.

Adacsi objected to the test, arguing before the Alberta Court of Appeals that the test would cause her additional anxiety, pain and suffering. However, the Court of Appeals upheld the prior decision, declaring that the defendants have a right to access evidence associated with the damages claim. "If the blood test shows that [Huntington's] to be a live possibility, it may indeed be relevant to assessing damages," the three-judge panel stated. "Since the appellant has chosen to sue for damages, she cannot deprive the respondents from acquiring evidence that may assist in their defense." Though the landlords pleaded guilty and were fined $90,000 for health and safety violations in 2009, if the testing reveals a high susceptibility for the disease, Adacsi will receive significantly less compensation for the more recent charges. Adacsi underwent the genetic test in the summer of 2013. The case will move forward once the results become available.

The legal ruling raises a variety of ethical and privacy concerns related to the treatment of personal genetic information. Critics argue that mandated genetic testing for diseases by employers and insurance companies is a form of discrimination. In 2008, the Genetic Information Nondiscrimination Act (GINA) became law in the U.S., prohibiting employers and health insurance companies from discrimination on the basis of genetic information [2]. However, Canada lacks substantial legislation on this issue [1]. Additionally, current genetic testing is limited—it cannot demonstrate whether an individual necessarily has a disease, the time of onset or severity of symptoms; it can only portray susceptibility or risk of development.

Many argue that individuals have the right to maintain discretion over their own genetic information; to decide what they want to know about their own health. "To force someone to learn this information is, I think, taking away a basic human right," said Bev Heim-Myers, CEO of the Huntington's Society of Canada [1]. "Genetic information is personal information. We all have a right to know or not to know what's in our genome." Revealed genetic information about an individual can impact the privacy rights of close family members. The need to undergo such testing can also deter plaintiffs from moving forward in legitimate lawsuits.

As Dr. Maya Sabatello points out, the Canadian lawsuit is particularly complicated because it advances justice by providing a more accurate assessment of damages, but simultaneously obstructs justice by infringing on Ms. Adacsi's rights [3]. Of similar concern is how the defendants acquired the knowledge that Adacsi had a family history of HD, and what guidelines exist for determining the pertinence of mandated genetic testing in legal proceedings.

[1]http://news.nationalpost.com/2013/09/26/woman-who-nearly-died-in-calgary-house-fire-ordered-to-undergo-genetic-testing-for-huntingtons-disease/

[2] http://www.genome.gov/10002077

[3]http://braingenethics.cumc.columbia.edu/genetic-testing-in-torts-litigation-justice-or-injustice/

Investigation Finds EPA Could Improve Human Study Subject Protection

*By **Josh Ettinger***

In late March, the U.S. Environmental Protection Agency's (EPA) Office of the Inspector General (OIG) released its findings from an investigation into the agency's human study subject protections [1]. The investigation was requested by Oversight Subcommittee Chairman Paul Broun, M.D. (R-Ga.), who raised concerns over several EPA studies examining the impact of diesel exhaust emissions on human health. The studies, conducted between 2010 and 2011, further explore the EPA's claims that diesel exhaust emissions harm human well-being and the environment.

In an October 2012 letter to the EPA's Inspector General, Arthur A. Elkins, Rep. Broun questioned whether the EPA had obtained sufficient approval to undertake the studies, obtained adequate informed consent from participants, and properly addressed any adverse events that occurred during the studies.

***News** continued on page 7*

***News** continued from page 6*

The OIG's report, released on March 31, 2014, claims that the EPA adhered to applicable regulations during the diesel exhaust emissions studies: the EPA obtained sufficient approval to conduct the studies from the EPA Human Studies Research Review Official (HSRRO) and a biomedical institutional review board (IRB); the EPA obtained informed consent from the 81 individuals who participated in the studies; and the EPA addressed adverse events during its studies and provided clinical follow-up.

While the EPA officials followed relevant legal policies and procedures, the OIG recommended several improvements to enhance the EPA's protection of human study subjects. After discovering that all study participants did not receive the same consent information, the OIG recommended that the EPA establish more consistent communication of health risks to participants. "Presenting consistent information about risks further ensures that study subjects can make the most informed choice about participating in a study," states the report. Additionally, the EPA did not include information on long-term cancer risks associated with exposure to exhaust emissions. While the EPA found cancer risks from short-term exposure to be marginal, the OIG emphasized that "evidence suggests that at least some human study subjects would like to know if a study involves risk of death, even if the risk is very small."

The OIG noted a lack of guidelines for study modifications. When the EPA made methodological changes to the diesel exhaust studies, it was unclear whether officials needed to confer with oversight committees. Similarly, there were inadequate guidelines on handling adverse events associated with human study subjects. Adverse events include immediate detrimental health impacts during a study. The EPA also reported several adverse events later than required, and neglected to report some events to the biomedical IRB. Though "the clinical follow-up appeared to be reasonable," the OIG recommended the establishment of consistent procedures when handling adverse events.

In response to the report, Rep. Broun stated that, "It is abhorrent for the EPA to be conducting these human experiments without providing robust information and notification to the patients about the risks of death and following the strictest protocols." [2]

In response to the OIG's investigation, the EPA agreed with all recommendations, prepared corrective actions and a timeline for proper implementation. "We are in the process of embracing their recommendations," wrote Bob Kavlock, deputy assistant EPA administrator for science, on an EPA blog. "Thanks to their generous spirit and contribution of time, our research volunteers play a vital role in helping EPA scientists advance the cause of protecting the health of all Americans." In 2013, the EPA strengthened protections of human study subjects involved in pesticide research [3].

[1]http://www.epa.gov/oig/reports/2014/20140331-14-P-0154.pdf

[2] http://science.house.gov/press-release/epa-conducted-experiments-humans-cancer-causing-and-lethal-pollutants

[3]http://www.epa.gov/oppfead1/guidance/human-test.htm

Resources

Presidential Bioethics Commission Releases Primer on Incidental and Secondary Findings

*By **Josh Ettinger***

In April 2014, the Presidential Commission for the Study of Bioethical Issues released a primer to help institutional review boards (IRBs) understand the Commission's recommendations on incidental and secondary findings. The recommendations were made in the Bioethics Commission's December 2013 report, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts.* The primer summarizes the report's recommendations for how to ethically manage the discovery of incidental and secondary findings.

Incidental findings are results outside of a study's original purpose. They can be either "anticipatable," or known to be associated with a particular procedure, or "unanticipatable," meaning that they were unexpected. Secondary findings are also ancillary to the main goal of a study; however, they are actively sought in the study, occasionally based on the recommendations of outside experts. There are several kinds of tests associated with incidental or secondary findings including, biological specimen analysis, genetic sequencing and medical imaging—such as X-rays, computed tomography (CT) scans and ultrasounds—which can yield findings of clinical relevance to individuals or family members.

The primer states that researchers should clearly express the possibility of incidental or secondary findings to participants before they provide consent; IRBs should ensure that participants enter the study adequately informed about the possibility of these findings. "Researchers should communicate the fundamental aspects of their research—including the possibility of discovering incidental or secondary findings and the plan for their disclosure or management—so that participants can make fully informed decisions about whether to enroll. IRBs should review informed consent materials to ensure that researchers have included information about incidental and secondary findings and the plan for management of these findings."

Researchers should build a management plan for additional findings based on the specific circumstances of their study. "Researchers should develop a plan based on evidence about the analytic and clinical validity of potential findings and their clinical or reproductive significance, and careful consideration of the benefits, risks, and costs of disclosure, including the risk that seeking or analyzing incidental and secondary findings might distract from the central goal of research."

***Resources** continued on page 8*

Resources *continued from page 7*

Researchers can inquire about what information participants want to receive; participants might choose to only be informed about findings that are of high clinical significance. The primer points out that while researchers are ethically obligated to create a management plan for incidental findings, they are not required to search for secondary findings. Even if researchers decide not to disclose any incidental or secondary findings to participants, they must still properly communicate this plan.

The primer suggests that IRBs ensure that research teams have individuals familiar with anticipatable incidental findings associated with the study's procedures. If a team does not have this expertise, IRBs may suggest that the team add members or seek experts for consultation. The primer is posted at http://bioethics.gov/sites/default/files/IRB%20Primer%20-%20Incidental%20and%20Secondary%20Findings.pdf.

Announcements

Award

Nominations are now being accepted for the AAAS Scientific Freedom and Responsibility Award. This award has been given by the American Association for the Advancement of Science since 1980. The successful candidate receives a plaque and $5000 and will be honored at a ceremony at the AAAS Annual Meeting (next February in San Jose). The award is given to scientists or engineers or their associations whose exemplary actions have served to foster scientific freedom and responsibility. Such achievements can include acting to protect the public's health, safety or welfare; focusing public attention on important potential impacts of science and technology on society by their responsible participation in public policy debates; or establishing important new precedents in carrying out the social responsibilities or in defending the professional freedom of scientists and engineers. All nominations should be submitted to Deborah Runkle. The deadline for nominating someone for this important award is September 1, 2014.

Call for Papers

It has been more than 20 years since the U.S. Supreme Court's landmark decision in Daubert v. Merrell Dow Pharmaceuticals about the admissibility of scientific expert witness testimony. Within the context of ongoing debates about how to evaluate expert testimony, the *Journal of Philosophy, Science & Law* invites authors to submit new manuscripts that address epistemological, ethical, or other philosophical issues pertaining to Daubert and related legal cases. Suitable topics include but are not limited to: whether Daubert offers a philosophically sound approach to evaluating the legitimacy of expert witness testimony, philosophical issues emerging from post-Daubert cases, whether theUS court system has appropriate procedures in place to evaluate expert testimony relating to emerging technologies, including neurotechnology, genetics, and surveillance devices, ethical issues relating to the development and use of scientific evidence in the courts, and comparative analyses between the standards of expert witness testimony in US and non-US court systems. Authors should submit their manuscripts and abstracts via email attachments no later than August 29, 2014 to Dr. Jason Borenstein: borenstein@gatech.edu. Accepted manuscripts will be published online in December 2014 / January 2015.

Essay Competition

At the recent 13th International Public Communication of Science and Technology (PCST) Conference in Brazil, the issue of the deficit model was raised in the session on science communication and its audiences. To stimulate the debate and to contribute to the community, the journal *Public Understanding of Science* announces an essay competition on: "In Science Communication, why does the idea of a public deficit always return?" In line with the new constitution of PCST, submissions from both younger and older scholars are encouraged. The essay will be fast tracked to print publication in 2015 and made freely available online. The deadline for submission is January 15, 2015. Send submissions to Sue Howard at pusedit@lse.ac.uk.

Ethics Bowl

The Association for Practical and Professional Ethics will host the 2014 Ethics Bowl summer workshop at St. Petersburg College in St. Petersburg, Florida. The dates of the workshop are July 12-13. The workshop will hold sessions pertaining to the Intercollegiate Ethics Bowl, the Two-Year College Ethics Bowl, and the National High School Ethics Bowl, in addition to sessions on coaching, judging, student voices, the future of the bowl, and organizing regional competitions. Further details can be found at http://appe.indiana.edu/ethics-bowl/ethics-bowl-summer-workshop/