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## LABORATORIES WITHOUT CHIMPANZEES

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The passion aroused by the use of chimpanzees in research is in inverse proportion to the actual number of animals used. That is, relatively few animals, great passion. Chimps have always constituted a very small proportion of animals in biomedical research [1], but their close genetic relationship with humans has made them a particularly valuable resource for studying select diseases and behaviors. However, it is this very same relationship that motivates opposition to the chimp as a research subject. Testifying before an Institute of Medicine (IOM) hearing, discussed below, Kevin Kregel, Professor of Integrative Physiology and Radiation Oncology at the University of Iowa, and a proponent of using chimps, acknowledged that “chimpanzees are a special case that deserves special scrutiny...” [2]

### Chimps in Research

Although not used often, chimps have played an important role in medical progress:

- Vaccines: Chimpanzees, along with thousands of monkeys were used in to identify attenuated strains of the polio virus that would protect humans against polio, without causing the disease [3]. Further, research with chimps led to the development of diagnostic tests for hepatitis A, B, and C and for vaccines for hepatitis A and B.
- HIV/AIDS: Chimps played an important role in the early stages of the drive to find a treatment for AIDS.

They were the only model available to explore the routes of infection of HIV, as well as viral replication and dissemination in the body [4].

- Monoclonal antibodies: Monoclonal antibodies tested in chimps have been used to treat B-cell non-Hodgkin’s lymphoma, rheumatoid arthritis, Crohn’s disease, and ulcerative colitis [5]. The IOM report discussed below stated that, “chimpanzee/human chimeric monoclonal antibodies... have proven to be effective in both in vitro and in vivo assays to neutralize infectious viruses or to block the action of bacterial toxins.” [6]
- Ebola: A viral disease with a mortality rate of up to 90% in humans, it is estimated to have killed approximately a third of the world’s gorillas, as well as many chimpanzees. “[B]y studying captive chimpanzees scientists are making progress towards an Ebola vaccine that they hope to test in wild apes and ultimately use to protect apes and humans...” [7]

Perhaps more appealing to the general public are behavioral studies. Scientists have demonstrated that chimps exhibit altruism [8]; have impressive memory skills [9]; and can solve complex problems [10]. More controversially, some researchers claim that chimps have “language” or “speech.” [11]

### Animal Rights Groups

Despite the fact that “[h]umankind has benefited handsomely [12]” from knowledge gained through chimp research, the opposition to the animal’s use, led by animal rights groups like the Humane Society of the United States (HSUS), has been strong and often effective [13]. Scientists and others working for animal rights groups have debated the value of chimpanzees in research on hepatitis and monoclonal antibodies. For example, Jarrod Bailey, a geneticist and science advisor for the New England Anti-Vivisection Society

(NEAVS), questions the value of all animal research, including chimpanzee studies [14]. Although there are now vaccines for hepatitis A and B, there is of yet no such preventive measure for hepatitis C, a fact that those working to prohibit chimpanzee research have hit upon as evidence that there is little value in using chimps for this purpose [15]. This conclusion ignores the fact that for many years, one could have concluded that non-human primates were useless in the search for a polio virus.

Opposition to chimpanzee research among the general public “has reached a historic high.” [16] People are accustomed to seeing chimps as cute and affectionate babies, not the 150 pound creatures that male chimps might become. Further, the pioneering work of Jane Goodall, studying chimpanzees in their natural habitat, has caught the imagination of millions who have watched documentaries, such as “Jane’s Journey,” with Angelina Jolie, or PBS’s “Jane’s Wild Chimpanzees,” featuring chimps charmingly named Fifi and her son Frodo.

And scientists’ cause isn’t aided with revelations of possible mistreatment of the animals. In 2009, HSUS reported that during the course of an undercover investigation at the New Iberia Research Center (NIRC) [17], it discovered “routine and unlawful mistreatment of hundreds of chimpanzees and other primates.” [18] On March 3, 2009, ABC’s “Nightline” featured disturbing video that was shot by an HSUS investigator who had obtained employment at NIRC [19]. Joseph Savoie, president of the University of Louisiana, issued a statement saying the university had a “clearly stated and direct no tolerance policy when the welfare of any animal in our care is threatened, and we will continue to strictly enforce that policy.” [20] Two months after that program aired, pursuant to a complaint filed by HSUS, the US Department of Agriculture announced that an “inspection revealed evidence of several issues with the facility’s compliance” with

federal regulations regarding the care of laboratory animals [21].

### GAPA and Other Legislation

Not surprisingly, the concern over chimp research has led to a variety of administrative measures regarding their use, as well as legislation, proposed or passed. In 1997, the National Institutes of Health (NIH) announced a moratorium on breeding government-owned chimps, and in 2007 stopped it altogether, citing cost concerns [22]. In 2000, Congress passed, and President Clinton signed, the Chimpanzee Health Improvement, Maintenance, and Protection Act (the Chimp Act, PL 106-551). The Act prohibited the euthanasia of chimps, except for humane health reasons; established a federally-funded “retirement” system for chimps no longer needed for research; and required the government to assume part of the cost of lifetime care for chimps outside of research settings (chimps can live to be 60 years old).

In 2008, Representative Edolphus Towns introduced the Great Ape Protection Act (GAPA) in the House of Representatives (H.R. 5852). The Act stated that the “highly

intelligent and social” apes cannot have their needs met in a research environment and that doing so causes the animals to “experience harmful stress and suffering.” GAPA would “prohibit invasive research and the funding of such research,” transporting apes for research purposes, breeding apes for research, and “require the permanent retirement of federally owned great apes.” [23] GAPA defined “invasive research” very broadly, so that it included any experimental procedure that could involve pain or distress; the testing of any drug that could be “detrimental to the health of a great ape”; research that involved tranquilizing or anesthetizing a great ape; or isolation or other “physical manipulations” that could be detrimental to an ape’s “psychological well-being.” The Act would have permitted only “close observation of natural or voluntary behavior of a great ape” if that observation would not require the ape to be removed from its social group.

Having failed in the 110<sup>th</sup> Congress, GAPA was re-introduced in 2009 (H.R. 1326) and again in 2010 (S.3694), but made no legislative progress. In 2011, taking note of the increasing concern over the national debt, the bill was re-named the Great Ape Protection and Cost Savings Act (GAPSCA) and introduced in both the House (H.R. 1513) and the Senate (S. 810). This time around, the bill was headed for the Senate floor, where it was successfully blocked by Senator Ron Wyden [24].

The scientific community was not silent during the repeated introductions of the legislation.

- In April 2009, the AAAS Board of Directors issued a statement stating, “Because of the unique role that studies of chimpanzees play in assuring continuing medical progress, AAAS opposes the Great Ape Protection Act....” [25]
- Also responding to the 2009 iteration, the American Society for Pharmacology and Experimental Therapeutics issued a statement saying, “These non-human primates are a critical animal model. Eliminating them from research will restrict advances in human medicine.” [26]
- On September 3, 2010, FASEB responded to the Senate version of GAPA via a letter to Senators Maria Cantwell, Susan Collins, and Bernard Sanders (co-sponsors of the legislation) from its president, William Tallman: “Passage of the *Great Ape*

*Protection Act* will inhibit medical advances and the research community’s quest to improve human health through new treatments and vaccines.” FASEB also issued an “e-action alert” to biomedical scientists, urging them to write to their senators opposing the Act [27].

- In April 2010, 171 scientists “from the most renowned universities” wrote to NIH Director Francis Collins “decrying” the measure, stating that “human-chimpanzee comparisons are essential for understanding the unique characteristics of human biology.” [28]
- In a letter to members of Congress, the American Physiological Society’s president, Joey Granger, “outlined the importance of the research at risk [29]” if GAPSCA passed.

### The IOM Report

In 2010, NIH announced that it was moving 186 chimpanzees from the Alamogordo Primate Facility at Holloman Air Force Base in New Mexico to the Southwest National Primate Research Center in San Antonio, where they would be used in hepatitis C research. The chimps had been housed at Alamogordo under a 10-year-contract between NIH and the military that prohibited biomedical research on the animals while at the facility but not their eventual use in research elsewhere. Alamogordo had a troubled history; the chimps had been removed from the Coulston Foundation, a New Mexico research laboratory that the federal government determined had been abusing and neglecting the animals [30].

The NIH announcement did not go unnoticed. Along with Jane Goodall and animal rights groups, then-Governor Bill Richardson expressed “outrage” at the attempt to transfer the chimps to an active research facility [31]. On the second-to-last day of his term, Richardson was notified that Francis Collins had decided to “delay” moving the animals. Consistent with a request made by the governor, Collins requested the NAS/IOM to “weigh in” on the use of chimps in medical research [32], and carry out an “in-depth analysis to reassess the scientific need for the continued use of chimpanzees to accelerate biomedical discoveries.” [33] The IOM formed an ad-hoc committee, which held three 2-day meetings from May-November 2011, several conference calls, and two “information-gathering” sessions [34].

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In its report, the committee acknowledged that it had been asked for its “advice on the scientific necessity of the chimpanzee as an animal model for biomedical and behavioral research,” and that it should not base its recommendations on cost or ethical considerations [35]. In fact, at its first public meeting, Sally Rockey, Deputy Director for Extramural Research at NIH, specifically ruled out the role of ethics in the committee’s charge, saying only that it wasn’t scientifically necessary to use chimpanzees in research, it certainly would be unethical to do so. Nevertheless, a bioethicist, Jeffrey Kahn, then Director and Professor at the Center for Bioethics, University of Minnesota, was chosen to chair the committee. Thus, not surprisingly, the committee “recognize[d] that any assessment of the necessity for using chimpanzees as an animal model... raises ethical issues, and any analysis must take these ethical issues into account.” [36]

The committee issued its report on December 15, 2011. The report set forth the criteria it used in making recommendations on the continuing need for chimpanzees in biomedical research:

- The knowledge gained must be necessary to advance the public’s health;
- 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
- The animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments or in natural habitats [37].

In addition to the criterion related to appropriate environments, the committee added the following criteria for comparative genomics and behavioral research:

- Studies provide otherwise unattainable insight into comparative genomics, normal and abnormal behavior, mental health, emotion, or cognition; and
- All experiments are performed on acquiescent animals, in a manner that minimizes pain and distress, and is minimally invasive [38].

Following are some of the committee’s key conclusions and recommendations:

- “[M]ost current use of chimpanzees for biomedical research is unnecessary.... “The committee allowed two

“potential” exceptions: (1) there might be a “limited number” of monoclonal antibodies already in development that could require further use of chimps, and (2) “the committee was evenly split and unable to reach consensus on the necessity of the chimpanzee for the development of a prophylactic hepatitis C... vaccine.”

- It may not be possible to study emerging or reemerging diseases in models other than the chimpanzee and, therefore, its use would be permissible.
- Because chimps and humans are so genetically similar, “[c]omparative genomics research may be necessary for understanding human development, disease mechanisms, and susceptibility....” Thus, when studies are conducted using existing tissue or when minimum pain and distress is involved in collecting samples from living animals, this research is allowed.
- When chimpanzee research could provide “insights to support understanding of social and behavioral factors that include the development, prevention, or treatment of disease” not obtainable through other means, it would be necessary [39].

Thus, although the IOM committee did not endorse a ban on research with chimps, it was hard not to interpret the committee’s conclusions as anything but a “watershed event” related to the use of chimpanzees in research [40], erecting formidable hurdles in the way of continuing federally-supported biomedical research, although not behavioral research, with chimpanzees.

#### **NIH Reacts**

Within hours following release of the IOM Report, Francis Collins made the following announcement: “I have considered the report carefully and have decided to accept the IOM committee recommendations.” He added that NIH was “in the process” of developing plans to implement the recommendations and that he had delegated the task to a working group of the NIH Council of Councils. The working group would “consider the size and placement of the active and inactive populations of NIH-owned or –supported chimpanzees” and no new awards for research involving the animals would be granted until the plans were in place [41].

Almost a year after its convening (January 22, 2013), the Council of Councils accepted the working group’s report, which included 28 recommendations, focusing on reviewing which currently-funded NIH

studies with chimps met the IOM committee’s guidelines, establishing a process for assessing future proposed research projects to determine whether they are scientifically necessary and consistent with the IOM guidelines, and advising on the conditions and placement of both currently active and inactive chimps. The working group called for ending many ongoing studies, but recommended the maintenance of a colony of 50 chimps, should they be needed for future emergency research, as envisioned by the IOM committee [42].

Although the IOM committee’s guidelines included the recommendation that “[t]he animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments or in natural habitats,” nowhere did it specify the nature of these environments. This gap was filled by 10 recommendations in the working group’s report, which set forth specifics, for example, regarding the size of a chimp’s living space, materials to build nests, and “an enrichment program developed for chimpanzees” that would include “relevant opportunities for choice and self-determination.” These criteria were an attempt to promote “a full range of behaviors that are natural for the species.” [43]

#### **Stakeholders React**

Given an opportunity to comment on this report, representatives of both the scientific and animal rights communities did so. An example of the latter are the comments of NEAVS and others activist groups that laid out in more detail the “exemplary” social and physical requirements of chimps [44]. The American Physiological Society expressed some of the research community’s concerns in its comments, which “urged” NIH to “revisit” the recommendations. For example, the society cited the working group’s “excessive reliance on inflexible engineering standards” in defining “appropriate” environments, rather than “performance standards” that “would better serve animal welfare.” [45] This particular critique was typical of the concern of scientists familiar with the issue, that is, the environmental requirements were unrealistic, at best, and more likely unrealizable. Some referred to the living space specifications as “condos for chimps,” and even Chimp Haven, the “gold standard” of retirement sanctuaries would not be able to meet the new requirements. Although the working

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group's report stated that "[t]he majority of NIH-owned chimpanzees should be designated for retirement and transferred to the federal sanctuary system," the fact is there was neither enough room in existing sanctuaries for these retired chimps nor the funds to maintain them. Further, many of the chimps in research settings were elderly and likely not to survive transfer from their current living spaces, not to mention the disruption in existing social groups this would entail.

On June 26, 2013, Collins accepted most of the working group's suggestions.

- Retain but do not breed a small group of chimpanzees for future research that meets the IOM guidelines;
- Provide ethologically appropriate housing facilities, like those that would occur in their natural environment;
- Establish a panel to review future projects that propose using chimps based on the IOM guidelines, after the standard NIH review panel had approved the research;
- Wind down ongoing projects using chimps that do not meet the IOM criteria; and
- Retire the majority of the NIH-owned chimps designated as unnecessary for research [46].

The animal rights community cheered this announcement, with Wayne Pacelle, president and CEO of HSUS, proclaiming, "This is an historic moment and major turning point for chimpanzees in laboratories." [47]

The only working group recommendation not adopted was the specification of 1000 feet of living space per chimp (more than in some small urban apartments) on the grounds that there was yet no scientific consensus on this criterion [48]. This modification in housing requirements meant that some chimps could continue to be maintained in research facilities [49].

### **Fish and Wildlife Service**

Just weeks before NIH's final action on chimpanzee research, the Fish and Wildlife Service (FWS), acting on a petition from several organizations – including HSUS, the Association of Zoos and Aquariums, and the Jane Goodall Institute [50] – proposed to classify all chimps, whether in the wild or in captivity, *endangered*. This would change the status quo, whereby only wild chimps were considered *endangered*, and captive animals were classified as *threatened* [51]. Fish and Wildlife Service

Director Dan Ashe said that the earlier split designation was designed to permit the NIH to fund biomedical studies with captive chimps, but was "flawed." [52] FWS justified this action by its determination that the Endangered Species Act "does not allow for captive-held animals to be assigned a separate legal status from their wild counterparts." [53] If, after a 60-day comment period, the proposal was adopted, "certain activities would require a permit.... Permits would be issued only for scientific [and certain other] purposes...." [54]

While the National Antivivisection Society pronounced the FWS proposal "welcome," [55] scientific societies expressed their worries about the implications of the action. Both the American Physiological Society and FASEB urged FWS to "expedite the permitting process" [56] for "critical research aimed at preventing or treating devastating diseases...." [57] but did not ask the agency to reconsider its decision. As of this writing, FWS has not issued a final rule.

### **Chimpanzee Rights**

On December 2, 2013, the Nonhuman Rights Project filed the first of three lawsuits in New York State courts on behalf of four chimpanzees, two of which were used for locomotion research at Stony Brook University. The judges were asked to grant the animals' right to "bodily liberty." [58] Steven Wise, president of the rights organization who has taught animal law at several universities, said that chimps "possess complex cognitive abilities that are so strictly protected when they're found in human beings." [59] In support of its argument, the rights organization submitted affidavits from what Wise termed "nine of the world's leading primatologists." [60] In a live "chat" sponsored by AAAS, Wise emphasized that he was not asking for "human rights" for the animals, rather he was seeking "chimpanzee rights," and that the animals should be declared persons who were being unlawfully imprisoned.

Wise also said he did not expect to be successful in any of the three lawsuits, a prediction that proved correct. According to Wise, two of the three judges expressed sympathy in their rulings dismissing the suits, with one of them saying "[y]ou make a very good argument." The third, in whose court the Stony Brook's chimps case was submitted, dismissed the suit hours after it was filed, without holding a hearing. Although a senior litigator for HSUS thinks the Nonhuman Rights Project's arguments are academically impressive, he finds them

"just not feasible" as a legal strategy [61]. The Project's Wise is undaunted, and plans to appeal the cases to the appropriate New York Appellate Divisions, saying the "struggle to attain the personhood of such an extraordinarily cognitively complex nonhuman animal as a chimpanzee has barely begun." [62]

### **The Future**

Building on their success at achieving the near-elimination of all biomedical research on chimpanzees, animal rights groups are reaching for higher goals. Writing in the *Hastings Center Report* in 2012, Kathleen Conlee and Andrew Rowan, vice president for animal research issues and chief scientific officer at HSUS, respectively, argued that "[t]he process that culminated in the phasing out of invasive research on chimpanzees in the United States in 2011 can and should be applied to all other nonhuman primates." Their reasoning sounds familiar: Research on primates should be halted for "ethical, scientific, and economic reasons." [63] The force of these arguments on the public, congress, the executive branch, professional ethicists, and even some scientists should not be underestimated.

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[62] "Chimpanzee Lawsuits Rejected in New York Court," <http://www.natureworldnews.com/articles/5270/20131211/chimpanzee-lawsuit-rejected-new-york-court.htm>.

[63] Kathleen Conlee and Andrew Rowan, "The Case for Phasing Out Experiments on Primates," *Hastings Center Report*, 42, no. 6 (2012).

## In the News

### FDA REBUKES PERSONAL GENOME SERVICE OVER CONCERNS ABOUT CONSUMER HEALTH DECISIONS

For just 100 dollars, you can have your genome decoded, ancestry traced and health risks for more than 250 diseases analyzed. So states the Personal Genome Service (PGS), 23andMe, which offered this package for 6 years until receiving a harsh warning letter from the FDA last November.

23andMe is one of the leading companies in the emerging industry of direct-to-consumer genome testing services. Consumers send in biological samples via saliva kits and the company then sends back a detailed analysis of their genes. 23andMe is the largest company of its kind, boasting a collection of 250 million data points constructed from the genomes of more than 500,000 customers who have participated in their service [1].

The FDA, however, claims the company failed to meet regulatory standards. Despite, "more than 14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications," 23andMe has consistently failed to comply with FDA guidelines and follow through on clinical studies confirming its effectiveness and adherence to health requirements [2]. The

FDA is particularly concerned about the consequences of the service on the health decisions of consumers: false positives or false negatives on disease assessment measures could lead consumers to circumvent their physicians and make irresponsible choices regarding their personal health. For example, if the results report a false-positive for ovarian or breast cancer, it could lead, "a patient to undergo prophylactic surgery, chemoprevention, intensive screening or other morbidity inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist." Others have also cited privacy concerns over 23andMe's handling of personal genetic information [3].

According to the FDA's letter to 23andMe, dated November 22, 2013, the company failed to gain the clearance necessary to clinically prove that its product fulfills its marketed purposes. "We have become aware that you have initiated new marketing campaigns, including television commercials that, together with an increasing list of indications, show that you plan to expand the PGS's uses and consumer base without obtaining marketing authorization from FDA." In response to the FDA, 23andMe's chief executive officer, Anne Wojcicki, acknowledged the FDA's directive and announced a suspension of health-analysis tests until receiving further FDA authorization [1]. The company will continue to provide new customers with ancestry information and raw genetic data without 23andMe's interpretation of the data.

Some observers are critical of the severity of the FDA's stance on 23andMe. An article published on January 16, 2014 in *Nature* argues that the FDA's actions against 23andMe were unwarranted [4]. The authors concede that 23andMe should be required to reveal the limits of their tests to consumers; however, according to their research, fears over harmful patient health choices are unfounded. After surveying 1,051 customers of 23andMe and a similar company, Pathway Genomics, they found that 58% of consumers did nothing with their genome results and out of the 42% who did make changes to their health routines, the majority only changed their diet or exercise frequency. Only 2% of the surveyed customers changed their prescription drug use without first consulting their physician.

In contrast, others laud the FDA's push for greater integrity in this industry. The *Washington Post* editorial board wrote, "Genetic testing should not become like the Wild West of the dietary supplement industry into which Americans pour billions annually even though quality varies massively and dubious claims go unchecked." [5] Though the FDA may have had tough words for

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23andMe, it simultaneously took steps to help the genetics industry grow as well. Last November, it approved the Illumina MiSeqDx, an innovative gene sequencing device which will further reduce the time and cost of genomic analysis [6].

- [1]<http://blog.23andme.com/news/23andme-provides-an-update-regarding-fdas-review/>
- [2]<http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm>
- [3]<http://www.scientificamerican.com/article.cfm?id=23andme-is-terrifying-but-not-for-reasons-fda&page=2>
- [4]<http://www.nature.com/news/regulation-the-fda-is-overcautious-on-consumer-genomics-1.14527>
- [5][http://www.washingtonpost.com/opinions/a-safe-smart-approach-to-genetic-testing/2013/12/01/2777b988-56e8-11e3-835d-e7173847c7cc\\_story.html](http://www.washingtonpost.com/opinions/a-safe-smart-approach-to-genetic-testing/2013/12/01/2777b988-56e8-11e3-835d-e7173847c7cc_story.html)
- [6][http://www.nejm.org/doi/full/10.1056/NEJMp1314561?query=featured\\_home&am&:](http://www.nejm.org/doi/full/10.1056/NEJMp1314561?query=featured_home&am&:)

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## HHS FINDS THAT PHYSICIAN OWNED DISTRIBUTORSHIPS CORRELATE WITH INCREASED SURGERIES

If physicians hold a financial stake in the surgical equipment they use, will they recommend more of their patients to undergo surgery? A new report, released on October 24, 2013, by the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), suggests that they will.

According to the report, “Spinal Devices Supplied By Physician-Owned Distributors: Overview of Prevalence and Use,” there was a direct correlation between physicians who are financially invested in their surgical devices through Physician Owned Distributorships (PODs) and an increase in the number of spinal fusion surgeries [1]. PODs are distributors of medical equipment that maintain financial relationships with physicians, hospital administrators or other health professionals. In the case of spinal surgeries, PODs are often responsible for the devices implanted into the spine for structural support including, plates, screws and rods.

The report found that one in five spinal fusion surgeries billed to Medicare used devices supplied by PODs in Fiscal Year (FY) 2011. In an analysis spanning from FY 2004 through FY 2012, spinal surgery rates grew faster at hospitals after they began purchasing from PODs than the rate of spinal surgery increase for hospitals overall. Increases in the number of spinal surgeries for hospitals supplied by PODs were three times the overall increase in spinal surgeries for all hospitals in the study (16% increase vs. 5% increase). Furthermore, the cost of spinal fusion surgeries that used POD devices were not lower than the cost of surgeries without POD devices, thus undermining a common

argument made by POD proponents that their business model is more cost-effective.

The report’s findings support criticisms of PODs by policymakers, healthcare officials and others. Conflicts of interest may cause physicians to make decisions that are not in the best interest of their patients (whether this is done intentionally or unconsciously is unclear). When physicians or hospital officials derive personal economic benefits from the use of a particular surgical device, they can be motivated to place more patients in surgery - which can be dangerous for patients. When choosing between medical devices, physicians may select the particular device in which they are invested, rather than the most suitable choice for a patient. Additionally, as a significant percentage of operations are funded by Medicare, unnecessary surgeries waste taxpayer dollars.

Senator Orrin Hatch (R-Utah) was one of several members of Congress to voice his concerns over PODs and call for an investigative report by the Department of Health and Human Services. “My deep-seated skepticism that physician-owned distributors operate in the best interest of patients and save taxpayers money has been confirmed by this non-partisan report,” Hatch said, “The HHS Inspector General’s finding that hospitals conduct a greater number of high risk spinal surgeries when they purchase products from physician-owned distributors shows why vigorous oversight is necessary to protect the health and safety of patients.” [2]

Before the report’s publication, HHS-OIG released a *Special Fraud Alert* on physician-owned entities in March 2013 [3], in which the HHS-OIG suggests that some PODs may be in violation of the Anti-Kickback Statute - a law under the Social Security Act that “makes it a criminal offense to knowingly and willfully offer remuneration to induce, or in return for, referrals of items of services reimbursable by a Federal health care program.” [1] According to the HHS-OIG, if PODs intentionally encourage greater Medicare covered surgeries by offering physicians financial rewards, they are not complying with this statute and may be prosecuted.

While the Inspector General’s report does validate some of the concerns of POD opponents, the results are limited to a particular type of surgery within a single medical field. There have been similar reported cases such as the high profitability of intensity-modulated radiation therapy (IMRT), a treatment for prostate cancer done by urologists that receives high Medicare reimbursement rates [4]; however, broader analysis of PODs will be necessary to accurately gauge their full impacts and guide future regulatory action.

[1]<http://oig.hhs.gov/oei/reports/oei-01-11-00660.asp>

[2]<http://www.finance.senate.gov/newsroom/chairman/release/?id=3145394a-3184-44d4-a730-b432d259d034>

[3][https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD\\_Special\\_Fraud\\_Alert.pdf](https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf)

[4]<http://www.medscape.com/viewarticle/813213>

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## COLLABORATIVE RESEARCH GUIDELINES

Since 2007, the scientific research community has held a world conference on research integrity to facilitate discussion around responsible research [1]. After the 2<sup>nd</sup> World Conference, *The Singapore Statement* was released and widely distributed on September 22, 2010 [2]. This was the first global effort to issue general research principles and responsibilities intended to challenge governments, organizations, and researchers to develop more comprehensive standards to foster research integrity, both locally and on an international basis.

In October 2013, emerging from the 3<sup>rd</sup> World Conference, *The Montreal Statement* was produced as an extension of *The Singapore Statement* [3]. This Statement offers guidelines specifically for cross-boundary research collaborations rather than just the broad topic of integrity applied to all research endeavors. The guidelines are divided into four sections: General Responsibilities, Management, Relationships, and Outcomes of Research [4]. Each one addresses a different component essential to collaborative research. The general responsibilities section looks at the vision and expectations of each individual, as well as the institutions involved. Management focuses on communication, leadership, and logistics. Relationships describes roles and how to handle conflicting situations in order to maintain effective collaboration. Finally, outcomes of research covers the responsibilities after the research is conducted including publication, dissemination, and response to misconduct.

Additionally, several themes appear within all the sections, emphasizing their overall importance to the practice of responsible collaborative research. First, trust and agreement show up repeatedly as fundamental to establishing and upholding strong partnerships. Collaborations are all about teamwork, and the job becomes more difficult when trust and agreement are absent. Second, procedure, assumptions, and transparency are also reoccurring concepts. They indicate that policies and procedures should be determined at the commencement of the project and clearly communicated to all parties. Third, authorship and acknowledgment illustrate that

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those responsible for the research, funding, and other contributions must be given adequate credit for their work and accomplishment.

In conclusion, *The Montreal Statement* advances expectations for collaborative research across all sectors, disciplines, institutions, and nations. Its publication and dissemination are intended to make it easier for others to provide the leadership needed to promote integrity in research on a global basis, with a common approach to the fundamental elements of responsible research practice. The Montreal and Singapore Statements are a reflection of how guidelines are adapting to changing research practice, significantly advancing the ethical discussion on science, impacting not only the research community but all those who benefit from the knowledge gained through their work.

- [1] <http://www.esf.org/ext-ceo-news-singleview/article/world-conference-on-research-integrity-to-foster-responsible-research-318.html>
- [2] <http://www.singaporestatement.org/>
- [3] <http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673613621261.pdf>
- [4] <http://www.cehd.umn.edu/olpd/MontrealStatement.pdf>

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## FEDERAL OFFICIALS REVEAL PLOTS TO STEAL PATENTED U.S. AGRICULTURAL TECHNOLOGY

In what reads like a spy thriller, the FBI recently uncovered two separate plots of Chinese individuals attempting to steal patented seed technology from the United States. In one of the cases, several Chinese men - including the chief executive officer of Beijing agricultural company, Kings Nower Seed - were observed stealing corn from test fields owned by Monsanto and DuPont Pioneer in Iowa [1]. After obtaining court orders, federal agents installed surveillance devices in their rental car, listened in on their plans and followed the men through several states as they collected additional corn samples. When Kings Nower Seed CEO, Li Shaoming, and an associate prepared to fly back to China, U.S. Customs agents searched the men and found seed samples hidden among their belongings. Another member of the group, a dual Chinese-Canadian citizen, was apprehended when attempting to cross the Canadian border with seed samples hidden under his car seat.

In a separate incident, two Chinese agricultural scientists working at research facilities in Kansas were accused of passing seed samples to a visiting Chinese delegation [2]. Yan Wengui and Zhang Weiqiang, working for the United States Department of Agriculture and an American biopharmaceutical company respectively,

were tied to seed samples discovered in the luggage of several Chinese delegation members. The accused in both cases are currently being prosecuted, some facing charges that include conspiracy to steal trade secrets. The two cases were made public last December, and it is unclear whether they are related.

The corporate facilities from which the Chinese men stole seeds are where large agricultural companies test new technologies. These companies typically invest millions of dollars into research and development efforts - Monsanto devotes over a billion dollars to R&D each year alone [3]. The innovations that result provide these companies with key competitive advantages in the agricultural market; therefore, companies are seriously concerned about the security of their research and manufacturing process.

- [1] <http://www.scmp.com/news/world/article/1380011/prosecutors-us-midwest-charge-six-chinese-plot-steal-seed-corn>
- [2] <http://www.theguardian.com/world/2013/dec/14/chinese-scientists-accused-seed-theft>
- [3] <http://www.monsanto.com/careers/Pages/research.aspx>

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## AUTHORSHIP GUIDELINES REVISED

Assigning credit for scientific discoveries, research, and analyses has always been a problematic endeavor. Timing, collaboration, and building upon results that have already been obtained are some factors that contribute to the increasingly more difficult task. At the end of the day, the credit will go to the names included in the byline of a published piece in a prominent scientific journal. This reality makes it critically important to establish guidelines that clearly distinguish authorship. Scientific journals, laboratories, and academic institutions are encouraged to set policies regarding authorship, and indeed many already have them in place. The fundamental purpose of the policies is to remove ambiguity about whether or not a contribution warrants authorship. These policies do not eliminate all confusion and disputes about authorship, but they are a valuable aid in mitigating them.

There are challenges that make determining authorship a less than straight-forward task that are worth noting. First, collaborative work is becoming more prevalent in the field of science. Complex research projects must employ a wide variety of scientists in order to broaden the depth of knowledge. Because no one is always an expert on every aspect of a project, "all collaboration should have in place an appropriate process for reviewing and ensuring the accuracy of the reported results, and all co-authors should be aware of this process." [1] To resolve this issue, senior scientists must be transparent about their expectations and policies. They should initiate

an explicit discussion about such processes at the beginning of a project.

Second, there is increased pressure to author published work. As stated in the *New York Times* a few years ago, "to survive professionally, scientists feel the need to publish as many papers as possible. And sometimes they cut corners or even commit misconduct to get there." [2] Ultimately, the standard for getting published is compromising scientific integrity, which not only affects the science but society's perception of science.

The challenges with defining authorship can be reconciled by adopting policies or guidelines. The International Committee of Medical Journal Editors (ICMJE) suggests that those identified as authors meet all of the following criteria: play a substantial role in the design of the research and the acquisition and analysis of the data; draft, revise and edit the work; have the authority to make the final approval before publishing; and take full responsibility for all aspects of the work [3]. In addition to accepting responsibility for the research, editing, and publication, ICMJE's criteria also emphasizes that the authors are accountable for anyone who contributes to the research. They must trust that the work and results are correct. This indicates that authorship is more than just a byline.

Some non-conventional methods have also been established to address authorship. Stanford University has a hands-off approach. There are not any specific guidelines because the university does not wish to, "impose formal mechanisms for determining authorship," rather they distribute a letter written by President Donald Kennedy in 1987 and revised in 2012, regarding intellectual contribution to all research laboratories to incite discussion and action [4]. Some publishers such as *Nature* even go as far as requiring author contribution statements to ensure the role of each author and contributor is explicitly stated. These statements "may go a long way toward resolving authorship issues by providing an additional dimension to the linear author lists of current papers." [5] The methods presented here are feasible for these particular organizations, but they may not work for all. Nevertheless, they inspire creative approaches to the ever growing problem of authorship to ensure standards are being set for the next generation of scientists.

- [1] <http://www.nytimes.com/2002/11/19/science/after-two-scandals-physics-group-expands-ethics-guidelines.html>
- [2] <http://www.nytimes.com/2012/04/17/science/rise-in-scientific-journal-retractions-prompts-calls-for-reform.html>
- [3] [http://icmje.org/roles\\_a.html](http://icmje.org/roles_a.html)
- [4] <http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/academic-authorship>

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[5]<http://www.nature.com/nchembio/journal/v5/n10/full/nchembio.f13.html>

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## Resources

### PRACTICAL GUIDANCE ON SCIENCE AND ENGINEERING ETHICS EDUCATION FOR INSTRUCTORS AND ADMINISTRATORS

The National Academy of Engineering's Center for Engineering, Ethics, and Society (CEES), in collaboration with the National Center for Professional and Research Ethics at the University of Illinois at Urbana-Champaign, has released proceedings from a workshop on Practical Guidance on Science and Engineering Ethics Education for Instructors and Administrators. It is the summary of a workshop convened in December 2012 to consider best practices for ethics education programs in science and engineering. The workshop focused on three key areas: goals and objectives for ethics instruction, instructional assessment, and institutional and research cultures. Leading experts summarized and presented papers on current research knowledge in those areas. The papers and workshop also included discussion of guidance checklists for instructors and administrators. This report presents the edited papers and a summary of the discussions at the workshop. It is available for free at: <http://www.nae.edu/Projects/CEES/70909/88312.aspx>

### PRESIDENTIAL BIOETHICS COMMISSION RELEASES REPORT ON INCIDENTAL FINDINGS

On December 12, 2013 the Presidential Commission for the Study of Bioethical Issues released a new report titled "Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts." According to the Commission's press release, the report offers an "ethical analysis and recommendations for clinicians, researchers, and direct-to-consumer testing companies on how to manage the increasingly common issue of incidental and secondary findings." [1] For more information and to read the official report, see: <http://bioethics.gov/node/3183>

## Announcements

**Book Series** - *Emerging Technologies, Ethics and International Affairs* is a new book series edited by Jai Galliot, Avery Plaw and Katina Michael. The series examines the crucial ethical, legal and public policy questions arising from or exacerbated by the design, development and eventual adoption of new technologies across all related fields, from education and engineering to medicine and military affairs. Further details of the series can be found at: [www.ashgate.com/ET](http://www.ashgate.com/ET).

**Call for Papers** - The Science Communication Project at Iowa State University is seeking paper submissions for a special volume on 'Science Communication Ethics: State of the Art.' Submissions are open to scholars in all disciplines who are able to connect their analyses to broader issues of theory in considering problems such as these: What are the underlying goals of science communication? What are the boundaries of appropriate advocacy and promotion? What ethical obligations do scientists have to communicate to broader publics? What ethical requirements should govern discussions of risks, benefits, "facts," and uncertainties? Papers should be submitted by October 15, 2014 to Susanna Priest at: [susannapriest@yahoo.com](mailto:susannapriest@yahoo.com).

**Call for Papers** - The *Hastings Center Report* and the Presidential Commission for the Study of Bioethical Issues seek papers for a special report on teaching bioethics. Papers are invited on the following broad topics: assessing the state of bioethics education, incorporating professional, clinical, research, and public health ethics education into medical and STEM education at secondary, undergraduate, and graduate levels, methods for bioethics instruction, and best practices in bioethics education. The deadline for submission is March 10, 2014. Manuscripts should be submitted to [editorial@thehastingscenter.org](mailto:editorial@thehastingscenter.org). For more information, go to: <http://goo.gl/kOcZ01>.

**Conference** - Trainer-of-Trainers Conference-Educating Scientists in Research Ethics for the 21st Century. Scheduled for June 8-11, 2014 in Annapolis, MD, this conference is designed to prepare university faculty and scientific society leaders to establish or improve instruction in research ethics. Participants will learn interactive approaches for providing instruction aimed at both novice and experienced instructors in research ethics. The conference is open to individuals in all research-oriented fields who will be providing training in research ethics, including other trainers. Registration is limited to 40 participants, who are selected competitively. Applications will be accepted on a rolling basis until all positions are filled. Limited financial assistance is available. Contact: Dr. Beth A. Fischer at [bfischer@pitt.edu](mailto:bfischer@pitt.edu) or visit [www.skillassist.org](http://www.skillassist.org).

**Fellowship** - The Poynter Center announces the opportunity for a non-stipendiary fellowship at the Center in academic year 2015. The Fellow will be expected to work on a significant research project in ethics and public life, broadly construed, and to participate in the Center's scheduled seminars, lectures, and symposia. Additional information is available here: <http://poynter.indiana.edu/research/fellowships/>. Applications are due February 3, 2014 and should be sent to Glenda Murray at: [glmurray@indiana.edu](mailto:glmurray@indiana.edu).

**Video Contest** - In celebration of its upcoming 50th anniversary, the National Academy of Engineering is launching the Engineering for You (E4U) Video Contest to show how engineering creations serve the welfare of humanity and the needs of society. The NAE is offering a \$25,000 prize to the most inspiring 1-2 minute video focused anywhere between 1964 and 2064. The contest will run from Nov. 1, 2013, to March 31, 2014. Learn more at: [www.e4uvideocontest.org](http://www.e4uvideocontest.org).

**Workshop** - The Poynter Center will host a workshop for research faculty and administrators on 'Promoting Research Integrity' on February 27, 2014. The workshop will be held in Jacksonville, Florida and will focus on reconsidering approaches to promoting research integrity and dealing with research misconduct and questionable research practices. More information is available here: <http://poynter.indiana.edu/teaching-research-ethics/workshop-details/>.

**Workshop** - AAAS will host a special workshop on responsible professional practices in a changing research environment in conjunction with its Annual Meeting in Chicago, IL on February 13, 2014. The workshop, which requires pre-registration and an additional fee of \$25.00, will focus on integrating research ethics education into the research environment. The workshop is designed to assist research faculty in creating concrete, discipline-specific strategies to incorporate research ethics education into the context of the research environment, whether it be a lab or field work. The workshop is grounded in a recognition that many research ethics issues are relevant to the practice and application of science, from developing hypotheses and designing a protocol, to data management and analysis, to reporting findings and advising others on the uses of the work, and that integrating ethics instruction in the context of performing those various stages of research can be an effective strategy for educating future researchers. Participants will be introduced to rationales, content, approaches, tools, and resources to give them the means to develop and implement research ethics education in their research environment. For more information, see: <http://www.aaas.org/event/workshop-responsible-professional-practices>