Professional Ethics Report

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HUMAN RIGHTS AND HUMAN SUBJECTS RESEARCH

A Look at the Report from the Presidential Commission for the Study of Bioethical Issues

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In December of 2011, the Presidential Commission for the Study of Bioethical Issues released its report *"Moral Science: Protecting Participants in Human Subjects Research* [1]*."* This report was one of several responses to the recent revelation that the U.S. Public Health Service supported research conducted in Guatemala between 1946 and 1948 that deliberately exposed more than 1,300 people to sexually transmitted diseases [2]. In his official charge to the Commission, President Obama requested both a fact-finding investigation into the historic details of the Guatemala study and a forward-looking review of existing human subjects protections "to determine if Federal regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the Federal Government [3]." *"Moral Science"* is the Commission's report on the second of the two inquiries.

Current federal regulations that protect human subjects in research, also known as the "Common Rule," are largely founded upon the ethical principles set forth in the 1979 Belmont Report: respect for persons, beneficence, and justice [4][5]. Although these regulations did not originate from international human rights treaties, human rights are incorporated into the Commission's charter, which states, "The Commission also may examine broader issues not linked to specific technologies, including but not limited to the protection of human research participants; scientific integrity and conflicts of interest in research; and the intersection of science and human rights [6]." As the Commission noted in "*Moral Science,"* the Common Rule shares a philosophical foundation with human rights that calls for protecting study participants' rights [7]:

"These norms also are reflected in the terms of international human rights treaties, such as the International Covenant on Civil and Political Rights, to which the United States is a signatory. Americans, like many people and nations, hold these norms to be fundamental moral duties owed to every person, each of whom is entitled to respect by virtue of their unique status as moral agents [8]."

By tying ethical concerns within human subjects research to existing human rights treaties that have similar underpinnings, the report makes connections to human rights as international norms. The report references the human rights standards for human subjects in general, and also looks to human rights more specifically in the context of ethical selection of research sites and with respect to compensation and reparation for injury suffered as a result of participating in biomedical research.

How does human subjects research invoke human rights?

Human rights laws are international agreements that articulate shared commitments to protect rights recognized as inherent to human beings. Human rights standards relating to human subjects research have been enumerated in treaties that invoke legal obligations, as well as in non-binding declarations that set out international expectations. The earliest of these documents is the Universal Declaration of Human Rights (UDHR), adopted in 1948, which all members of the United Nations promise to uphold as a core requirement of membership. The UDHR sets out the fundamental and interconnected rights to life, liberty, physical integrity, equal protection, justice and human dignity. Almost two decades later, the United Nations codified those rights in the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (IESCR). Together, these three instruments compose the International Bill of Human Rights.

The provision in these documents most relevant to research involving human subjects, Article 7 of the ICCPR, provides that, ''No one shall be subjected without his free consent to medical or scientific experimentation." As a member of this treaty, the U.S. government acknowledged its responsibilities to uphold Article 7 in its December 2011 report to the United Nations Human Rights Committee, which is tasked with overseeing implementation of the ICCPR. That report details the official response to the revelations regarding the study in Guatemala, as well as the existing Federal protections for research subjects [9].

Although not as directly related to human subjects research as Article 7 of the ICCPR, the ICESCR provides some general principles that could also apply. Article 12 of the ICESCR articulates the right to the highest attainable standard of physical and mental health, and Article 15 guarantees the right to enjoy the benefits of scientific progress and its applications. Although the U.S. signed the IESCR in 1979, it is not yet a full member of the treaty. However, 160 countries have ratified the IESCR, including many of those with which U.S.

researchers regularly collaborate. These broad ideals therefore take their place among the guiding principles for internationally harmonized standards to protect study participants.

When governments ratify these treaties, they accept the responsibility to prevent these rights from being violated by government actors and by private actors, including adopting domestic laws that criminalize human rights violations, fully investigating and prosecuting those crimes when evidence suggests a violation has occurred, and providing victims (and citizens generally) with ways to access information about human rights violations. Governments are also expected to provide legal mechanisms for victims to assert their rights and hold perpetrators accountable, ensure that the prescribed punishment fits the severity of the violation, and provide appropriate remedies to victims, which may include monetary compensation, return of property, rehabilitation care, formal apologies, and other actions as appropriate [10].

While these remedies are intended to provide some measure of justice to the victims, they are also necessary as deterrents to future violations. Human rights violations are not mere misjudgments or accidents; they are abuses of power that cause grave harm and undermine public trust in the government, and in doing so, threaten the social balance. Therefore, ensuring that remedies for human rights violations are both legally available and congruent with the gravity of their harm must be undertaken with the utmost seriousness [11].

How are human rights principles incorporated into the Commission report?

As a result of its review, the Commission concluded that current U.S. regulations provide "substantial protections for health, rights and welfare of research subjects," but noted "significant room for improvement in several areas, where, for example, immediate changes can be made to increase accountability [12]." The Commission identified six areas for improvement:

1) increasing accountability
2) compensation for injured research participants
3) international standards for equivalent protections
4) fostering a culture of responsibility among researchers
5) ethical site selection
6) increased community engagement.

Generally, these areas all have connections to international human rights principles. The UDHR, ICCPR and ICESCR give priority to accountability, transparency, and participation as necessary for protecting rights and deterring violations. As noted by the International Research Panel that advised the Commission during its inquiry, since these values and the specific obligations enumerated in the treaties have been widely recognized as universal norms, they may provide guidelines for international research where the Common Rule may not apply [13].

In its discussion of two of these six areas - ethical site selection and compensation - the Commission noted the relevance of human rights standards more explicitly.

Site Selection

The Commission referred to human rights law directly when discussing the ethical concerns raised by the increasingly globalized nature of biomedical research. Although not a formal recommendation, the Commission highlighted the importance of careful research site selection. The Commission writes,

"Taking research to specific sites that are less expensive because of lower costs associated with care or recruitment, or because of the relative ease of identifying populations with the condition under study who might be treatment naïve does not necessarily mean the research is ethically unacceptable. But when the circumstances of selecting research sites suggest the possibility or appearance of exploitation and failure to respect individual human dignity or appropriate community interests, site selection - both domestic and international - needs to be examined more carefully than it has been at times in the past [14]."

The footnote to this comment ties the ethical considerations surrounding site selection more directly to human rights, citing the International Convention on Civil and Political Rights as a human rights treaty that has been motivated by similar issues related to "universal rights to bodily integrity and health [15]."

Compensation

As one of its official recommendations, the Commission urged the federal government to study the need for a national system of compensation for research-related injury. During the Commission's investigations, an international panel of experts provided information on the compensation provisions required by many other countries [16]. Although this type of compensation is not currently mandated in the US, some branches within the federal government have instituted compensation policies in their own human subjects regulations [17]. While acknowledging the challenges associated with executing a compensation system (i.e., scope of coverage, mechanisms for qualification, insurance, etc.), the Commission concluded that the ethical obligations researchers owe to participants demand solutions to those challenges. The report states, "ethics requires that subjects harmed in the course of human subjects research ought not to individually bear the costs of care required to treat qualified harms resulting directly from that research [18]." In this context, the Commission cited a number of human rights texts, including the European Convention on Human Rights, as examples of standards for reparation for victims of unethical research [19]. To be clear, the Commission noted that existing policies based on human rights principles provide reparations for *unethical* research. Based on its overall findings, however, the

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Commission recommends compensating research participants for the adverse affects of their involvement in a study, regardless of whether the study is determined to be ethical.

While the Commission's recommendations are not specific to the Guatemala study, the question of reparations for the harms that study caused has been raised by victims and human rights groups. The U.S. has formally apologized to the government of Guatemala and to the victims and their families for the study, and has committed more than $2.5 million through the Department of Health and Human Services and the Centers for Disease Control to monitor, treat and prevent sexually transmitted diseases in Guatemala [20]. However, the victims and surviving family members have not been compensated directly, and they have filed a federal lawsuit against U.S. government officials and the director of the World Health Organization for violating international human rights principles. The U.S. government acknowledged this specific case's relevance to its human rights obligations under the ICCPR, as well as the general expectation that remedies will be available to victims, in its report to the United Nations Human Rights Committee in December 2011 [21]. However, in January 2012, the U.S. Department of Justice filed a motion to dismiss the lawsuit on grounds of sovereign immunity [22]. The lawsuit is still pending.

Conclusion

As international biomedical research grows in importance, so too will the pressure for U.S. regulations and research ethics to incorporate internationally recognized standards for protecting participants, including human rights laws and principles. Successful international research collaboration may depend on harmonizing the multitude of national regulations governing scientific research [23]. This is supported by the Commission's recommendation that the government respect equivalent protections and develop a formal process for evaluating requests from foreign governments and institutions for equivalent protections for human subjects research [24].

In addition to its request for the U.S. government to assess the need for a system of compensation, the Commission also included a recommendation that the government follow-up its assessment with a formal position statement on the question of compensation. In its report the Commission stresses the need for this subsequent recommendation, noting the government's unresponsiveness to similar recommendations from past ethics commissions and advisory bodies [25]. The Commission's recommendations are expected to influence other efforts to improve ethical standards for human subjects research, such as the Department of Health and Human Services' Advance Notice of Proposed Rulemaking, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators [26]."

It remains to be seen whether similar initiatives to harmonize federal regulations across departments and across borders will integrate references to human rights law and principles as in the Commission's report.

References

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[2] *"Ethically Impossible" STD Research in Guatemala from 1946 to 1948*. Presidential Commission for the Study of Bioethical Issues, September 2011. [hereafter, 'Guatemala Study Report] http://bioethics.gov/cms/sites/default/files/Ethically%20Impossible%20%28with%20linked%20historical%20documents%29_0.pdf
[3] Memorandum to Amy Gutmann. November 24, 2010. http://bioethics.gov/cms/sites/default/files/news/Human-Subjects-Protection-Letter-from-President-Obama-11.24.10.pdf
[4] Federal Policy for the Protection of Human Subjects ('Common Rule') http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html
[5] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[6] *Charter of the Presidential Commission for the Study of Bioethical Issues*. http://bioethics.gov/cms/sites/default/files/Charter-of-the-Presidential-Commission-for-the-Study-of-Bioethical-Issues-03.10.10.pdf
[7] Commission Report, page 31, footnote 47.
[8] Commission Report, page 31
[9] *Fourth Periodic Report Of The United States Of America To The United Nations Committee On Human Rights Concerning The International Covenant On Civil And Political Rights*, [hereafter "U.S. ICCPR Report"] paragraphs 187-194, 664-669. http://www.humanrights.gov/wp-content/uploads/2011/12/ICCPR_Fourth_Periodic_Report.pdf
[10] Dinah Shelton, *An Introduction to the History of International Human Rights Law* (August 2007) (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1010489).
[11] Shelton, *Ibid*.
[12] Commission Report, page 5.
[13] *Research Across Borders: Proceedings of the International Research Panel of the Presidential Commission for the Study of Bioethics*, September 2011. http://bioethics.gov/cms/sites/default/files/PCSBI-IRP_Research-Across-Borders.pdf
[14] Commission Report, page 45.
[15] Commission Report, page 45, footnote 67.
[16]http://blog.bioethics.gov/2011/11/17/compensation-expert-addresses-commission/
[17] See *Professional Ethics Report*, "DoD Issues Policy Revisions for Protection of Human Subjects in Research," Volume 24, Number 4. http://srhrl.aaas.org/newsletter/per/archives/newper67.shtml#DoD
[18] Commission Report, page 62.
[19] Commission Report, page 120, footnote 107.
[20] See Kristen Minogue, *ScienceInsider*, "U.S. Officials Apologize for 'Appalling' 1940s Syphilis Study," http://news.sciencemag.org/scienceinsider/2010/10/us-officials-apologize-for-appalling.html
[21] U.S. ICCPR Report, paragraphs 193 and 669, http://www.humanrights.gov/wp-content/uploads/2011/12/ICCPR_Fourth_Periodic_Report.pdf
[22] See Mariano Castillo, CNN, "U.S. Rejects Guatemalans' STD Lawsuit, Offers Aid,"http://articles.cnn.com/2012-01-10/americas/world_americas_us-guatemala-std-experiments_1_syphilis-chancres-gonorrhea?_s=PM:AMERICAS. Sovereign immunity is a principle of international and U.S Constitutional law that protects the government from lawsuits in its own courts unless it consents to them.
[23]. Alan I. Leshner and Vaughan Turekian, "Harmonizing Global Science," *Science*, Volume 326, Page 1459, 11 December 2009,

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http://www.sciencemag.org/content/326/5959/1459.full.pdf
[24] Commission Report, pages 74-77.
[25]Commission Report, pages 56-57.
[26] See "Commission Work Will Dovetail Nicely with HHS' ANPRM," http://blog.bioethics.gov/2011/11/16/commission-work-will-dovetail-nicely-with-hhs%E2%80%99-anprm/

Special Report

INFLUENZA RESEARCH SPARKS DEBATE OVER PUBLICATION

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In late November 2011, the National Science Advisory Board for Biosecurity (NSABB) recommended that the details be redacted from two research papers on influenza transmissibility that were slated for publication in the journals *Science* and *Nature*. This was the first time in the life sciences that a government body has recommended that publication of data be limited because of security concerns, sparking controversy and ongoing debate among influenza researchers and biosecurity experts. In the intervening months, NSABB members, government officials, journal editors and the international scientific community have been grappling with how to proceed. The fray has recently attracted Congressional attention, with a letter from Republican Congressman Jim Sensenbrenner questioning the Administration's response. At the request of the National Institutes of Health, the NSABB will revisit its recommendations in a meeting on March 29-30, 2012.

The studies, both funded by the National Institute of Allergy and Infectious Diseases, were conducted by Yoshihiro Kawaoka at the University of Wisconsin and Ron Fouchier at the Erasmus Medical Center in Rotterdam, the Netherlands. Both research teams were able to convert the avian flu virus H5N1 into a form that could be easily transmitted between ferrets (the animal model that most closely resembles human flu responses). The results of both studies indicate it would be possible for an H5N1 virus to be transmitted in mammals, raising the specter of a deadly pandemic if the viruses spread from person to person. This risk could emerge from either random mutations in nature or from accidental or intentional release of the mutant viruses.

Because the mutated virus could be used as a biological weapon, the NSABB conducted a review of the two papers and determined that the journals should not publish the full methods or specific gene sequences that enabled the viruses to become airborne. After alerting the journals on November 30, the NSABB publicly announced its recommendations on December 20. In an explanation submitted for publication at both journals in early February, the NSABB wrote, "Our concern is that publishing these experiments in detail would provide information to some person, organization, or government that would help them to develop similar mammal-adapted influenza A/H5N1 viruses for harmful purposes. We believe that as scientists and as members of the general public, we have a primary responsibility 'to do no harm' as well as to act prudently and with some humility as we consider the immense power of the life sciences to create microbes with novel and unusually consequential properties [1]."

The NSABB recommendations fueled an immediate reaction from infectious disease experts. From the perspective of many public health experts, the information from these studies is essential to preparing for and preventing flu pandemics. Full publication of the research results would allow for surveillance for dangerous mutations in affected bird populations in certain countries. Knowing which mutations can make the virus more transmissible between mammals would help with surveillance for potential outbreaks. Skeptics argue that countries most at risk for outbreaks do not have the capacity to monitor for genetic mutations in viruses. In response to this argument, Kawaoka told *ScienceInsider* and *Nature* that we should help these countries develop capacity for better surveillance infrastructure. WHO Assistant Director-General of Health Security and Environment Keiji Fukuda stated in a WHO press release that the new studies demonstrate that the "H5N1 viruses have the potential to transmit more easily between people underscoring the critical importance for continued surveillance and research with this virus."

While the information could be seen as fuel for bioterrorism, many scientists, including Kawaoka and Fouchier, believe there is already sufficient information available for capable people to produce similarly transmissible viruses, so the risk of full publication is not great when compared to the risk of not pursuing this valuable research. In contrast, NSABB member Michael Osterholm argued that only a few labs in the world have the scientific capability to replicate the Kawaoka and Fouchier studies without the redacted experimental details.

In addition, there is no system in place to determine who, and under what circumstances, can or should have access to the full methods and findings of the studies. Fouchier and Kawaoka have both publically opposed the redactions, and the journals are unwilling to publish redacted versions unless there is a system in place to grant access for legitimate uses. The moratorium on research is intended in part to give the US Government and international stakeholders time to develop a strategy for granting access. A group of international influenza experts gathered at a WHO meeting in February believe that, in the absence of such a strategy, the full papers should be published: "A consensus was reached that the redaction option is not viable to deal with the two papers under discussion in view of the urgency of the… public health needs [2]."

While mode of transmission and host adaptability is of central concern, the lethality of the wildtype and mutated viruses has launched a secondary debate in the press and in scientific journals. NSABB members stress that the specific lethality rate was not a primary driver of their recommendations, and new information about lethality is unlikely to alter their decision. Although 59% of the 583 confirmed human cases of H5N1 have been fatal, many mild cases are never reported; in fact, a recent meta-analysis published in *Science* calculated that 1.2% of people across Southeast Asia have been exposed to H5N1 without developing serious illness. Even if the case fatality rate is orders of magnitude lower than 59%, an H5N1 outbreak could have an impact far greater than the 1918 pandemic.

At a special panel discussion at the American Society for Microbiology meeting on February 29, Fouchier explained that the ferrets in his study did not die from airborne transmission; they only became severely sick if experimenters injected a lot of virus deep into the airways [3]. Additionally, previous studies have shown that ferrets exposed to seasonal flu are protected from H5N1, allaying fears that humans would have no pre-established

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H5N1 immunity. Kawaoka's mutant virus also did not cause severe illness in ferrets. However, the ferret model is not a perfect predictor of transmissibility or disease severity in humans.

Because of the unknown potential of the mutated viruses, some biosecurity experts question whether the research should have been conducted in the first place. With regard to the immediate risks of the research, work on H5N1 is subject to biosecurity regulations that have been in place for years.

Researchers and journal editors are in a holding pattern until international governments and the scientific community reach consensus about how to provide access to sensitive experimental results. The journals had originally planned to publish partially redacted papers in mid-March, but given recent developments, it is unclear when and in what form the studies will be published. On January 20, influenza researchers, including Kawaoka and Fouchier, announced a temporary moratorium on H5N1 mammalian transmissibility studies, in part to allow organizations and governments around the world sufficient time to settle the conflict over publication and access. The current research moratorium will also allow regulatory bodies to determine what an appropriate level of security should be for future research. In its letter to *Science* and *Nature*, the NSABB called for an international effort to establish better policy for H5N1 dual use research. "This must be done quickly and with the full participation of multiple societal components." The WHO plans to continue its efforts in this area with a second meeting planned for mid-summer.

[1]http://www.sciencemag.org/content/335/6069/660.full?sid=731d3414-23ff-460c-8ed4-b43e6b186f6a
[2]http://www.who.int/influenza/human_animal_interface/mtg_report_h5n1.pdf
[3]http://www.asmbiodefense.org/index.php/program-information/nsabbs-recommendations-for-h5n1-research

In the News

CHIMPANZEES IN RESEARCH CONTROVERSY

The most recent controversy over research that uses chimpanzees was sparked by a 2010 NIH proposal to move chimpanzees from the Alamogordo Primate Facility to a research center where invasive research could be conducted. The outcry from animal rights groups prompted NIH to request a study by the Institute of Medicine (IOM) on the uses of chimpanzees in research. The resulting IOM report concludes that most of the research on chimpanzees currently underway is unnecessary. The report specifically cited "advances in non-chimpanzee models." Such models include "in vitro culture systems and small animal models containing human cells [1]."

The IOM report also proposed the following criteria for evaluating proposed research on chimpanzees [2]:

1. The knowledge gained must be necessary to advance the public's health;
2. There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects; and
3. The animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments or in natural habitats.

The NIH Director has accepted the IOM recommendations and charged a Working Group with developing an implementation plan and research review process. The Working Group is also charged with analyzing current NIH-funded research that uses chimpanzees and providing guidance about the future of NIH-owned or NIH-supported chimpanzees [3].

The IOM report recognizes that research on monoclonal antibodies, hepatitis C, and diseases yet to be discovered may not be effective using new technologies or other species. In the case of monoclonal antibodies, non-chimpanzee models have been developed and can effectively replace research involving chimpanzees. However, the IOM report recognizes "that there may be a limited number of monoclonal antibodies currently in the development pipeline that may require the continued use of chimpanzees." The IOM report suggests that these studies be assessed using the committee's biomedical research criteria.

When considering the necessity of chimpanzees for the development of a prophylactic hepatitis C vaccine, the committee was split down the middle. Therefore, the Working Group will be responsible for determining whether or not NIH funded hepatitis C research using chimpanzees will continue. In studying the IOM report, some hepatitis C researchers who use chimpanzees have concluded that their research is unlikely to meet IOM criteria. As such, they are concerned that hepatitis C research will be inhibited by disallowing the studies that are necessary precursors to trials involving humans [1].

More generally, researchers that use chimpanzees are concerned that further restrictions on the use of chimpanzees as a result of the IOM report will raise the cost of conducting research. In addition, the expertise that they have developed would be lost [4]. The guidelines presented in the IOM report, if adopted, would stop most current research on chimpanzees. Some behavioral studies using chimpanzees would likely be permitted.

The IOM report is limited to chimpanzees and did not address research conducted on other non-human primates. This is especially important in light of the Great Ape Protection and Cost Savings Act of 2011 introduced in Congress. If passed, this Act would ban all invasive research involving chimpanzees, bonobos, gorillas, orangutans, or gibbons [5].

[1] http://www.nature.com/news/chimp-research-under-scrutiny-1.9693
[2] www.iom.edu/chimpstudy
[3]http://dpcpsi.nih.gov/council/working_group.aspx
[4]http://www.sciencemag.org/content/335/6064/41.short
[5]http://www.govtrack.us/congress/bill.xpd?bill=h112-1513

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NSB RELEASES FINAL REPORT ON NSF MERIT REVIEW CRITERIA

The two criteria that the National Science Foundation uses to evaluate grant applications - intellectual merit and broader impacts - have been clarified in the report "National Science Foundation's Merit Review Criteria: Review and Revisions," released by the National Science Board (NSB) in early January. The report contains detailed recommendations regarding each of the Merit Review Criteria and summarizes the decision-making processes that contributed to the recommendations.

The NSB review process began in February 2010, when it established a Task Force on Merit Review to evaluate and make recommendations about the current grant review process. Grantees had been

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concerned that the criteria had been implemented inconsistently and that there was no clear guidance on what constituted broader impacts. (See "NSF Proposed Merit Review Criteria Revisions," *PER*, Summer 2011 for a previous report on the progress of the Task Force). The Task Force's analysis led the NSB to conclude that the two established Merit Review Criteria remain appropriate, but that greater clarity of the Criteria was needed.

An essential component of the Task Force's analysis was to seek input from a range of stakeholders. The report outlines how input was solicited and summarizes the results of stakeholder surveys and public comments. Overall, those surveyed were generally satisfied with the intellectual merit criterion, but frustrated with the implementation of the broader impacts criterion. The majority of those surveyed believed that changes were needed in the broader impacts criterion, and 41 out of 219 people who responded to a question on what those changes should be wrote that Broader Impacts should be dropped. However, the America COMPETES Reauthorization Act of 2010 requires that Broader Impacts remain one of the criteria.

In an introduction to the report, NSB Chairman Ray M. Bowen writes, "Ultimately, the Board did not change the two Merit Review Criteria, which remain Intellectual Merit and Broader Impacts. However, the Board did work to define more clearly the two Criteria in hopes that the NSF community has a better understanding of each criterion and how they relate to one another." To help clarify the merit criteria, the NSB report articulates the principles underlying both criteria and the elements that should be considered for both.

In addition, the NSB recommends implementation guidelines to the NSF, including revised language in funding announcements and a unified "OneNSF" communication strategy, in which NSF should make clear that both criteria are important and should be given full consideration. New guidance should be developed and distributed to potential grantees, and a universal frequently-asked-questions webpage should be launched. NSF should make clear that it expects PIs to be accountable for carrying out the activities intended to address the broader impacts criterion; although not all individual projects can be effectively evaluated for broader impacts, evaluations of larger projects or aggregations of projects should be required and funded by the NSF. Finally, the use of additional review criteria may be appropriate for some solicitations, where there are specific requirements that are not explicitly captured in these two criteria. NSF should create guidance for NSF staff to use when developing new solicitations.

The full NSB report is available on the NSF website:
http://www.nsf.gov/nsb/publications/2011/meritreviewcriteria.pdf
NSF press release:
http://www.nsf.gov/news/news_summ.jsp?cntn_id=122794

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SYNTHETIC BIOLOGY OVERSIGHT

In mid-March, *The Principles for the Oversight of Synthetic Biology* was released and endorsed by a coalition of 111 organizations from around the world [1]. This publication is the first attempt to establish international oversight guidelines for the biological sciences. The publication focuses primarily on providing general, guiding principles for the regulation of synthetic biology. It does not, however, propose a specific implementation framework for the principles. Principally, this publication is intended as a first step in establishing more formal regulatory guidelines for synthetic biology.

In addition to providing a starting point for further discussion, the publication calls for immediate actions on the part of those who use synthetic biology. Most notably, the coalition calls for an immediate moratorium "on the release and commercial use of synthetic organisms and products." The moratorium is intended to allow for time to develop "enforceable, prosecutable, synthetic biology-specific regulations." The coalition asserts that the "precautionary principle" needs to be employed. In other words, safety precautions with regard to synthetic biology need to be taken to protect against any potential dangers, even when the likelihood of said dangers has not been established.

They also believe that any entity wishing to release a synthetic biological product should be required to prove that it is financially capable of mitigating any potential harm that could be caused by the product. In addition, the coalition believes that a successful means of sequestering synthetic organisms needs to be developed prior to their release. If the release of a synthetic organism causes unintended consequences, they believe it will be too late to develop a sequestration method and successfully contain the organism efficiently.

The coalition emphasized the importance of elevating public health, worker safety, and environmental protection above the importance of economic gains. They also raised concerns about the potential for synthetic biology to "deepen economic and social injustices." Overall, the coalition hopes that this publication will serve as the first step in transitioning from self-regulation to formal oversight in synthetic biology.

[1] http://www.foe.org/news/blog/2012-03-global-coalition-calls-oversight-synthetic-biology

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FEDERAL AGENCIES TO RELEASE SCIENTIFIC INTEGRITY POLICIES

On February 15, Office of Science and Technology Policy (OSTP) Director John Holdren instructed all covered Federal entities to release their final or latest draft scientific integrity policies for public comment by March 30, 2012. OSTP has completed its review of the draft policies submitted last December and, with a few minor recommendations, found them to fulfill or exceed the minimum OSTP requirements. Many agencies have already posted final or draft versions for public comment or are circulating them internally for administrative signoff.

The issuance of new scientific integrity policies was prompted by a 2009 presidential memorandum articulating six principles of scientific integrity. OSTP published a subsequent memorandum in 2010 to provide further guidance to executive departments and agencies to implement the Administration's policies. In keeping with this guidance, the new agency policies require that federally supported science and scientific information be undiluted and untainted by political influence; agencies practice openness with the public and the media; Federal Advisory Committees operate transparently and free of problematic conflicts of interest; and Federal scientists and engineers be afforded the same opportunities to advance their professional careers as their private counterparts.

Some in the scientific community have

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been critical of the slow pace with which agency policies have been developed and made available for public comment.

View John Holdren's blog posting at: http://www.whitehouse.gov/blog/2012/02/15/scientific-integrity-policies-approach-public-release
Read the OSTP policy guidance memorandum here: http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf

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OSHA RESTRUCTURES WHISTLEBLOWER PROGRAM

The Occupational Safety and Health Administration (OSHA) was established in 1970 with the passage of the Occupational Safety and Health (OSH) Act. The "rights afforded [to workers] by the OSH Act include employee participation in safety and health activities, such as complaining to OSHA and seeking an OSHA inspection, participating in an OSHA inspection, participating or testifying in any proceeding related to an OSHA inspection, and reporting a work-related injury, illness, or fatality [1]." As such, the Whistleblower Protection Program is responsible for the enforcement of 21 different whistleblower laws and serves functions central to OSHA's responsibilities.

In audits conducted in both 2009 and 2010, the Government Accountability Office (GAO) "found significant problems with OSHA's transparency and accountability, training for investigators and managers, and the internal communication and audit program [2]." In response, OSHA commissioned a "Top to Bottom" review, which proposed actions to address each of GAO's concerns. The proposed changes affected training, internal tracking systems, and program policies. In addition, major restructuring was proposed in August 2011, and enacted on March 1, 2012.

The Office of the Whistleblower Protection Program (OWPP) has been moved to report directly to Assistant Secretary of Labor instead of reporting to the Directorate of Enforcement. Furthermore, whistleblower activities have their own line item in the FY2012 Budget. This is "to better track and hold accountable its activities and accomplishments." Lastly, one of OSHA's regional whistleblower offices is currently participating in a pilot program for determining the effectiveness of investigators reporting to regional supervisory investigators and an Assistant Regional Administrator.

These changes are intended to strengthen whistleblower enforcement and to expedite the handling of claims.

[1] http://www.whistleblowers.gov/
[2]http://www.whistleblowers.gov/report_summary_page.html

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In the Societies

NATIONAL ACADEMIES TO UPDATE RESPONSIBLE SCIENCE REPORT

The Committee on Science, Engineering and Public Policy (COSEPUP) of the National Academy of Sciences has convened an expert committee to update the 1992 COSEPUP report *Responsible Science, Volume I: Ensuring the Integrity of the Research Process* [1]. The new Committee on Responsible Science, which is made up of science educators, bioethicists, and researchers, held its first meeting March 18-20 in Washington, DC [2]. At this meeting, the committee heard from representatives from the federal agencies that are sponsoring the study, and a panel of invited experts.

The study is sponsored by the Department of Health and Human Services, the Department of Energy, the Department of Veterans Affairs, the Department of the Interior, the Environmental Protection Agency, and the National Science Foundation. Some emerging issues that sponsors want the revamped report to address include biospecimen handling and biobanking; managing privacy, access and use of large databases; community-based research; research with dual use potential; and the increasingly blurred distinction between research and clinical treatment.

The 1992 report confined the definition of research misconduct to falsification, plagiarism and fabrication, and the federal agencies want recommendations to respond to a broader range of questionable research practices. Sponsors also hope a new report can encourage harmonization and clarity in regulations to decrease regulatory burden and confusion. In addition, sponsors emphasized the need for high quality, interactive ethics training for scientists at all levels, and the importance of a culture and environment conducive to responsible conduct of research.

[1]http://www.nap.edu/catalog.php?record_id=1864
[2]http://www8.nationalacademies.org/cp/projectview.aspx?key=49387

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Announcements

Call for Papers - The Australian Association for Professional and Applied Ethics invites paper submissions for its upcoming 19th Annual Conference on Ethics, Values and Civil Society. The conference will take place June 28- July 1, 2012 at St. John's College, University of Queensland. Papers are welcome from both academics and practitioners in all areas of professional and applied ethics. Apart from AJPAE there is opportunity for Conference papers to be published in: *Ethics Issue in Organizations* (RIEO) and *Australian Ethics*. The deadline for submissions is May 17, 2012. Papers should be submitted to Rev. Prof. John Morgan, St John's College, the University of Queensland: aapae2012@stjohns.uq.edu.au. For more information, go to: http://www.stjohns.uq.edu.au/aapae2012/call.htm

Call for Papers - The 4th annual meeting of The Society for the Study of Nanoscience and Emerging Technologies (S.NET) is seeking abstract submissions. The meeting will be held at the University of Twente, the Netherlands, on October 22-25, 2012. Submissions are encouraged in one of the following six categories related to emerging science and technologies: R&D practices, innovation, governance, visions and cultural imaginaries, public relationships, and politics and ethics. The deadline for abstract submission is April 2, 2012. For more information, visit: www.utwente.nl/snet2012

Call for Papers - The 38th Conference on Value Inquiry, on "Free Will, Responsibility, and Science," will be hosted by Salem State University on April 18-20, 2012. Papers and proposals that address the interplay of free will with moral responsibility and deliberation, as well as the role of science in giving scope to notions such as free will and responsibility, are welcome. Topics may be disciplinary and range over issues within a single field such as ethics, political theory, or economics. Submissions will be reviewed until the program is filled. To submit a

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paper for review or for more information, contact: William Cornwell, Salem State University at: conference.on.value.inquiry@gmail.com

Call for Papers - Center for Applied Ethics and Philosophy (CAEP) invites paper submissions for its 7th International Conference on Applied Ethics. The meeting will take place on October 26-28, 2012 at Hokkaido University, Sapporo, Japan, and will focus on 'Risk, Justice and Liberty.' Paper submissions are invited for the following topics: meta/normative ethics, bio/medical ethics, engineering ethics, ethics of science and technology, information ethics, environmental ethics, business ethics, feminist ethics, international/global ethics. CAEP also welcomes submissions on topics that address social, cultural, political, economic areas of applied ethics beyond the conference theme. Those wishing to present papers are requested to submit an abstract to caep@let.hokudai by June 30, 2012. For further details, visit: http://ethics.let.hokudai.ac.jp

Conference - The Poynter Center for the Study of Ethics and American Institutions will host the annual Teaching Research Ethics Workshop on the campus of Indiana University Bloomington, May 15-18, 2012. Sessions will feature techniques for teaching and assessing the responsible conduct of research. In addition to plenary sessions, participants will select an intensive track to meet with the same group twice and two breakout sessions. Session topics include: overview of ethical theory, trainee and authorship issues, conflicts of interest, human subjects in clinical and non-clinical research, and responsible data management. For more information contact Glenda Murray, Poynter Center, Indiana University at: glmurray@indiana.edu. Registration and additional information are available at: http://poynter.indiana.edu/tre.

Conference - Be part of the discussion of the future of science and technology policy with leaders in the field at the annual AAAS Forum on Science and Technology Policy. The Forum will be held April 26-27 in Washington, DC. Now in its 37th year, it is the conference for people interested in public policy issues facing the science, engineering, and higher education communities. This year's program features a keynote address by Presidential Science Advisor John P. Holdren, and sessions on the budgetary and policy context for R&D in FY 2013, key policy issues involving science and technology in the 2012 elections, innovating our way to jobs and economic recovery, the implications of instant communication for science, and an evaluation of R&D during tight budget times. Visit www.aaas.org/forum for registration and full program details. Early registration ends April 1.

Service Learning Opportunity - The Association for Practical and Professional Ethics at Indiana University announces a new service learning opportunity for ethics classes. The program will involve student preparation of "Ethics Alerts" (EAs), which identify and analyze the significant ethical implications of media stories. Student participants will search independent and foreign media sources for ethically significant stories that have been underreported, unreported, or otherwise not sufficiently broached by the major networks, newspapers, and other mainstream media sources. Students will vet the fact-claims involved in the selected stories, consult other professors, community experts, or individuals involved in the story, and examine relevant means of confirming factual claims. Project Censored, a nonprofit organization affiliated with Sonoma State University, has offered to build an edifice for the development and delivery of this program on its website, at: http://www.mediafreedominternational.org/ For more information contact Elliot D. Cohen, Ph.D., Indian River State College, at ecohen@irsc.edu.

Survey - The Woodrow Wilson International Center for Scholars is soliciting public opinion on the most critical ethical, legal, and social implications (ELSI) for synthetic biology in a new online survey, which will provide guidance as federal agencies, foundations, industry, NGOs, and other stakeholders with limited resources seek to address key ELSI concerns. The online survey asks respondents to rate a number of actions that could address ELSI issues, such as ensuring long-term effects of synthetic biology are benign, tracking public and private investment in the field, or labeling products that include synthetic biology in their manufacture. The results of this anonymous survey will be analyzed and compiled into a report, which will be released in mid- to late-May 2012. This survey builds on a workshop held Nov. 8-9, 2010, at the Wilson Center in Washington, D.C. The workshop culminated in a July 2011 report, *Issues Arising from Synthetic Biology: What Lies Ahead?*, which identified potential challenges and pressing research needs. To take the survey, go to: http://www.synbioproject.org/news/project/6617/

Training - The Theory and Skills of Ethics Teaching course, taught by Deni Elliott, will run June 25-29, 2012 at the University of Montana-Missoula. This 5-day course provides graduate students and those currently teaching ethics in educational and non-traditional settings the opportunity to create materials for their specific learning environments. Participants have included K-12 teachers, post-secondary instructors who teach ethics in a variety of standard curricula, along with those working in medical, military, corporate, and governmental settings and graduate students who aspire to teach ethics in any venue. For more information about the course, visit: http://www.umt.edu/ethics/. If you have questions, contact Deni Elliott at: elliott@usfsp.edu.

Website - The Hastings Center announces the release of its first website aimed at the general public. The website, *Help with Hard Questions*, is an online community intended to help people think through the ethical dimensions of dilemmas arising from advances in science and medicine - advances like genetic screening and personalized medicine, as well as reproductive technologies, children's mental health, and advanced illness. These and other bioethics issues are raised in *Cracking Your Genetic Code*, a NOVA special produced in association with The Hastings Center that airs on PBS on March 28, at 9 pm/8c.

Workshop - The University of Oxford, eResearch Centre will host a workshop on "Identifying and addressing ethical issues in technology-related social research," May 21-22, 2012. The workshop will bring together researchers from different fields of the digital social research community with a view to developing principles, protocols and technical tools to support the identification and resolution of ethical issues around these three areas. The workshop will address issues such as the anonymization of data, intellectual property, data collection and user profiling. For more information and to register, go to: http://responsible-innovation.org.uk/frriict/ai1ec_event/identifying-and-addressing-ethical-issues-in-technology-related-social-research/