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HUMAN RIGHTS AND NON-LETHAL WEAPONS RESEARCH*

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The potential of neuroscience, pharmacology and other scientific fields to develop new kinds of non-lethal weapons has brought both excitement and dread. Potential weapons include chemical agents that can lead to unconsciousness or hallucinations, optical weapons such as lasers that are disorienting or blinding, acoustical weapons that can affect bodily functions, drugs that alter affective status, and forms of energy that cause pain without damaging tissue. The excitement derives from the potential to gain intelligence and to use these tools to affect the memory, perceptions, and affective status of enemies. Some proponents believe they will be especially helpful in asymmetrical warfare in heavily-populated areas, lowering the risk of death to civilians.

Research for these weapons is accelerating. Weapons research inevitably raises moral issues, such as whether their development, even when undertaken in the name of national defense, actually stimulates conflict or diverts resources that could otherwise be spent on the well-being of populations. But even beyond these profound concerns, which need to be resolved through transparent and democratic processes, lie particular human rights questions that scientists, scientific

organizations and universities, as well as government, ought to address in meeting their own obligations to respect human rights. Typically, though, consideration of human rights concerns in weapons research is limited to those emerging from the Nuremberg Code and the guidelines and regulations it has spawned to protect human subjects in research. In fact, human rights principles can and should be brought to bear as scientists, their sponsors, funders, and societies consider their engagement in this research.

In this brief essay I can only sketch out some of the questions, and will focus on two dimensions of human dignity at the core of human rights. One is the dignity of the individual, that is, the freedoms, protections and material supports needed to live a decent life. Under international human rights law, these include, among others, rights to free expression, protection against arbitrary arrest, detention and punishment, and access to decent housing, sufficient food and health care. Rights within this realm also include those established under international humanitarian law – the law of war – especially the protection of civilians in armed conflict. A second dimension of human dignity involves rights of citizenship and governance, e.g., democratic participation and accountable institutions.

In the dimension of individual dignity, the new non-lethal weapons research raises questions about the weapons' capacity to discriminate between civilians and military targets, about due process of law, and about respect for personhood. The first of these concerns, discrimination or distinction, is one of the

most straightforward yet deeply embedded principles of the law of war. It holds that warring parties must distinguish between civilians and combatants by refraining from attacking civilians and civilian facilities and minimizing harm to civilians when targets are military in nature. The principle applies both to the conduct of war and to the weapons used. If a weapon, by design, inherent nature, or typical use does not effectively distinguish between military targets and civilians, it breaches the principle of discrimination. It is this principle that animated successful movements to ban anti-personnel landmines and cluster bombs, since mechanisms designed to assure that they will not unduly impact civilians and are removed after the fighting ends have proven ineffective. The same principle should guide research in non-lethal weapons. Some advocates of these weapons claim that their development could save lives, especially the lives of civilians, where an alternative is the use of artillery, bombs or tanks [1]. But if the consequence is to inflict disproportionate or indiscriminate, unnecessary suffering on civilians, or to spread terror in the population, the use of such weapons still breaches humanitarian law principles, and scientists and their sponsors should decline to develop them [2].

Raising the next question, about due process of law, may seem odd since we associate due process with fair decision-making, not war. But the new non-lethal weapons are likely to be used, and even developed, for circumstances having nothing to do with conventional war, such as intelligence gathering, crowd control, and law enforcement. The

potential domestic uses are indeed extensive, and it takes little imagination to view them as instruments for controlling political opposition. In such cases, the use of a non-lethal weapon may well amount to the infliction of pain or personality or perceptual disruption without any determination of guilt or innocence. This possibility is not just theoretical. Non-lethal weapons such as stun guns are already used on prisoners and amount to an infliction of pain or a punishment without due process. Scientists should be attentive to these potential uses and decline to participate in the development in these weapons if there exists a likelihood that they will be employed in law enforcement.

My last concern in the realm of individual dignity may seem elusive, but perhaps is the most central. The weapons are designed to affect the personality, perception, affective status, and consciousness of the individual against whom they are employed -- all aspects of what it means to be human. The Universal Declaration of Human Rights recognizes that, at root, human dignity is about personhood. So it provides that everyone should be recognized as a person before the law (Article 6), that no one should be deprived of his or her nationality (Article 16), and that because social, cultural and economic rights that are "indispensable for his dignity and the free development of his personality,"

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people should have a right to participation in the cultural life of the community (Article 27). Education, too, is "directed to the full development of the human personality." Since the very goal of some new weapons is to undermine this sense of personhood, their development may well be an affront to human rights [3].

Let's now look briefly at the implications for new non-lethal weapons development in the other dimension of human dignity, the political level. The first concern in this realm is about the consequence for open government. Weapons development, of course, always brings tension between the need for secrecy and principles of openness essential for democratic accountability; we see this, for example, in concerns about dissemination of dual use technologies. The problem with non-lethal weapons development is that it vastly expands the realm of scientific inquiry relevant to weapons to neuroscience, pharmacology and other branches of science, thus raising questions about how much scientific research will be fenced in from public review.

As the realm of scientific inquiry related to weapons development expands, we need to look as well at the potentially corrupting influence of such research on scientific organizations. One needn't rail against the military-industrial complex to cite instances where the needed independence of professional scientific organizations on human rights questions can become compromised as the organizations themselves receive ever more funding for research on intelligence and weapons activities. In recent years, for example, searching questions have been raised about whether the American Psychological Association's receipt of government funds for research on use of psychology in national intelligence matters influenced its position on the ethical and human rights question of participation of psychologists in interrogation. The point is that the expansion of the realms of basic science

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.

for military use raises the potential for conflicts of interests even on critical issues of human rights.

Finally, new non-lethal weapons may have high potential for undermining political opposition, expanding the potential tools of repression far beyond the use of Billy clubs and tear gas. Of course, many weapons never designed for civilian use, such as tanks, have been used to stifle political participation, but the difference here is that the very design of many of the new non-lethal weapons, to temporarily paralyze or knock people out, makes it more likely that they will be used for political control rather than for any legitimate military purpose. As a result, we must seriously examine the potential impact of these weapons for undermining principles of governance based on human rights.

Every potential new non-lethal weapon warrants granular analysis under these human rights principles, and perhaps others I have not identified. What is critical is that scientists, scientific organizations, sponsors of scientific research in this field, and oversight agencies take human rights considerations seriously when they consider engaging in research oriented toward development of these weapons.

*This article is based on a talk given at a meeting of the AAAS Science and Human Rights Coalition, Washington, DC, January 22, 2010.

[1] Michael Gross, *Medicalized Weapons and Modern War. Hasting Center Report*, January-February 2010.

[2] International Committee of the Red Cross, *Guide to the Legal Review of Non-Lethal Weapons, Means and Methods of Warfare: Means and Methods to Implement Article 36 of the Additional Protocol I of 1977 Geneva*: International Committee of the Red Cross, 2006).

[3] Jonathan Moreno, *Mind Wars: Brain Research and National Defense* (New York: Dana Press, 2006).

STEM CELL AMENDMENT BILL INTRODUCED TO HOUSE OF REPRESENTATIVES

On March 10, 2010, H.R. 4808, titled "Stem Cell Research Advancement Act of 2009," was introduced in the House of Representatives. The bill proposes amendments to the Public Health Service Act to allow for human stem cell and human embryonic stem cell research. Although President Obama issued Executive Order 13505 to increase federal funding, the National Institutes of Health's guidelines for human stem cell research have made it difficult for scientists to continue work on stem cell lines approved during the Bush administration. Scientists fear that lines may not be approved for further funding under the new standards, resulting in years of wasted research and grant money.

H.R. 4808 provides that research on human stem cells, including human embryonic stem cells, should be conducted and supported. Human embryonic stem cells should be eligible if: 1) cells were derived from excess embryos donated from in vitro fertilization (IVF) clinics and were no longer needed by the individual seeking treatment; 2) individuals seeking IVF were informed that donated embryos would never be implanted in a woman and may be discarded; and 3) individuals seeking IVF who donated embryos must provide written informed consent and may not receive any compensation for their donation. The bill requires that the NIH guidelines must be maintained, reviewed "not less than every 3 years", and updated as necessary. The bill also prohibits funding for human cloning research that results in implantation of an egg containing nuclear material transferred from a somatic cell, but does not ban the creation of such cells.

The bill was referred to the House Committee on Energy and Commerce.

To view H.R. 4808, visit:
[http://frwebgate.access.gpo.gov/cgi-](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h4808ih.txt.pdf)

[bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h4808ih.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h4808ih.txt.pdf)

To view Executive Order 13505, visit:
<http://edocket.access.gpo.gov/2009/pdf/E9-5441.pdf>

To view the NIH stem cell guidelines, visit:
<http://stemcells.nih.gov/policy/2009guidelines.htm>

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SACGHS RELEASES GENE PATENTING REPORT AND RECOMMENDATIONS

Following several meetings and much discussion, the Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) voted on February 5 to send its controversial gene patenting report to Secretary Kathleen Sebelius.

The report outlines six recommendations. In summary, they are:

- Support exemptions from liability for infringement of certain gene patents.
- Work to increase adherence to current guidelines that promote non-exclusive licensing of diagnostic genetic/genomic technologies.
- Work to enhance transparency in licensing.
- Establish an advisory body on the health impacts of gene patenting.
- Work to provide relevant expertise to the U.S. Patent and Trademark Office.
- Work to ensure patient access to genetic tests with clinical utility.

The first recommendation has drawn the most focus from stakeholders. Some groups, like the Association for Molecular Pathology [1], have expressed support for SACGHS's conclusions, while organizations such as the Association of American Universities [2] and the Biotechnology Industry Organization [3] have released statements critical of the report. Wrote BIO: "We believe that the recommendations, if implemented, would unravel two sets of laws that are the foundation of life science innovation in this country - the patent system and the Bayh-Dole Act. This would do more harm to patients than good, by impairing the research,

development and commercialization of the medicines and diagnostic tests of tomorrow." The Bayh-Dole Act is the landmark 1980 legislation that allowed universities, small businesses and nonprofits to have intellectual-property control over inventions developed through federally funded research.

As SACGHS is an advisory committee with no rulemaking authority, it is now up to Secretary Sebelius to decide how to proceed. The timing of the report's release coincided with arguments in a major case involving a legal challenge against gene patents held by Myriad Genetics and initiated by the American Civil Liberties Union [4].

To view the SACGHS gene patenting report, visit:
<http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Patents%20Report%20Approved%20202-5-20010.pdf>

- [1] The Association for Molecular Pathology, 02/04/10, "Comments to the Secretary's Advisory Committee on Genetics, Health and Society";
<http://amp.org/Gov/Position%20Statements/AMPcommentstoSACGHSFeb2010.pdf>
- [2] http://www.aau.edu/policy/patent_reform.aspx?id=9604
- [3] Biotechnology Industry Organization, 02/04/10, Letter to the Secretary;
http://bio.org/ip/genepat/documents/SACGHSign-onletter2-4-2010final_000.pdf
- [4] GenomeWeb Daily News, 02/02/10, "Myriad, ACLU Clash over Gene IP in NY Court";
<http://www.genomeweb.com/dxpgx/myriad-aclu-clash-over-gene-ip-ny-court>

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ENGLAND TO REVIEW LIBEL LAWS

In December of 2009, Justice Secretary Jack Straw announced an impending review of England's libel laws in response to increased campaigning from science and free speech groups and mounting public concern. Academic debate and open discussion are necessities of the scientific process, yet many groups complain that England's libel laws prevent scientists, medical researchers, science writers, and publishers from engaging in such

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activities without danger of legal action.

Current lawsuits against scientists and science writers demonstrate the stifling impact of libel laws on the scientific community. Henrik Thomsen, radiologist and director of the Department of Diagnostic Sciences at the University of Copenhagen, warned colleagues about the risks of Omniscan for renal patients in a 2007 lecture given in Oxford. Manufactured by GE Healthcare, Omniscan is one of several drugs used to enhance MRI scan images, but is thought to cause nephrogenic systemic fibrosis in patients with kidney problems. In response to his warnings, Thomsen was sued in England by GE Healthcare.

In another case, the British Chiropractic Association (BCA) sued UK author and journalist Simon Singh after he questioned the effectiveness of the BCA's chiropractic treatments for children in the April 2008 issue of *The Guardian*. Similarly, NMT Medical has sued Peter Wilmshurst, consultant cardiologist at Shrewsbury hospital, for questioning its heart implant device, Starflex, at a 2007 cardiology conference.

The abovementioned lawsuits serve as warnings to the scientific community: don't speak out against large corporations, the rich or powerful. Fear of libel charges has influenced the way science is conducted and discussed, as well as the decision-making process for publishers of scientific work. For example, Dr. Fiona Godlee, editor of the *British Medical Journal* (BMJ), revealed in a December 2009 *Times* article that the BMJ journal *Archives of Disease in Childhood* turned down a number of case reports due to legal advice about libel risks [1]. Journalists have also been reluctant to write articles that could result in a Simon Singh repeat [2]. By limiting the scope of scientific articles and journalistic investigations, publishers limit the spread of potentially life-changing information; consequently, research suffers. The simple threat of legal action is enough to hinder the entire process and impede the sharing of vital information with colleagues and patients.

In support of Simon Singh, the charitable trust Sense About Science launched a petition to fight the use of English libel laws in silencing "discussion of medical practice and scientific evidence" [3]. Then, in December 2009, England's libel law reform movement made progress publicly and politically. Sense About Science joined with free speech groups English PEN and Index on Censorship in the Libel Reform Coalition to campaign for libel law reform in England and Wales. English PEN and Index on Censorship also launched a national petition in support of English libel law reform.

Coupled with their petition, the free speech groups issued a report with recommendations to restore balance between free speech and the protection of reputation sought through libel law. The report states that "English libel law has a negative impact on freedom of expression, both in the UK and around the world" [4]. Freedom of speech, academic criticism, and open discussion are vital components of scientific and medical research. Ben Goldacre, writer, MD and supporter of the Libel Reform Campaign, explains how vital the criticism of "ideas and practices without fear of disproportionate consequences" is to the scientific community. In a statement on the Libel Reform Coalition website, Goldacre notes the particular importance of debate within medical research, observing that "our ideas only improve through critical appraisal, and any law that stifles this is a danger to patients and the public."

In response to the Coalition's report and public concern, Justice Straw acknowledged the imbalance of the current system and announced the formation of a working group on libel reform [5]. The group responded to recommendations in the English PEN and Index on Censorship report, as well as a February 2010 report from the House of Commons Culture, Media, and Sport Committee on press standards, privacy, and libel. Additionally, Straw's group addressed concerns over "libel tourism," where individuals or parties from foreign countries sue for libel in the English courts. The working group report was released in March 2010.

To view the English PEN and Index on Censorship report, visit:
<http://www.libelreform.org/our-report>

To view the House of Commons Culture, Media, and Sport Committee report, visit:
<http://www.publications.parliament.uk/pa/cm200910/cmselect/cmcomeds/362/36202.htm>

To view the Report of the Libel Working Group, visit:
<http://www.justice.gov.uk/publications/docs/libel-working-group-report.pdf>

[1] The Times, 12/10/09, "Scientists urge reform of 'lethal' libel law";

<http://www.timesonline.co.uk/tol/news/science/medicine/article6951054.ece>

[2] New York Times Opinionator, 09/15/09, "Cracking the Spine of

Libel": <http://opinionator.blogs.nytimes.com/2009/09/15/cracking-the-spine-of-libel/>

[3] <http://www.senseaboutscience.org.uk/index.php/site/project/334>

[4] <http://www.libelreform.org/our-report/download-the-report#>

[5] The Sunday Times, 11/22/09, "Jack Straw pledges action to end libel tourism": <http://business.timesonline.co.uk/tol/business/law/article6926997.ece>

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UK GOVERNMENT AND SCIENTISTS CLASH OVER ADVISING PRINCIPLES

In October 2009, following his public statement that alcohol is more dangerous than many illegal drugs (e.g., cannabis, ecstasy, LSD), Professor David Nutt, chair of the United Kingdom's Advisory Council on the Misuse of Drugs, was fired by Home Secretary Alan Johnson. Though rooted in science, Nutt's statement diverted from the government's current drug policies, leading Johnson to dismiss him from a position he has held for ten years. In the following weeks, five scientists resigned from the Council due to unsettled differences with the government. The incident, occurring only months after the government's July publication *Putting science and engineering at the heart of government policy*, has sparked a row between the scientific community and the UK government, regarding the government's acknowledgment of the scientific process.

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On November 6, 2009, approximately 90 scientific advisors, scientists, and the charity Sense about Science drafted the “Principles for the Treatment of Independent Scientific Advice,” which was then provided to the government for response. The document is framed around three main principles: academic freedom, independence of operation, and proper consideration of advice. In the first principle, academic freedom is described as scientists’ right to express views “openly and without restriction” so long as they act professionally and clarify whether they are speaking for the government. The second principle, independence of operation, gives science advisors the right to discuss “evidence and advice that are not accepted by the government” in a public forum. The last principle, proper consideration of advice, suggests that government officials give evidence and advice thorough examination. Should the government choose to reject or challenge evidence, they should avoid misrepresenting findings and criticizing the scientists providing the evidence or advice.

On December 15, 2009, the UK government published a revised set of principles, titled “Principles of scientific advice to Government”, in response to those provided in the previous month. The revision is based on three main principles: trust and respect, independence, and transparency and openness. The first principle emphasizes that the government should respect and value scientific advisors, but that scientists should also respect the authority of the government in developing policy, working together to reach a “shared position.” The second principle, independence, acknowledges scientists’ right to communicate findings, so long as they remain unbiased and disclose the position from which they are speaking. The third principle states that independent scientific advice should be discussed with the government prior to release. Scientific advisors should announce their confidence in provided evidence and share any uncertainties. The government will explain all reasons for rejecting or making a policy decision that is at odds with scientific advice and

will discuss future sackings with the chief scientific advisor prior to acting.

The UK government allowed members of the scientific community, government, and public to provide consultation on these principles until February 9, 2010. The consultation was incorporated into the larger discussion on the pending revisions of Guidelines for the Use of Scientific Analysis in Policy Making (2005). On February 7, 2010, a letter signed by over 40 senior scientists, was submitted to the consultation, criticizing their revised principles, stating that further damage to the collaboration of science and government may ensue. On March 2, 2010, in an effort to rekindle the relationship between government and science, the House of Commons published a review of the principles. The review includes specific recommendations, revisions, and critiques, and establishes that a revised set of principles will be published and incorporated into Guidelines for the Use of Scientific Analysis in Policy Making.

To read the July 2009 publication, visit: <http://www.publications.parliament.uk/pa/cm200809/cmselect/cmduis/168/168i.pdf>

To view the original principles, visit: <http://www.senseaboutscience.org.uk/index.php/site/project/421>

To view the government revisions, visit: <http://nds.coi.gov.uk/clientmicrosite/content/Detail.aspx?ReleaseID=409612&NewsAreaID=2&ClientID=431>

To view Guidelines for the Use of Scientific Analysis in Policy Making, visit: <http://www.bis.gov.uk/assets/biscore/government/g/guidelines-scientific-analysis-policy-making.pdf>

To view the government’s review of the principles, visit: <http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/384/384.pdf>

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HHS INSPECTOR GENERAL FINDS FAULT IN CENTER FOR DISEASE CONTROL AND PREVENTION’S ETHICS PROGRAM

On December 18, 2009, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released “CDC’s Ethics Program for Special Government Employees on Federal Advisory Committees.” The report results from an investigation into the Center for Disease Control and Prevention (CDC) and its compliance with ethics requirements, specifically conflict-of-interest reporting.

CDC committees advise the government on vital public health topics such as cancer and immunization. To ensure the integrity and credibility of committee recommendations, committee members must disclose conflicts of interest and complete CDC ethics requirements, including ethics training. This is particularly important for special government employees (SGE) who are temporary government workers. SGEs serve as topic experts and often work in similar areas outside of their government positions; thus, they may have conflicts of interest with committee work. Before participation in any advisory committee, members must complete financial disclosure forms. Their information is reviewed by the CDC, with remaining conflicts of interest resolved through ethics agreements or waivers.

OIG completed a review of SGE financial and conflict-of-interest disclosure forms from 2007 for 246 members on 17 CDC committees. The report found that CDC and SGEs on advisory committees did not follow ethics requirements. CDC failed to ensure the completion of financial disclosure forms for almost all SGEs; identify or resolve conflicts of interest for over half SGEs; and confirm the completion of SGE ethics training. Fifteen percent of SGEs also violated ethics requirements during committee meetings; for example, voting on matters in which an ethics waiver forbade participation, or participating without Office of Government Ethics forms on file. These ethics breaches occurred within

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committees that made well-known public health recommendations, such as the recommendation to routinely vaccinate US females for the prevention of cervical cancer.

To improve oversight of SGE ethics requirements, OIG recommended that CDC:

- Ensure the completion of SGE financial disclosure reports prior to certification
- Identify and resolve conflicts of interest before allowing SGE participation in committee meetings
- Increase collaboration with HHS Office of General Counsel
- Ensure that CDC employees and SGEs receive ethics training
- Monitor and track SGE compliance with ethics requirements

In response, CDC has strengthened its financial disclosure and conflict-of-interest process by redistributing responsibilities and oversight and strengthening controls to prevent conflict of interest omissions. Overall, CDC agreed with OIG's report recommendations.

To view the OIG Report and CDC report comments, visit:

<http://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf>

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HHS INSPECTOR GENERAL REPORTS ON MANAGING CONFLICT OF INTEREST IN RESEARCH

In November 2009, the Office of Inspector General (OIG) released a report entitled *How Grantees Manage Financial Conflicts of Interest in Research by the National Institutes of Health (NIH)*. Congress requested that OIG identify vulnerabilities presented by the grantee institutions' oversight of their researchers' financial conflicts of interests. Federal policy mandates that each grantee institution identify any such conflict and prepare written policy for its management, reduction, or elimination. In its report, OIG also provided

recommendations to NIH on how to eliminate those vulnerabilities.

OIG found that equity ownership was the most common type of conflict reported to NIH. Other conflicts included inventing or developing technology related to the grant research, receiving royalties, or consulting, writing, or holding a position for an outside company. OIG reported that researchers at many grantee institutions only have to report the financial interests that they deem to be affected by their research, and that nearly half of the reporting institutions do not require researchers to disclose exact amounts of money or equity involved.

The most frequent method of conflict management reported by grantee institutions was requiring researchers to fully disclose their reported conflicts. According to OIG, several other methods commonly used do not directly address researchers' conflicts, such as requiring researchers to certify their primary commitment to the grantee institution or that they will follow conflict of interest procedures. OIG was also concerned that conflict information reported by researchers is rarely reviewed by grantee institutions.

OIG stressed that vulnerabilities in NIH grantee institutions' oversight need to be resolved in order to ensure that federal money is not supporting biased research. The report included several recommendations to NIH. For example, OIG recommended that NIH:

- Request grantee institutions to provide details to NIH on the nature of all reported financial conflicts of interest and how they are managed, reduced, or eliminated;
- Require grantee institutions to collect information on all significant financial interests held by researchers, not just those deemed by researchers to be reasonably affected by the research;
- Require grantee institutions to collect information on specific amounts of equity and compensation from researchers;
- Develop and disseminate guidance on methods to verify researchers' financial interests.

NIH responded, stating that many of OIG's recommendations are already being handled by its Advanced Notice of Proposed Rulemaking (ANPRM) in the *Federal Register* earlier this year, which addresses the responsibility of applicants in promoting objectivity in research [1]. Of those recommendations not already being addressed, NIH will consider OIG's recommendation to develop materials to teach grantee institutions how to verify their researchers' conflicts. However, NIH noted that many of OIG's other recommendations cannot be implemented because of current NIH regulations. In response, OIG advised that NIH make the amendments necessary to enact its recommendations.

To view the full report, visit:

oig.hhs.gov/oei/reports/oei-03-07-00700.pdf

[1] The National Institutes of Health's Advance Notice of Proposed Rulemaking (ANPRM) in the *Federal Register*: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-099.html>

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FDA RELEASES RECOMMENDATIONS TO PROTECT STUDY SUBJECTS

On October 26, 2009, the Food and Drug Administration (FDA) released "Guidance for Industry on Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects." The document provides an overview of the principle investigator's responsibilities while conducting clinical trials of drugs, biological products, or medical devices.

The guidance states that investigators should personally conduct or supervise the investigation, and are accountable for any regulatory violations that result from failure to provide adequate supervision. If the trial calls for delegation of tasks, it is the investigator's responsibility to ensure that individuals are qualified, trained, and knowledgeable about the study. Investigators should maintain lists of these individuals and the tasks that have been delegated, along with their qualifications. Staff members not

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employed directly under the investigator should also be qualified and trained. It is the investigator's responsibility to supervise the tasks performed by these individuals. Investigators should also review reports from external sources contributing to the study, to confirm that results appear reasonable and consistent.

In clinical trials, investigators should ensure that medical care is available to a subject for any adverse events that may occur and that such care is provided until subjects have recovered from any condition related to the study that develops during or after their participation, even if care extends beyond the duration of the study. Investigators should inform participants of any condition or illness that requires medical care that is identified during the screening process. For trials involving drugs with toxicity or potential for abuse, the investigator should be available by phone or electronic communication 24 hours a day, and should remain in close proximity to the site for the duration of the study.

To read the full report, visit:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>

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JOINT COMMITTEE CALLS FOR STRENGTHENED RESEARCH INTEGRITY IN CHINA

On August 26, 2009, the Joint Committee for Promoting Research Integrity of China released *Opinions on Strengthening Research Integrity of Our Country*, a policy document that demonstrated the shortcomings of research integrity in the nation and ways to implement a better system.

China has a long history of innovation through scientific research, but lax regulation of integrity, and ineffective codes of conduct have hampered the country's progress. The Committee states that academic as well as scientific institutions should play an active role by promoting integrity that upholds the Deng Xiaoping Theory, the "Three

Represents," and the socialist core value system. These institutes are also responsible for regulating issues that arise from conflicts of interest in the scientific community. In order to handle research misconduct, the institutions need to establish a mechanism for receiving allegations of breaches in research integrity. Aside from intensifying supervision in areas of research activity, sanctions should also be placed on individuals who fail to comply with laws that promote research integrity. The Committee suggests that misconduct needs to be made public, and civil or criminal liability pursued by those in authority.

China also seeks to improve the legal system by implementing positive changes in terms of its enforcement of research integrity in the scientific community. Some of the solutions highlighted by the Committee are to protect the rights and interests of scientists, define boundaries of research misconduct, and investigate research integrity-related legal institutions. In terms of dealing with the management institutions, current objectives are to establish and perfect the information disclosure system related to research projects in order to increase transparency of administrative agencies. In addition, reform is needed in performance assessments so that peer review and compliance measures are improved, which will hopefully lead to improved integrity and scholarship. Realizing that research integrity issues originate in the universities and colleges, the Committee has asked that they immediately strengthen their teaching methods on matters such as ethical behavior and intellectual property in the sciences.

The Joint Committee stated that an investment in the promotion of research integrity will be beneficial to science and technological societies in China because it will force them to take the necessary steps toward self-improvement. The international goals of the Committee include: participating in the development of accepted conduct in terms of research integrity, reducing misconduct in international collaboration, and promoting general cooperation among other countries.

To view the entire document, visit:
http://www.sinori.cn/jsp/archives/archive_sViewDtEn!archivesViewDtEn.action?modelId=1&columnId=&archivesId=3621

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In the Societies

AMERICAN PSYCHOLOGICAL ASSOCIATION AMENDS ETHICAL PRINCIPLES

On February 24, 2010, the American Psychological Association (APA) announced amendments to the "Ethical Principles of Psychologists and Code of Conduct" (2002). The changes establish that psychologists may never use the standards to justify or defend violations of human rights. APA began evaluation of the language of the principles after questions emerged during the Bush administration, following the Justice Department's authorization of enhanced interrogation techniques.

The amendments occur in the Introduction and Applicability section and in Ethical Standards 1.02 and 1.03, which address "Conflicts between Ethics and Law, Regulations, or Other Governing Legal Authority" and "Conflicts between Ethics and Organizational Demands." Potentially ambiguous language has been replaced, clarified, and supplemented with the sentence: "Under no circumstances may this standard be used to justify or defend violating human rights."

These changes will go into effect on June 1, 2010.

To read the press release, visit:
<http://www.apa.org/news/press/releases/2010/02/ethics-code.aspx>

To read the ethical principles, visit:
<http://www.apa.org/ethics/code/index.aspx>

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Announcements

Call for Applications – The Department of Health and Human Services invites grant applications from institutions or organizations to study “Research on Integrity in Collaborative Research.” Areas of interest include the clarification of community norms and standards, the effectiveness of self-regulation, the societal, organizational, group, or individual factors that affect integrity in research, or the impacts of non-adherence to accepted codes of conduct. Deadline: April 07, 2010; Contact: GrantsInfo@nih.gov. For more information on application materials, funds, and eligibility, visit: <http://grants.nih.gov/grants/guide/rfa-files/RFA-RR-10-001.html>.

Call for Papers – The PrimeLife/IFIP Summer School invites extended abstracts from Masters or PhD students for the Sixth International Summer School on Privacy Identity Management for Life, to be held in Helsingborg, Sweden from August 2- 6, 2010. As part of the Ethical Issues of Emerging ICT Applications project, the school will address emerging information and communication technologies and resulting ethical, privacy and identity issues. Deadline: May 2, 2010. To submit, visit: <http://www.it.kau.se/IFIP-summerschool/>.

Call for Papers – *The Hasting Center Report* is hosting an informal essay contest to identify new and critical issues in bioethics. Essays might examine new approaches to bioethics, explore underexamined topics, or address issues such as clinical care, public health, health policy, new technologies, and medical research. Contest winners will be published in the November-December issue. Send essays to editorial@thehastingscenter.org by August 15, 2010.

Conference – The Ordham University Center for Ethics Education is hosting “MORAL HEAT: Ethical Dimensions of Environmental Regulation and Economics in the 21st Century” on April 20, 2010 in New York City. The conference will explore the intersections and tensions between the ethics of environmental sustainability, the

workings of markets, and the roles of government and society in protecting and advancing an ecologically-responsible common good. Contact: ethics@fordham.edu.

Conference – The UNESCO Chair in Bioethics international conference on “Bioethics Education: Content, Methods, Trends” will be held May 2-5, 2010 in Zefat, Israel. The conference will address topics such as educational programs, student evaluation, study resources, and teaching methodology and objectives. Visit: www.isas.co.il/bioethics2010; Contact: seminars@isas.co.il.

Conference – The International Federation for Information Processing’s Working Group on Computers and Social Accountability is holding an International Working Conference on “Converging Technologies: body, brain, and being” from May 17-18, 2010 in Maribor, Slovenia. The conference will address the merging of information and communication technologies with other technologies such as nano and cognitive sciences. Contact: Diane Whitehouse, diane.whitehouse@thecastlegateconsultancy.com.

Conference – The British Science Association and the Wellcome Trust are organizing the 2010 Science Communication Conference, to be held May 24-25 in London. This year’s theme is “audiences for engagement,” and the conference will address key issues facing science communicators in the UK. Visit: <http://www.britishtscienceassociation.org/web/ScienceinSociety/ScienceCommunicationConference>.

Conference – The James F. Drane Bioethics Institute at Edinboro University is hosting Founders of Bioethics: International Congress from June 3-5, 2010. For registration, conference, and continuing education information, visit: <http://bioethics.edinboro.edu/home/>.

Conference – The University of Pennsylvania Center for Neuroscience and Society will convene on July 23 – 25, 2010 for the Penn Conference on Clinical Neuroscience and Society. This Conference will review the latest developments in brain imagery, psychopharmacology, and medicolegal practices while exploring ethical issues. Psychiatrists, psychologists, neurologists, counselors, social workers, bioethicists,

physicians, and other professionals interested in neurobioethics are invited to attend. For more information, see: <http://www.neuroethics.upenn.edu/index.php/events/clinical-conference>.

Conference – The Section for Medical Ethics and the European Association of Centres of Medical Ethics (EACNE) are holding the EACNE 2010 Annual Meeting, “Empirical Ethics,” in Oslo, Norway from September 16-18, 2010. Topics will include empirical ethics and methodology, clinical practice, benefit sharing and research, biopolitics, and human rights. For more information, visit: http://www.med.uio.no/iasam/sme/seminar/eacme_2010/; Contact: post-sme@samfunnsmed.uio.no.

Course – PRIM&R is offering five educational programs from May 3-6, 2010 in Chicago, IL. Courses include IRB 101sm, IRB 201, IRB Administrator 101, Building Trust Between Minorities and Researchers: A Bioethics Research Infrastructure Initiative, and Tissue Banking in 2010 and Beyond. IRB/HRPP members, administrators, and staff are encouraged to attend and may choose to participate in up to three of the five programs. Contact: Shaquanna Philip, sphilip@primr.org, 617.423.4112, ext. 22. Visit: <http://www.primr.org/Conferences.aspx?id=8027>.

Course – UNESCO is offering an Ethics Teacher Training Course at the Inter University Centre in Dubrovnik, Republic of Croatia from June 28 - July 2, 2010. Courses were developed following mapping of existing training programs by the Ethics Education Program. Registration deadline: May 1, 2010. For more information, visit: http://portal.unesco.org/shs/en/ev.php-URL_ID=13033&URL_DO=DO_TOPIC&URL_SECTION=201.html

Course – The University of Montana-Missoula is offering a Theory and Skills of Ethics Teaching Seminar from June 14-18, 2010. Professionals and students planning to teach ethics in traditional and non-traditional settings are encouraged to enroll. For more information, visit: www.umt.edu/ethics. Contact: Deni Elliott, elliott@mail.usf.edu.