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The Kennewick Man Controversy: An Ethical and Legal Overview

By Matt Zimmerman

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In July of 1996, two unsuspecting students found what they believed to be a murder victim's bones along the Columbia River in Washington. In actuality, they had stumbled upon a very ancient human skeleton. The remains, dubbed Kennewick Man after the town in which they were found, are a remarkable find. Carbon dating indicates that the bones are over 9,000 years old, yet Kennewick Man's features seem so Caucasian that James Chatters, the first anthropologist to examine the remains, initially thought they were from a European settler. Kennewick Man and other recent finds are currently causing scientists to reevaluate their theories about how the Americas were first populated. Such discoveries, though, also cause friction between scientists and Native American communities who view such remains as sacred.

Many scientists are eager to study the Kennewick Man's bones and DNA in the hope that they will learn more about North America's prehistory, how the land was populated and what twists and turns may have occurred in the development of the Native American populations that exist today. Chatters suggests that by studying the Kennewick Man, scientists could even learn more about diseases like type 2 diabetes and rheumatoid arthritis that strike modern Native Americans. The Confederated Tribes of the Umatilla Indian Reservation and other Native American's, though, are equally eager to reclaim what they see as a lost kinsman and give him a long overdue proper burial.

The Native American groups claiming the skeleton as their ancestor do not believe that scientific study is appropriate for the Kennewick Man or other ancient Native American remains. They believe that these human remains are connected to the spirit of the deceased. Therefore, respect for the body is equivalent to respect for the dead individual. Keeping the body above ground unnecessarily and subjecting it to experiments, especially those involving the removal or destruction of tissue, are serious breaches of Native American cultural mores and cause suffering for the dead person's spirit.

In a position paper released after Kennewick Man's discovery, Armand Minthorn, Board of Trustees member and religious leader with the Confederated Tribes of the Umatilla Indian Reservation, explained that his people believe that they have occupied the land where Kennewick Man was found since the beginning of time, and that scientific study of the remains would have little value for them. In the meantime, Minthorn noted that "thousands of native human remains sit on the shelves of museums and institutions, waiting for the day when they can return to the earth, and waiting for the day that scientists and others pay them the respect they are due."[1]

In an effort to balance the interests of science and the cultural needs of Native Americans, Hawaiians, and Samoans, Congress passed the Native American Graves Protection and Repatriation Act (NAGPRA) in 1990.[2] NAGPRA established that rights to Native American cultural artifacts and remains unearthed on federal or tribal lands should

belong to the tribe that has the closest cultural affiliation to them. If a cultural affiliation for the artifacts and remains cannot be determined, they go to the tribe that is recognized as aboriginally occupying the land on which they were found. NAGPRA allows for scientific study of human remains by guaranteeing access to artifacts that are "indispensable for completion of a specific scientific study" which would yield "major benefits" for the public.[3]

Since the U.S. Army Corps of Engineers owns the land where the Kennewick Man's remains were found, NAGPRA governs their dispensation. Upon learning how old the remains were, the Corps seized the bones, intending to turn the them over to the Umatilla tribes. The Corps based this decision on the age of the remains and the Umatilla's historical claim to the land where they were found.

Return of the remains was halted, however, by an appeal from eight prominent scientists who claimed that the Corps was misreading NAGPRA. NAGPRA specifically states that scientific examination may be necessary to aid in properly identifying the cultural affiliation of an artifact.

Compounding the scientist's frustration is the apparent age of the Kennewick Man. In scientific terms, the remains may bear little or no relationship with any current population. From their perspective, turning the remains over to any cultural group[4] would be an arbitrary decision based upon political pressure rather than objective analysis and reason.

When the scientists filed their suit with the federal court, the fate of the Kennewick Man situation became the subject of a large public controversy. Both sides mobilized public relations efforts to stake out clear and strong negotiating positions. On one hand, Native Americans argued that historical justice, cultural respect, and the sacredness of death demanded the return of the Kennewick Man to the earth. On the other hand, scientists aspired to expand knowledge and improve the human condition, their access to and treatment of the remains justified by the worthiness of their goals.

Although Congress established NAGPRA to provide a framework for considering opposing cultural perspectives, it was not implemented effectively in the case of the Kennewick Man. The Army Corps of Engineers acted too swiftly to hand over the bones to the Umatilla, leaving open the question of whether or not the remains bore any scientifically demonstrable biological or cultural affiliation with the tribes. The absence of careful consideration of both perspectives played a large part in leading to the dispute that remains unresolved two years later.

In response to the controversy and lawsuit, Rep. Doc Hastings (R-WA) introduced a bill in Congress earlier this year to amend NAGPRA. The Hastings amendment would retroactively remove the part of the law that grants ownership of artifacts on the basis of aboriginal affiliation with the land where they were discovered. While this bill was welcomed by many anthropologists and archeologists,[5] Native American interests felt that it ceded too much decision making authority to science and that it violated the balance established in NAGPRA.

The National Park Service, the branch of the U.S. Department of Interior responsible for implementing and overseeing NAGPRA, also staked out a position in support of NAGPRA as-is, stating that the issues raised by Kennewick Man are best dealt with through "regulations and guidance,"[6]

U.S. Magistrate Judge John Jelderks apparently agrees. He has ordered that the Kennewick remains be transferred from the Pacific Northwest National Laboratory to the Burke Museum in Seattle. They will be studied this fall by the Department of Interior to determine scientifically whether the remains can truly be affiliated with the Indians claiming them.

References

1 Armand Minthorn, *Human Remains Should Be Reburied*, Position Paper, Confederated Tribes of the Umatilla Indian Reservation, September 1996.

2 U.S. Code, Title 25, Chapter 32.

3 25 USC Sec. 3005.

4 The Umatilla are not the only group who filed for ownership of the Kennewick Man. The Asatru, a group of modern-day worshippers of ancient Nordic deities have also laid claim to them, arguing that the remains belong to an individual descended from Northern Europeans who sailed to North America.

5 The bill, H.R. 2893, was endorsed by both the Society of American Archeology and the American Association of Physical Anthropologists. 6 Katherine H. Stevenson, National Park Service, in testimony before the U.S. House of Representatives Committee on Resources, June 10, 1998.

IN THE NEWS

AFRICA PROCLAIMS RIGHTS TO GENETIC AND BIOLOGICAL MATERIALS

In late March, the Scientific, Technical, and Research Commission of the Organization of African Unity (OAU) issued a draft model law on community rights and access to biological resources that acknowledges native peoples as the owners of the nation's resources, and awarding them a voice in granting access to their resources. The goal of the model legislation is to maintain control by indigenous communities of their natural resources, knowledge, and technologies.

Article 4 of the OAU's draft legislation applies to access to the community's knowledge, technologies, biological resources, and genetic resources. It gives priority to studies carried out in the country itself, as opposed to the export of information and materials. State and local communities must give their informed consent before others may gain access to biological or genetic resources. However, once permission is granted, the competent national authority retains the right to terminate the agreement if the collector violates "…any of the mutually agreed terms, or if the overriding public interest so demands." Article 4 of the draft legislation stresses the priority of the community by stating that the human health quality of life, and cultural identity of the local communities will be deciding factors in granting access to biological or genetic resources.

The foundation for the role of the community in bioprospecting is further described in Article 5 of the mode law, "Community Rights." The State recognizes the ownership of, and right to collectively benefit from the use of, the knowledge, innovations, and practices by local communities. Furthermore, the State recognizes the right of the local communities to deny access to restrict access to biological and genetic resources if the access compromises the integrity of the community's natural or cultural patrimony.

Although supporting the model law in principle, several of the 53 members of the OAU have begun to negotiate deals with bioprospecting organizations. The international Cooperative biodiversity Groups (ICBG), sponsored by the U.S. government, is one such organization that seeks to find plants in Africa that could produce disease fighting drugs. In return, the ICBG offers financial compensation to the host country, corresponding benefits for the nation's traditional medicine and local research, and comprehensive patent applications to recognize all those who contributed to the invention.

The draft was discussed at the 34th Ordinary Session of the Assembly of Heads of State and Government of the Organization of African Unity in June. Recommendations were made for governments of the member states to 1)give due attention as a matter of priority to the need for regulating access to biological resources, community knowledge and technologies and their implication for intellectual property rights; 2)adopt the draft Model Legislation; 3)initiate a process of negotiation among African countries to formulate and adopt an African Convention on Biological Diversity; and 4)develop an African Common Position to safeguard the sovereign rights of member states. The Assembly also requested that the Secretary General designate the OAU/STRC as the focal point for the coordination and follow-up activities on issues of biological resources and community rights.

NEW HHS ADVISORY COMMITTEE ON GENETIC TESTING

On August 7th, Heath and Human Services (HHS) Secretary Donna Shalala announced that HHS will create an Advisory Committee on Genetic Testing. The Advisory Committee will help HHS formulate policies on the

development, validation and regulation of genetic tests.

In 1994, the National Institutes of Health (NIH) Department of Energy (DOE) Working Group on Ethical, Legal, and Social Implications of the Human Genome Research reviewed the report of the Institutes of Medicine's Committee on Assessing Genetic Risks. Among the concerns raised in the report were, "the imperfect predictability of tests, the quality of laboratories providing clinical genetic tests, the lack of proven interventions for many disorders, and the limited ability of many health care providers to explain genetic tests accurately and nondirectively to patients." To consider these problems further, the Working Group convened the Task Force on Genetic Testing. The Task Force then reviewed genetic testing in the United States and made recommendations to ensure the development of "safe and effective" genetic tests. The Task Force recommended that an HHS "advisory committee or its designate should establish a system for determining which genetic tests require stringent scrutiny," and stressed the need for HHS to coordinate policies on genetic testing. The recommendations of the Task Force can be found on the WWW at http://ww2. med.jhu.edu/tfgtelsi.

The HHS Advisory Committee on Genetic Testing will be responsible for making recommendations on broad policy issues arising from genetic testing. The Advisory Committee will have overlapping membership with the Medical Devices Advisory Committee and the Clinical Laboratory Improvement Advisory Committee. Recommendations of the Advisory Committee will be reported to the HHS Assistant Secretary for Health.

JUNGER LOSES ENCRYPTION BATTLE

On July 3, the US District Court for the Northern District of Ohio ruled against Professor Peter Junger in his case challenging US export controls of software. Junger, a Case Western Reserve University Law School professor, had wanted to publish a number of encryption programs on his website as reference materials used in his course, but was restricted by current regulations administered by the Department of Commerce. Concurrently, the chapters of his books containing the source code for the same programs could be exported without any restrictions. For national security purposes, the policy requires that a license be obtained before disclosing any encryption software in any form to "foreign persons", thereby prohibiting the dissemination of the software in any electronic form or media such as the Internet or the World Wide Web. However, the regulations permit the export of the same software in books and other "hard copy."

Junger sued the government, claiming that encryption software is a form of speech and that regulations restricting its export violate First Amendment rights. The government contended that while encryption software can be used to communicate, it is "functional" rather than expressive and, thus, does not deserve the same protections as speech. The Court agreed with the government, deciding that current Export Regulations do not violate constitutional rights because of the inherently functional nature of encryption source code, and because the regulations do not seek to restrict encryption ideas, only distribution of the encryption software. Furthermore, the Export Regulations do not apply to academic discussion of software or software in print form. The Junger decision is counter to a California federal court ruling in a similar challenge brought by University of Illinois professor, Daniel Bernstein.

INTANGIBLE EXPORTS

In July, the United Kingdom Department of Trade and Industry issued a White Paper on "Strategic Export Controls," that contains "proposals for a new legislative framework for strategic export controls and improvements to export licensing products."

A section on intangible exports has major implications for the academic community. The section, "Transfer of technology by intangible means," proposes to provide that documents transferred abroad containing controlled technology should be subject to export licensing requirements, whether exported physically or electronically. We propose, for the time being, to limit this wider offense to technology related weapons of mass destruction and long-range missiles." Ross Anderson, a professor at the University of Cambridge opposes the proposal, arguing that it is not clear enough. "Presumably bookshops will have to remove from their shelves such standard titles as Fieser and Fieser's Organic Chemistry (which contains the recipe for mustard gas) and the Feynman Lectures in Physics (which tells you how atom bombs work)."

Anderson notes that this measure would have a disastrous effect on the British software industry, science and technology research groups, and research universities. He also argues that 20% of his class on 'Security' is complicated by the presence of foreign students. It would be unlawful for him to teach, for instance, how chemical bombs work. He contends that "it would make it an offence for me to even talk to my daughter (a South African citizen) about technology related to weapons of mass destruction and long-range missiles as this would constitute an oral export." The curricula of many science undergraduate and graduate courses, including the basic natural science courses, would be affected if the proposal is passed by the Parliament. For a copy of the White Paper consult the WWW at http://www.dti.gov.uk/export.control/stratex/.

DUPONT AND NIH REACH AGREEMENT OVER GENETIC MICE

A landmark agreement resolving long-standing issues of access by academic researchers to commercially-owned technology was reached on August 19 between the National Institutes of Health (NIH), DuPont Pharmaceuticals, and the Jackson Laboratory. The agreement encompassed the use of the cre-lox recombination system, developed and patented by DuPont Pharmaceuticals, whose usefulness in revealing gene function in mice is widely recognized. Approximately three years ago, DuPont Pharmaceuticals began to tighten control over the rights to use the cre-lox mice, requiring researchers to sign an agreement limiting their freedom to use and share these materials, including submission of prepublic-ation copies of scientific reports to the company. DuPont also tried to acquire commercial rights to future innovations that may arise by using this technique. A resulting contentious two year legal battle between researchers and DuPont Pharmaceuticals culminated with the signing of a new agreement under which the company will make the technology freely available to NIH researchers and grantee institutions for non-commercial purposes.

Also, NIH researchers may disseminate cre-lox materials to other academic research laboratories under a Materials Transfer Contract. Recipient institutions will require a separate agreement with DuPont Pharmaceuticals in order to fur-ther transfer the materials. However, commercial use of the technology is "restricted"; such use must be covered by a license, and would require the payment of transfer fees. Scientific publications resulting from the use of cre-lox technology will not be "restricted." The Jackson Laboratory will breed and distribute these mice to both academic and commercial organizations. However, the agreement excludes the use of cre-lox genetic modifications in the production of mouse embryonic and stem cells as well as in agricultural research. Some observers believe that the agreement could serve as a precedent for similar agreements between academic and commercial research organizations, thereby facilitating research access to new technologies.

NBAC DISCUSSES DRAFT REPORTS

The National Bioethics Advisory Commission (NBAC) convened its 23rd meeting in Alexandria, VA, September 16-17. NBAC Commissioners discussed three draft reports: "The Use of Human Biological Materials In Research"; "Comprehensive Human Subjects Project"; and "Research Involving Persons with Mental Disorders that May Affect Decisionmaking Capacity."

During the first day, Commissioners focused on the first two reports. On the topic of human biological materials, Commissioners discussed issues such as what would constitute personally "identifiable" material and "minimal risk." NBAC's interest in this topic arose out of current advancements in DNA technology, and its ability to identify specific donors from a few pieces of human tissue. A final draft is expected by the end of this year.

C.K. Gunsalus from the University of Illinois gave an overview of her report for NBAC on "Standard Models for Human Subjects Oversight." She recommended that: 1) deficiencies in current and past projects involving human subjects be remedied 2) federal oversight be unified into one office or agency, using the Office of Special Counsel and the Nuclear Regulatory Commission, as models and 3) regulation be changed and expanded incrementally rather than suddenly. Commissioners commended her work and will continue monitoring issues related to the oversight of Institutional Review Boards (IRB).

The second day focused on the draft, "Research Involving Persons with Mental Disorders that May Affect Decisionmaking Capacity." This report grew out of NBAC's determination that, "a wide variety of research studies using human subjects has long played an essential and irreplaceable role in advancing biomedical and behavioral

science…," but at the same time, "scientific validity and importance as well as their ethical acceptability" must be certified. Thus, justification for the report stemmed from concerns that IRBs may not have guidelines that adequately address the use of human subjects with cognitive impairments.

At the onset of the discussion, the Commissioners raised concerns about the scope of the report. For example, Commissioner Bernard Lo commented that the report does not include people suffering from other disorders that may not be medically categorized as a mental disorder, yet can still affect decision making-capacity. Discussion then progressed towards issues such as: whether research could be done with another population if the research will offer potential benefit to subjects, informed consent, advance planning, and the use of legally authorized representatives. Commissioners also wanted to ensure that the report will not stigmatize any group of people defined by its recommendations.

The meeting ended with Commissioners unanimously voting in favor of having an independent qualified professional assess and monitor the health status of subjects with mental disorders throughout any research trial. However, they were unable to agree whether an independent qualified professional is always mandatory. Commissioners also were unable to reach majority consensus on other issues dealing with the ethical assessment of subject's mental capacity, and whether differences should be drawn in the recommended standards for clinical and biomedical research.

The next draft of this report is expected in mid-October, with the final draft due by the end of this year. Further information and draft reports can be accessed on the WWW at http://www.bioethics.gov

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IN THE SOCIETIES

NSPE PROMOTES AN INTERNATIONAL CODE OF ETHICS

The June 1998 issue of the Engineering Times (Vol. 20, No. 5), published by the National Society of Professional Engineers (NSPE), addresses issues associated with drafting an international code of ethics for professional engineers. The NSPE advocates an international code that would account for cultural and societal differences that currently erect barriers to fair and ethical practices. Exploitation of cheap labor, discrimination, bribery, money laundering, and lower environmental standards are described by NSPE as ethical challenges that US engineers face in the global community. Following a meeting of US, Canadian, and Mexican engineers, a section entitled "Principles of Ethical Conduct in Engineering Practice" was included in the North American Free Trade Agreement (NAFTA) in 1995. The NSPE cites the NAFTA agreement as providing a promising precedent, and encourages both organizations and academia to become involved in establishing an international code of engineering ethics.

STATEMENT ON RESEARCH COLLABORATION AND SHARING

Bruce M. Alberts, President, National Academy of Sciences; Kenneth I. Shine, President, Institute of Medicine; and Wm. A. Wulf, President, National Academy of Engineering issued the following statement on September 8.

Progress in science and technology depends on the participation of a global research community, as well as on broad public trust and support. Nearly every "proprietary" discovery can be traced to a foundation of theory and results that has been built up over many years from the freely exchanged ideas and efforts of individual researchers.

Sustained national investment in the research enterprise, coupled with rapid commercialization of research ideas by the private sector, has brought great public benefits. However, competitive drives for individual or national pre-eminence, or pressures of commercial secrecy, can inhibit the traditional openness of communication as well as the effective utilization of new research tools. A number of meetings sponsored by the Academy complex have highlighted some disturbing trends. In particular, participants from all three sectors in a program of the Academy's Government-University-Industry Research Roundtable expressed concern that increasing secrecy and proprietary pressures could jeopardize the value and utility of academic research for both public and private ends.

We share this concern, and therefore urge that our colleagues place a high priority on the following actions:

Professional Societies

Openness practices are different in the many fields of science and engineering, depending on the nature of the research or the particular applications of the research results. While a single standard of openness is neither necessary nor practical, we urge our science and engineering colleagues to use their own professional organizations to create a dialogue on the appropriate norms of open communication to ensure research vitality within each of their disciplines.

Academic Leaders

We urge the leaders of our academic research institutions to generate a strong, local dialogue concerning acceptability of any restrictions on research communications, material transfers, and the sharing of research tools. A common stand on these matters can help prevent erosion of the healthy traditions of openness among researchers, and will support individuals who may be under pressure from their own or outside organizations.

Industry

We urge industry leaders to engage in similar dialogue, examining the long-term collective benefit for U.S. industry if the tradition of open communication in U.S. research universities is preserved, and seeking the least compromise of this tradition that is compatible with their commercial investments. A joint effort between industry and academia to develop model codes or standard agreements would greatly facilitate this dialogue.

ETHICS, LAW & PUBLIC POLICY

HALF-FULL OR HALF-EMPTY? EVALUATING IRB PERFORMANCE

by Barbara Mishkin and Nalini Ariand, attorneys with Hogan & Hartson, Washington, DC

As many readers know, Institutional Review Boards ("IRBs") are the primary means for protecting human research subjects. Their composition and responsibilities are set forth in federal regulations applying to each institution that receives federal support for research involving human subjects.[1]

In performing initial review of protocols, IRBs must determine that the risks are justified by the anticipated benefits (to the subjects or others), that risks are minimized to the extent possible, and that prospective subjects are provided with full and fair information about the risks and potential benefits of participation, as well as of alternatives to participation. IRBs also perform continuing review of ongoing research (at least annually) to assure that the risks continue to be justified by the anticipated benefits, and that subjects are kept informed about new and relevant information. An essential component of continuing review is consideration of adverse events and accumulating outcome data.

In June 1998, two reports evaluating current IRB performance were issued. Notably, although they surveyed the same territory and identified many of the same problems, they drew sharply different conclusions. The HHS Office of Inspector General released a report entitled "Institutional Review Boards: A Time for Reform," ("IG Report")[2] in connection with a Congressional Hearing.[3] At about the same time, the NIH Office of Extramural Research released a report prepared by an NIH contractor ("NIH Study").[4] Although the two reports differ in tone and in their general conclusions, their recommendations are similar in many respects. Moreover, research groups who commented on the IG Report at the Congressional Hearing endorsed at least some of the IG's recommendations at the same time that they objected to the alarmist tone of the commentary.[5]

IG Report

The IG Report concluded that the IRB system is overburdened and in jeopardy as a result of an increased number of protocols, proliferation of multi-center trials, new types of research, expansion of managed care, increased commercialization of research, and increased consumer demand for access to clinical trials. Notwithstanding the

increase in IRB workloads, staffing levels and budgets have remained constant at many IRBs. The IG report stressed that without increased staff, financial resources, and efficiency, IRBs will have insufficient time for initial and continuing reviews of research, thus jeopardizing the protection of human subjects.

The IG report expressed particular concern about continuing review, stating that it is often relegated to the last few minutes of an IRB meeting and that there may be little or no IRB discussion of individual studies. In addition, the IG Report asserted that there is poor communication between IRBs and Data and Safety Monitoring Boards, which monitor accumulating data in clinical trials. Moreover, the numerous adverse-event reports that the IRBs receive typically arrive without sufficient contextual information to assist the IRB in evaluating them. The IG Report also noted that when FDA issues a warning letter to a clinical investigator, it typically does not inform the IRB, and when a sponsor or investigator submits a clinical trial (for a new drug or device) to the IRB, it is not required to tell the IRB about any prior review of the protocol by another IRB.

The report also expressed concern that the proliferation of clinical trials spread across hundreds of sites, sometimes around the world, has lead to a flood of adverse event reports for IRBs to review, but they often lack access to important information concerning the status of ongoing research. In addition, the report asserted that scientific advances such as genetic therapy, as well as increased research in areas that do not currently receive federal funding (e.g., new reproductive technologies), require highly specialized expertise on the IRB and raise complex ethical issues for which there is little federal guidance. Other concerns raised by the IG Report include insufficient training for researchers and IRB members, and inadequate attention paid to evaluation of IRB effectiveness by FDA, NIH, and the IRBs themselves. Finally, the IG Report alleged conflicts of interest between IRBs and the institutions that support their activities.

NIH Study

In contrast to the IG Report, the NIH Study concluded that despite the rising volume of human subjects research, the IRB system continues to provide an adequate level of protection at a reasonable cost. Nonetheless, the study also concluded that protection of human subjects can be further improved by fine-tuning IRB procedures and providing increased education and training to researchers as well as to IRB members and staff.

The NIH Study reports on a 1995 survey of 491 IRB chairs, 300 IRB administrators, and 640 IRB members (out of nearly 500 IRBs that had "Multiple Project Assurances" approved by NIH and that reviewed more than 10 new protocols per year) and found that the volume of protocol reviews was distributed unevenly among the IRBs surveyed. Specifically, 10% of the IRBs surveyed handled over one-third of the protocols, and multicenter clinical trials comprised 30% of the protocols submitted for initial review to all IRBs. In the typical full board meeting, the time spent on each continuing review was about one-seventh of that for each initial review. Thus, among the IRBs surveyed, approximately one-third of the total protocols submitted underwent initial review, but consumed about two-thirds of the meeting time.[6] By contrast, 41% of the protocols underwent continuing review but took only 13% of the meeting time. Significantly, when asked their opinions about IRB workloads, IRB members and Chairs indicated that, in general, they considered their workload to be manageable without compromising the quality of review.

The NIH Study revealed important demographics of IRB personnel, and glimpses of IRB practices. Notably, women and minorities are significantly under-represented on IRBs, despite federal requirements for diversity of "race, gender, and cultural backgrounds."[7] IRB membership is overwhelmingly white (95% of Chairs and 92% of members) and fewer than one-quarter of those IRBs surveyed had female Chairs.8

Current IRB practices do not seem to take full advantage of opportunities to reduce their workload. Many IRBs appear to be reviewing "exempt" research and subjecting protocols eligible for expedited (one person) review to full IRB review. Indeed, IRBs chose to exempt less than half of exemptible research.9 They also fail to take advantage of available resources. The "IRB Guidebook," an NIH publication, was viewed by over 90% of Chairs surveyed as being "very useful" or "somewhat useful"; however, fewer than one-quarter of IRBs provide it routinely to IRB members, despite the absence of copyright barriers to making multiple copies.10 Finally, for the most recently completed record year, the NIH Study found that over a third of the IRBs surveyed had suspended or terminated approval of one or more protocols, primarily because of researchers' failures to obtain IRB approval before initiating a study or to adhere to an

IRB-approved protocol.

As noted in the NIH Study, the study design contains two potential limitations. The validity of the findings depends on the memories of the respondents and on the accuracy of their estimates and factual reports. Review of IRB minutes conceivably could reveal different allocations of IRB resources and time, and different estimates of workload.

Study Recommendations

Although the IG Report issues a strong warning about the current effectiveness of IRBs, its recommendations build on the existing system. The report encourages NIH and FDA to identify federal requirements that can be eliminated or modified to decrease the workload of IRBs, for example: (1) the requirement that IRBs conduct full, annual reviews of each approved protocol, which prevents them from concentrating on research involving greater risks;[11] and (2) the requirement that IRBs approve proposed research before grant applications are reviewed.

Other IG recommendations include: (1) periodic evaluations of IRB performance; (2) submission of periodic compilations and assessments of adverse-event reports to IRBs, particularly from multi-site clinical trials; (3) disclosure to IRBs of FDA actions taken against investigators under the IRBs jurisdiction; (4) disclosure to IRBs of any prior IRB review of a submitted protocol; and (5) increased IRB on-site monitoring of research. The report also advocates the enactment of federal laws to ensure adequate education of researchers and IRB members, and to insulate IRBs from apparent conflicts of interest. In addition, the report strongly urges that federal regulations require institutions to provide sufficient resources to IRBs to fulfill their responsibilities, and that indicators of minimally adequate resource levels be specified. Finally, the report suggests shifting the focus of federal oversight from technical compliance to performance indicators.

NIH Study respondents emphasized the need for improved education and training of IRB members, staff, and researchers. They also endorsed many recommendations in the literature designed to improve IRB operations. Examples include: computerizing IRB offices, splitting large IRBs into two or more smaller ones,[12] reviewing protocols only after funding decisions have been made, and extending the scope of human subjects protection to research that is conducted without federal funding or FDA oversight.

Conclusion

The IG Report and NIH Study both describe an increasing volume and complexity of research which likely will intensify burdens on IRBs. Clearly, IRBs need sufficient resources (both financial and otherwise) to handle these challenges. Funding agencies could help institutions by providing financial support for their IRB activities — perhaps as a percentage of each grant for research involving human subjects. This was suggested by the Association of American Medical Colleges ("AAMC") at recent Congressional hearings.[13] Some institutions already tax industry sponsors for IRB review. Without increased federal support, research institutions may be hard pressed to provide the training, staffing, and other resources (such as improved computer technology) necessary for IRBs to handle their increased workload without compromising protection of human subjects.

One cost-effective way to enhance training of IRB members would be to routinely distribute the IRB Guidebook, which is currently available and highly valued by IRB Chairs. In addition, (as suggested by the Health Industry Manufacturers Association), industry, government agencies and patient advocacy organizations might cooperate to explore new technologies, such as videotape and interactive software, for promoting subjects' understanding of clinical research.[14]

As both reports note, many protocols reviewed by IRBs are never funded because federal agencies require IRB approval before they will review a grant application. Changing the system to require IRB review only if a grant is awarded would greatly reduce the IRB workload.[15] (Of course, it could also increase burdens on agency review.) As noted above, IRBs' workloads would also decrease if they took full advantage of streamlining tools, such as exemptions and expedited review, which are already authorized by federal regulations. To deal with multi-center clinical trials, the Pharmaceutical Research and Manufacturers of America ("PhRMA") recommends using regional or national IRBs to decrease the number of protocols and adverse-event reports that local IRBs must process.[16] Another means of assisting IRBs in processing adverse-event reports would be for NIH and FDA to create an annual review

form that would require principal investigators to summarize the outcomes of adverse events that took place in the preceding year, as well as the current status of the research and accumulating data.

Finally, FDA and NIH could reconsider a suggestion made by the President's Commission 25 years ago, that a private accreditation body perform IRB site visits, similar to those conducted by the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO").[17] Site visits conducted by individuals with expertise in IRB policies and procedures would assist IRBs in assuring effective review, and accreditation would relieve cognizant federal agencies of the burdens of routine oversight.

In sum, the IRB system is not in jeopardy, but it does need help. Efforts to improve IRB operations should build on the strengths of the existing system and fill in any gaps that may exist. In addition, the government should provide financial support for what is, after all, a federal activity performed by local institutions.

References

1 See 45 C.F.R. Part 46, and the "Common Rule" adopted by 16 federal departments and agencies. 56 *Fed. Reg.* 28002 (June 18, 1991).

2 Department of Health and Human Services, Office of Inspector General, "Institutional Review Boards: A Time for Reform," Doc. # OEI-01-97-00193, June 1998. This report can be found on the WWW at http://www.dhhs.gov/progorg/oei/whatsnew.html.

3 Hearing on "Institutional Review Boards: A System in Jeopardy," before the Subcommittee on Human Resources, Committee on Government Reform and Oversight, U.S. House of Representatives, June 11, 1998 ("Hearing").

4 James Bell Associates, "Evaluation of NIH Implementation of Section 491 of the Public Health Service Act, Mandating a Program of Protection for Research Subjects," June 15, 1998. This report, supported by NIH contract No. NO1-OD-2-2109, can be found on the Internet at http://www.nih.gov/grants/oprr/hsp_report/hsp_final_rept.pdf.

5 See, e.g., Testimony of Robert J. Levine, Professor of Medicine, Yale University School of Medicine, and Chairperson, Institutional Review Board, Yale-New Haven Medical Center, on behalf of the Association of American Medical Colleges, supra, note 3; Testimony of Bert Spilker, Senior Vice President, Scientific and Regulatory Affairs, Pharmaceutical Research and Manufacturers of America, supra note 3.

6 See Figures 1 & 21 of NIH Study, supra note 4.

7 45 C.F.R. § 46.107(a).

8 See Figure 13 of NIH Study, supra note

9 Id. at Figures 15 & 16.

10 Id. at Figures 18 & 44.

11 As noted above, federal regulations already include provisions for exemptions or expedited (one-person) review of lower risk studies, but many IRBs do not take full advantage of these options. 45 C.F.R. §§ 46.101(b), 46.110.

12 According to Figure 14 of the NIH Report, IRBs with the highest volume of reviews average approximately twenty members per IRB. This suggests that splitting at least some IRBs would be feasible.

13 See Levine, supra note 5.

14 Statement of the Health Industry Manufacturers Association at Hearing, supra note 3.

15 See Levine, supra, note 5.

16 See Spilker, supra note 5. Readers may be interested to know that on October 27-28, 1998, Public Responsibility in Medicine and Research ("PRIM&R") will sponsor an invited workshop on "Central IRB Review in Multi-Site Trials" in Rosslyn, VA. For more information, contact Joan Rachlin at 617-423-4112 or rachlinj@aol.com.

17 See, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, "Implementing Human Research Regulations" (March 1983), pp. 114-18.

RESOURCES

Integrity in Scientific Research is a series of five video vignettes available from the Program on Scientific Freedom, Responsibility and Law at AAAS.The videos range from 8-10 minutes in length and portray realistic situations that raise ethical issues in research, making them ideal for stimulating discussion. The intended audience for the videos includes scientists, post-doctoral fellows, graduate and undergraduate students, research administrators, and technicians. A Discussion and Resource Guide accompanying the videos includes for each video an abstract of the scenario, a summary of key issues, and a set of discussion questions. A compendium of resources on the teaching of ethics and on issues of research integrity and scientific misconduct are also included. For ordering information, contact Sanyin Siang at 202.326.6792 or ssiang@aaas.org or check out WWW at http://www.aaas.org/spp/video/video.htm.

ANNOUNCEMENTS

The International Association of Bioethics, in conjunction with the Asian bioethics Association, will convene the Fourth World Congress of Bioethics, "Global bioethics: East and West, South and North." The meeting, is planned for November 4-7 in Tokyo. The Congress is open to all persons interested in any topic of bioethics; it offers a forum for interdisciplinary discussion and reflection, within a general focus on cross-cultural bioethics of the whole global biosphere. Satellite meetings will focus on cloning (November 4) and brain death (November 7). Contact Secretariat IAB4, Department of Philosophy, Nihon University, 3-25-40 Sakurajosui, Setagaya-ku Tokyo 156, Japan.

The Bioengineering Alliance of South Carolina is putting out a call for Papers for the 18th Southern Biomedical Engineering Conference and the 2nd International Conference on Ethical Issues in Biomedical Engineering. The conference will be held in Clemson, South Carolina, April 2-4, 1999. Papers are solicited on new developments in theory, concepts, applications and techniques in all facets of Biomedical Engineering. Suggested bioethics topics for presentation include codes of ethics, clinical trials, ethical concerns in medical informatics, use of animals in the testing of medical devices, and HMOs and ethical issues. Deadline for receipt of abstracts is November 2. Contact Subrata Saha, Bioengineering Alliance of South Carolina, 313 Rhodes Research Center, Clemson University, Clemson, SC 29634; (864) 656-7603 or (864) 656-5561; Fax (864) 656-4466; Email amarand@clemson.edu

The Third Annual Laurier Conference on Business and Professional Ethics, "Educating the Ethical Professional," will be held October 22-23 at the Wilfrid Laurier University in Ontario, Canada. Drawing on a number of experts across business, engineering, education, and the clergy, the conference will provide a forum for participants to learn about and discuss such questions as: Can ethical behavior be taught? What are the goals of ethical education for professionals? What methods should be used in ethics instruction? Should admission to professional practice and licensing reflect ethical concerns? Can ethical cultures be created and sustained within professions and organizations? Contact Ann Galea, Dean's Office, School of Business and Economics, Wilfrid Laurier University 75 University Avenue West, Waterloo Ontario Canada N2L 3C5; (519) 884-0710; WWW http://www.wlu.ca/~wwwsbe/

The Medical University of Warsaw is sponsoring a conference on "Scientific Misconduct: An International Perspective" on November 16 at the Medical University of Warsaw, Poland. Topics will include Responding to Allegations of Scientific Misconduct, From Case Management to Preventive Guidelines, Sociology and Psychology Within the Scope of Scientific Dishonesty. Conference proceedings will appear in Science & Engineering Ethics. Contact Andrew Gorski, Office of the Rector, The Medical University of Warsaw, 30 Filtrowa St. 02032 Warsaw, Poland; [48] 22-82-54-799; Email agorski@ikp.atm.com.pl

Public Responsibility in Medicine and Research (PRIM&R) and Tufts University School of Medicine are sponsoring PRIM&R's annual IRB meeting in San Diego on November 8-9. The two-day conference on, "IRBs in the Shifting Sands of Public Opinion" will include discussion of a number of regulatory initiatives, including the just-released reports of the Inspector General and NIH, the NIH Report on the inclusion of children in research, the NBAC reports on research with cognitively impaired persons and the implementation of the common rule to all Federal agencies, and the revision of subpart B governing research with pregnant women and fetuses. Contact PRIM&R at (617) 423-4112; Email prmr@aol.com WWW http://www.aamc.org/research/primr

The Stanford University Program in Genomics, Ethics, and Society will hold its annual conference on October 17, 1998, at Stanford University. The topic of this year's conference is "Individual Genetic Variation: Implications of the Coming Transformation of Medicine." As we understand more about the medical implications of individual genetic variations and as sequencing genes becomes less expensive, medicine and public health will be transformed. It will become possible to use information about specific genetic variations to personalize interventions. Join this day-long event featuring a number of distinguished speakers from a variety of fields, including medicine, genetics, biotechnology, ethics, law, and the humanities. The cost of the conference is $35, including lunch. Contact Laura McConnell. (650) 498-6934; Fax: (650)725-6131; Email lauramcc@stanford.edu; WWW http://www.stanford.edu/dept/scbe/indconf.htm

The National Institutes of Health will sponsor a conference on the key professional and ethical issues raised by managed care on October 30-31 at the Hyatt Regency Hotel in Washington, DC. Contact Gary Wackernah (703) 902-1264; Email bioethics@circsol.com