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## Big Basket or Mission Creep?

*by Maureen H. Fitzgerald, PhD*

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In my research on the ethical review process as culture and cultural process I regularly ask key informants in the countries involved if the ethical review process is really about ethics.[1] The most common initial response is (here I will use the answer as people in the US express it because it has come to resemble a mantra or a spouting of the "party line"): "It is about the protection of human subjects and compliance with the regulations." I ask again: "But is it about ethics?" I get two responses to this repeated query. Either the person simply repeats the statement or (sometimes after asking the question a third time) people admit that it is not really about ethics or at least it is no longer primarily about ethics. Those who provide the first response and adamantly stick to it are often people in administrative positions, in particular ethics officers, or lay members of committees.[2] The second group is more diverse and includes researchers, researcher committee members, policy makers, and, often, Chairs of committees.

Responses from key informants; observations of ethics committees in the process of deliberation; reviews of policy documents, ethics application guidelines and websites; and reviews of the literature on the ethical review process all suggest that the ethical review process has come to involve much more than attention to the ethics of a proposed research project or its potential ethical implications. Key informants in one interview in Australia used the analogy of a basket, and suggested that the responsibilities or areas of responsibilities of ethics committees have just kind of evolved over time and that it was now time to start "taking things out of the basket." Like others, what they described was a process where ethics committees have slowly taken on responsibilities or oversight of areas that either no one else seemed to be dealing with or at least they felt no one was doing so — or doing so adequately. The result is that committees in Australia and elsewhere now give much attention to such things as liability and legal issues, risk management for the institution and the researchers involved, conflict of interest issues, budget and money management, including resource allocation and redistribution, and intellectual property issues. In some committee meetings these topics seem to be the second most dominate area of the discussion of applications undergoing review (the first is information sheets and consent forms).

Those who believe these issues belong within the domain of ethics review committees present them as ethical issues. Few would deny that there are ethical issues related to all of these, but are these necessarily the domain of committees commissioned for the ethical review of research proposals? Is the ethical net being cast too wide? Was attention to such issues within the intention of the original drafters of the guidelines for committees or, as Gunsalus (2003) notes, the drafters of the Common Rule that provides the regulation foundation for research involving humans in the US?

What informants, particularly in Australia, refer to when we talk about the "Big Basket," Gunsalus (2003) and Bruner (2004) from the University of Illinois talk about as "mission creep." Gunsalus (2003, p. 1) associates mission creep with the US and the "highly publicized university-wide research 'shut downs' by federal regulators and the goal of limiting institutional liability, combined with sincere desire to assure protection of human subjects of research." We can include in this list highly publicized research "scandals," the products of the "controversy machine" (Chalmers & Pettit, 1998). The scandals and the controversy machine have also affected the mission of committees in other countries, each has had its own scandals, and all have been affected at least indirectly by the scandals and the shut downs in the US. We live in a global community, and much of what affects ethical review in one nation has a ripple effect in others, particularly when many research collaborations cut across borders, and a project must obtain ethical approval in each country involved.

Although the big basket and mission creep ideas initially appear to be describing the same phenomenon, the terms suggest slightly different things and have different implications. The big basket suggests the conscious taking on or the imposition of additional responsibilities not necessarily specifically within the domain of research ethics. One example of this in Australia is placing review of research applications in relation to the Privacy Legislation within the domain of the ethics committee. This occurred in 1989 by what was then called the Medical Research Ethics Committee (MREC), the Australian Human Ethics Committee's (AHEC) predecessor. One informant noted that this was a conscious decision and, for this informant, is "a clear example of adding something to the basket

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because at that stage the only research involved was medical research, something that the MREC believed that institutional ethics committees knew most about — and were probably right." This informant thinks this now deserves reconsideration. Most of us would agree that privacy issues can have ethical implications and ethics committees should consider these implications. The issue here is whether or not they should be considering the applications specifically in relation to the legal aspects.

In some of the committees I have observed the lawyer member has, on occasion, been asked to provide a legal opinion (albeit not binding), as opposed to an opinion about whether legal advice should be sought. According to some of my informants, the move in Britain to remove the requirement of lawyers on the committees (although they can continue to be members) is a move towards taking legal issues out of the basket.

I would suggest that risk management is another example that in some cases is mission creep and in others putting things into the basket. Several committees in Australia have developed policies that will not generally allow researchers to interview people in the respondents' homes. If the committee allows such interviews, there must be a chaperone. Apparently this policy came out of situations where some health professionals encountered difficult situations in clients' homes. However, it is unclear if it related to any specific instance where the health professional was in the role of researcher as there are multiple variants of the story underpinning these committees' decision, which has important methodological and ethical consequences.

The data suggest, however, that the committees involved in my study made a conscious decision to institute this as policy (allegedly in the guise of protecting the researcher and the research subject from "harm" or allegations of misconduct). In some cases it is explicit on the committee's website and, if they have one, their policy document. This is not a policy handed down from the national level and is not in the published national guidelines. In fact, in the institutions involved such situations would normally fit within the responsibility of the institution's risk management office or its professional code of conduct, and any problems in this area would fall within the institution's normal policies for work conducted by its staff and students.

Mission creep seems to be a more insidious process and may involve the unconscious taking on of responsibility for areas that are not specifically within the domain of research ethics. Liability, legal, and risk management issues may fall within this heading. Committees have a responsibility to raise researchers' awareness if there might be a legal, liability, or safety issue involved, but should it be within their domain to make decisions related to whether or not the research should proceed in relations to issues like data collection methods when the issue is a legal or risk management issue and not strictly or primarily an ethical issue? In fact, many of the examples in my data suggest that key informants see the committees' actions in relation to such issues as protecting the institution and, perhaps, the researcher rather than research "subjects." This, too, raises important methodological and ethical concerns, some of which have been addressed in the growing body of literature on ethics committees.

The distinction between these two descriptive concepts might seem trivial given that they have had much the same result: the expansion of the domain of ethics committees. I think the distinction is important because the implications are different, particularly if there is a decision to review the purpose and function of ethics committees. At varying levels of elaboration, this kind of review is going on in the countries in which my research is taking place.

If this expansion is the big basket phenomenon involving the conscious or imposed expansion, then the approach to change might be different than if it is the result of mission creep. It may be easier to consciously and intentionally take things out of the basket. This might involve the rewriting of guidelines or legislation (and widely publicizing the changes) and institutional reorganization where some areas are moved to other committees or departments (legal issues to the lawyers, risk management to the risk management office, scientific review and methodological critiques to domain experts), without making the process more onerous. One approach might be parallel reviews of applications by representatives of these other offices rather than sequential reviews. Or it may require better recognition and integration of policies and procedures that are already part of the institution's general and research infrastructure.

On the other hand, if it is mission creep, evoking change may be more difficult. It may be harder for committees or at least some members to "let go" of some of the issues. One reason is fear that if the committee does not address them, then no one will. If they have become convinced that these are ethical issues that belong within the domain of the committee, it will be more difficult for them to let them go. That is, if they let them go, they may feel they are "not doing their job."

So, change means dealing with the attitudes, values and beliefs of committee members, all of which, as my research demonstrates, can become deeply ingrained in a very short period of time. As others have noted, it will require clearer and more useful definitions of such core concepts as research ethics, research, audit, human subject, risk and

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harm (and to whom and how they apply) and a better understanding of the ethical issues associated with the range of research paradigms being reviewed. Most importantly, it will require a clearer articulation of the committees' areas of responsibility and what should not be within their domain. It will also require a clearer understanding of where the line is between professional ethics and research ethics, and what falls within professional ethics codes of practice, including those aspects related to research, and do not need to be specifically addressed in the ethical review of applications. For many, it will require a change in attitude towards researchers and their professional colleagues and associations from one of inherent distrust to one of trust.

Gunsalus and Bruner are just two of a growing body of writers making these points. My point is not just that these things must be addressed, but that they may need to be addressed in different ways depending on how such things have entered the system. I would also suggest that this is not an either/or situation. Both processes have been involved, but one or the other may have been more instrumental in relation to some issues. Identifying which process has been involved might lead to more effective approaches to much needed change. Being aware of them might keep us from letting them take over again in the future. As far too many writers note, the system is often the source of problems, and if these are not resolved (and soon) then we could very well end up with less ethical rather than more ethical conduct of research. We need to be aware of how the basket gets filled and how mission creep occurs so we can control them.

Change in the system needs to be part of a conscious decision making process that keeps the mission in view and under control. As McNeill (2002) notes, change needs to focus on freeing committees from the burden of excessive detail (and unnecessary kinds and amounts of work) so that ethics can be understood as, and actually become, part of a larger ethical and research enterprise. Ethical review needs to become part of an administrative structure that allows committees responsible for the review to independently deal with what is supposed to be its area of concern: the facilitation of ethically responsible research.

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[1] This project is funded by a three-year Australian Research Council (ARC) Discovery Grant (DP0343014). To date data have been collected in Australia, Canada, New Zealand, and the United States of America. Britain is to also be included in the study.

[2] The term used to refer to the ethics committee's administrative staff member/s varies across institutions and countries. Thus, I am using "ethics officer" as a generic term. As the terms used to refer to the committee or group that reviews the ethical aspects of applications also varies across institutions and countries, I use ethics committee as a generic term to refer to the committee responsible for the review of the ethical aspects of applications for research involving humans.

## IN THE NEWS

**CHANGING THE VISA PROCESS**

Twenty-five scientific, engineering, and higher-education groups representing about 95 percent of the U.S. research community released a statement May 12, 2004, urging the Departments of State and Homeland Security to "make the visa process less cumbersome and more transparent." Since this statement was originally released, other organizations have endorsed it. The statement makes six recommendations to modify the current visa application and renewal process, which has become increasingly restrictive towards foreign scientists, students, and scholars.

The groups believe that this problem needs to be addressed immediately, as approximately half of the students in scientific graduate programs come from abroad and foreign-born scientists make up a substantial portion of the high-tech workforce. By restricting foreign students, scholars and scientists entering our country, the U.S. risks losing access to the top scientific minds from around the world and the scientific leadership it enjoys.

This is not a question of balancing science and security, according to the signing organizations, but using one to enhance the other. By allowing "the brightest and best" minds from around the world to study, teach, and speak in the U.S., "a robust network of global interactions" can be made to address many issues, including the war on terrorism.

The recommendations include ideas on how to improve the processing and renewal of visa applications, such as:

- Extending the validity of Visas Mantis security clearance, which protects against sensitive technology transfer;
- Establishing a timely process by which F (international students) and J (Exchange Visitor Program for students and scholars) visas can be revalidated;
- Creating a mechanism for applicants to track the status of their pending visa;
- Revising visa reciprocity agreements with other nations to extend the validity of a visa for members of certain countries;
- Updating training for consular offices to ensure that Visas Mantis security checks are used in the most appropriate manner;
- Implementing a fee collection system for Student and Exchange Visitor Information System (SEVIS) to allow for quick, safe, and secure fee payment methods.

"Statement and Recommendations on Visa Problems Harming America's Scientific, Economic, and Security Interests" can be found at http://www.aaas.org/news/releases/2004/0512visa.shtml **RG*

**HHS PROTECTS HUMAN SUBJECTS FROM FINANCIAL CONFLICTS OF INTEREST**

Since the death of Jesse Gelsinger in 1999, the U.S. Department of Health and Human

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Services has taken a critical look at the relationship between clinical trial patients and researchers. In 2000, the agency announced five initiatives to strengthen human subject protection in clinical research. Among those initiatives was the development of guidance on financial conflicts of interest affecting research participants. In August 2003, HHS convened a conference focusing on the issue, and a draft interim guidance was distributed. The document was revised in response to comment, and on May 12th of this year, Secretary Tommy Thompson released the official guidance.

"Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Protection" is primarily intended for IRB's (Institutional Review Boards), individual investigators, and research institutions. It applies to all research conducted under regulation of the FDA or funded by HHS. However, as contested heavily by patient rights activists, "The document is nonbinding and does not change any existing regulations or requirements." It situates the obligation to manage financial interests on individual institutions rather than the federal government. Institutions are also responsible for deciding whether financial ties should be reported to research volunteers. Opponents insist that stricter and more specific rules capping compensation and requiring disclosure are critical to ensuring patient safety. Researchers have responded by arguing that universities must be flexible to cope with the unique circumstances of every study they propose. In an attempt to appease each group, HHS officials intend to examine the effectiveness of these non-binding guidelines before considering more stringent regulation in years to come.

As guidance, the report offers "points of consideration" to be reviewed by scientists and clinicians developing research programs. They include:

- What financial relationships and resulting financial interests could cause potential or actual conflicts of interest?
- At which levels should those potential or actual financial conflicts of interest be managed or eliminated?
- What procedures would be helpful, including those to collectand evaluate information regarding financial relationships related to research?
- Who should be educated regarding financial conflict of interest issues and policies?
- What entity would examine individual and/or institutional financial relationships and interests?

Responsible parties are encouraged to use these considerations in evaluating current studies as well as prospective ones. According to the document, Conflict of Interest Committees (COICs) should be set up to review the financial interests of all researchers involved in almost any study. "All who take part in research deserve the strongest possible protection," according to Secretary Tommy Thompson. Most HHS officials remain optimistic that the guidance will help researchers manage valuable research without needlessly endangering patients. **CM*

**NEW GENETICS POLICY RECOMMENDATIONS**

For its June 2004 meeting, the Secretary of Health and Human Services Advisory Committee on Genetics Health and Society (SACGHS) released four draft reports on the future of genetics policy. Addressing topics such as genetics education and training, direct-to-consumer marketing of genetic technologies, and a comprehensive vision report of the integration of genetics into health and society, the Committee is urging the Secretary of Health and Human Services to make genetics a top priority in American health care policy.

**Genetics education and training of health professionals**

Recognizing that advances in genomic knowledge have the capacity to greatly expand and improve health care, the SACGHS is stressing the importance of genetics in the education and training of health care professionals. Various surveys of federal agencies and professional organizations have revealed both a need and a desire for enhanced access to and integration of new genetic technologies into medicine. Provisions should be made that not only facilitate educational programs in human genetics, but also encourage professionals to maintain, catalog and share the genetics knowledge they acquire. The Committee wants to see adequate support for federal programs willing to offer faculty training in the implementation of application-based genetic education models, as well as possibilities for increased accreditation or licensure for professionals who take continuing education courses in human genetics.

**Direct-to-consumer marketing of genetic tests**

With more than one thousand tests for genetic disorders available now or in the process of development, the SACGHS is concerned about how these tests are marketed to the public. Since no agency currently has regulatory authority over the marketing of genetic tests, the Committee is apprehensive about advertisements that may mislead consumers or promote test sales without recommendations to seek medical or genetic consultation. Genetic tests hold great promise for patients, but their benefits may be compromised if individuals receive incorrect information regarding usage and results. The Committee wants appropriate steps taken to ensure that the marketing of genetic tests is monitored not only by the FDA, but also by the Federal Trade Commission.

*Note: The Committee determined at its June meeting that further deliberations with the Secretary need to be conducted before a resolution regarding direct-to-consumer marketing of genetic tests can be recommended. Among the issues that need to be resolved is which agency or agencies should have primary jurisdiction over the approval, marketing and distribution of genetic tests.*

**Vision report**

The SACGHS also drafted a comprehensive vision report on the integration of genetics into medicine and society that addresses the following issues:

- access to genetic technologies
- coverage and reimbursement of genetic technologies
- genetic discrimination
- genetic exceptionalism
- large population studies

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- oversight of genetic technologies
- patents and access
- pharmacogenomics
- public awareness and understanding of genetic technologies

Of these issues listed, the SACGHS identified the passage of genetic non-discrimination legislation and the creation of coverage and reimbursement plans for genetic technologies and services as being the issues of highest priority for its work in 2004.

To read the complete versions of all the SACGHS's draft reports, go to: http://www4.od.nih.gov/oba/SACGHS/meetings/June2004/SACGHSJun2004.htm **AC*

**NIH BLUE RIBBON PANEL'S RECOMMENDATIONS ON CONFLICT OF INTEREST POLICIES**

On May 5, 2004, a draft of the Report of the National Institutes of Health (NIH) Blue Ribbon Panel on Conflict of Interest Policies was released. The Panel was commissioned in early 2004 after allegations surfaced that top NIH officials were involved in external consultations that conflicted with their duties at NIH. The Panel was asked to review existing policies, rules and regulations concerning real and apparent financial conflicts of interest, and the requirements for reporting of financial interest by NIH staff, including which employees are required to make public disclosures of financial information. The Panel did not look at any specific allegations, but rather assessed the overall picture at the NIH, for which they found a complex set of rules ill understood by the people to whom they applied.

Among the 18 recommendations made by the Panel, many deal with creating more transparency about the nature and those participating in outside consultation, while still allowing scientists to accept compensation under certain approved conditions. Some recommendations include:

- Employees responsible for making decisions on grant funding will be barred from consulting with industry or academia;
- Total amount of compensation an employee receives from outside consultation may not exceed more than 50 percent of her annual salary, where no one source may contribute more than 25 percent of her annual salary;
- Compensation may not take the form of stock options, and the number of hours an employee spends in outside consulting may not exceed 400 hours per year;
- NIH scientists should be allowed to receive compensation for teaching, speaking or writing about their research in a public forum or at academic institutions and professional society meetings.

The recommendations have brought fire from the House Committee on Energy and Commerce Subcommittee on Oversight and Investigation. Several members have suggested that a total ban on compensation for external consulting may be required for NIH scientists. However, Dr. Elias Zerhouni, director of NIH, has maintained that to ban all forms of compensation hampers the competitiveness of NIH in attracting highly talented scientists.

In testimony on June 22, 2004, Dr. Zerhouni presented his proposal to address the ethics problems that have arisen since the NIH relaxed its outside consultation practices in 1995. One of the key features of this proposal is the creation of the NIH Ethics Advisory Committee (NEAC), an internal NIH committee that would provide a centralized review of all consulting arrangementswith commercial industry, awards exceeding $2500, and all requests of senior NIH officials. His proposal also includes strict guidelines on the interaction of NIH employees with private companies, and that prohibit participation on industry boards and the holding of stock in individual biotechnology or pharmaceutical companies, as currently done at the FDA. The number of positions that are required to publicly disclose financial information has increased by 93 positions, with a request by HHS to expand those requirements to another 508 positions. NIH will continue to allow certain types of outside activities, including teaching, lecturing and collaborations with private industry, under strict rules that prohibit the involvement of senior NIH leadership in industry consultation to remove conflicts of interest. This reflects Dr. Zerhouni's desire to avoid an all out ban on industry consultation, but address the conflict of interest issues that have prompted recent scrutiny.

The Panel's report can be found online at http://www.nih.gov/about/ethics_COI_panelreport.pdf **RG*

**REVISED RESEARCH MISCONDUCT PROPOSAL RELEASED**

The U.S. Department of Health and Human Services (HHS) released a revised set of regulations on research misconduct in HHS funded research and training programs for public comment in the *Federal Register* on April 16. The regulations are based on the 1989 Public Health Service (PHS) policies on the same topic, and incorporate guidelines from the National Institutes of Health and the White House Office of Science and Technology Policy.

Several of the most notable changed provisions address the definition of research misconduct, which is consistent with OSTP regulations issued in 2000.

- The regulations will cover "fabrication, falsification, or plagiarism" not only in performing research, but in reviewing research as well. Jurisdiction would be expanded to include non-HHS funded researchers if the alleged misconduct involves HHS funded research undertaken by others. The changes would increase the scope of jurisdiction under the regulations.
- Coverage would be expanded to include intramural research by government scientists in addition to extramural research.
- The proposed regulations would be limited to allegations of misconduct occurring no more than six years prior to the allegation, with some exceptions.

A major part of the proposed regulations describes in some detail the process for pursuing allegations of misconduct, several of which have raised questions for researchers in the past. They include:

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- A distinction is made between the terms "inquiry" and "investigation." An "inquiry" is defined as the process of obtaining information to determine whether a formal investigation is necessary in the situation.
- During the investigation process the complainant, or "whistleblower," will be limited to participation as a witness only. The complainant will no longer be allowed to act as a "party" in the proceedings.
- Small institutions will have the option of using an outside entity to implement the new regulations in response to allegations of misconduct.
- In the appeals process, hearings will be heard by a single Administrative Law Judge as opposed to a three-person Departmental Appeals Board panel, in order to increase efficiency of the proceedings.

The proposed regulations also stress that institutions receiving HHS funding, while required to follow the new PHS regulations, would not be prohibited from applying their own internal policies and standards in responding to allegations of research misconduct.

The proposed regulations can be found at http://ori.dhhs.gov/multimedia/acrobat/42CFRParts50and93.pdf. The deadline for comments was June 15, 2004.
**LS*

**SENATE LOOKS AT EVOLVING – AND SCARY – TACTICS OF ANIMAL RIGHTS EXTREMISTS**

In recent years, animal rights activists have adopted more aggressive and frightening methods intended to halt the use of animals in research, testing, and the food industry. These tactics include outright violence – such as bombing facilities – and harassment of individuals who are sometimes only tangentially related to professional activities involving animals.

At a May 18, 2004 hearing of the Senate Judiciary Committee, William Green, Senior Vice President and General Counsel of Chiron Corporation – a biotech company that develops vaccines and other health products – testified that not only had Chiron facilities been bombed twice, but its employees had become "victims of a sustained campaign of intimidation, harassment and extortion." Actions against employees include the theft of credit card numbers that were subsequently posted on the internet; "home visits" that involved blaring horns in the middle of the night; vandalism; disruption of social activities; and threatening and obscene phone calls. Further, the conveners of a scientific conference were warned that they would be victims of acts of violence if a Chiron employee was allowed to speak. All this because Chiron was once a customer of Huntingdon Life Sciences, a contract testing company that has been in the bulls eye of extremists for several years.

Chairman Orrin Hatch (R-UT) convened the hearing to take testimony from individuals who were victims of these attacks and to determine whether these activities have crossed the line between free expression and criminal behavior. The hearing also focused on the adequacy, or lack thereof, of current statutory law to meet these challenges and considered whether new legislation is needed.

John Lewis, Deputy Director of the Counterterrorism Division of the FBI, and McGregor Scott, U.S. Attorney for the Eastern District of California, expressed their rustration with the current Animal Enterprise Protection Act of 1992 (AEPA), which is no match for the evolving tactics of today's extreme activists. While AEPA provides penalties against those who engage in *physical* acts against animal enterprises, the statute does not address the economic damage against these enterprises by threats, coercion, and other acts of intimidation. The Department of Justice, therefore, is asking that the statute be amended to "prohibit the use of threats, vandalism, property damage, trespass, persistent and harassing communications, intimidation, or coercion in order to cause economic disruption to an animal enterprise."

Senator Hatch is expected to introduce an amendment to AEPA sometime in the future and is seeking Democratic support. Clearly, that support will not be coming from the Ranking Democratic Member, Senator Patrick Leahy (D-VT). His statement for the record questioned the seriousness of the threat posed by activists, the need for the hearing, and the possible erosion of civil liberties that might result from more rigorous law enforcement authority.
**DR*

**STUDENT BLAMES UNIVERSITY FOR FAILING TO STOP HIS OWN PLAGIARISM**

A student at the University of Kent at Canterbury has threatened to sue the University for neglecting to tell him that the plagiarizing he had continually committed in his courses was against the rules.

Michael Dunn, who was soon to graduate with an English degree, was recently found to have plagiarized, and informed he may not be able to graduate as a result. Dunn admitted he had used the Internet to plagiarize throughout his time at the University, but had never realized it was not allowed. University officials have stated that all students are informed when they enroll that plagiarism is not permitted.

If Dunn decides to sue, he wants the University to refund a portion of his student-loan debt.
**LS*

**URGENT CALLS FOR GENETIC NON-DISCRIMINATION LAWS**

With the human genome sequenced, scientists and doctors are constantly learning more about how genes influence our health. Through genetic testing, doctors hope to, and in some limited cases now can, use our genomes as tools to tailor the medications and procedures that would be best for us. At the same time that such testing is revolutionizing medicine, this increased knowledge about the ailments to which we are predisposed could be a source of valuable information to others, such as insurance companies or employers. If they have access to people's genetic test results, there is a fear that a new type of prejudice could emerge: genetic discrimination.

Scientists and doctors want to be able to use this new technology in research and for treating patients, but they also want to be able to reassure research subjects and patients that no discriminatory repercus

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sions will follow. In the UK, the Human Genetics Commission seeks a ban on genetic discrimination. The Genetic Equality Proposal, introduced to the Commission in May by Commission member and Nobel laureate Sir John Sulston, would make discrimination based on one's genetic make-up illegal.[1] Claiming this to be a matter of human rights, equivalent to race or gender discrimination, Sulston and the Commission feel that genetic discrimination has no place in society.

The most controversial application of genetic knowledge is in the insurance industry. There are people hesitant about undergoing potentially beneficial genetic tests because of the fear of losing health insurance coverage based on the test results. Currently, the UK's insurance industry is bound by a moratorium prohibiting the use of genetic information to set premiums. The moratorium expires in 2006, however, so the Commission wants to set regulations now.[2]

Among groups particularly supportive of genetic non-discrimination legislation in the US is the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS). Prohibiting genetic discrimination in the US is one of the Committee's highest priorities for 2004. Dedicated to the dissemination of genomics in health care, Committee members see genetic discrimination as one of the biggest barriers to the utilization of genetics within medicine. As SACGHS points out in a draft report to the Secretary of Health and Human Services, with so many Americans receiving their health care coverage from their employers, individuals are reluctant to have genetic tests for fear of losing not only their health insurance, but their jobs.[3] Although many states have already created genetic non-discrimination laws, the Committee is wary of the variation between states and would like to see comprehensive protection at the federal level. Congress does have this issue on the table. The Genetic Information Nondiscrimination Act of 2003 unanimously approved in the Senate would prevent health insurers and employers from using genetic information to determine eligibility, set premiums, or hire and fire employees. A similar bill was introduced in the House in 2003, but it has yet to be voted on. **AC*

[1] *The Guardian*, "Where Ignorance Is Bliss." May 18, 2004.
[2] Sample, Ian. *The Guardian,* "Ban on Genetic Bias, Says Nobel Scientist." May 15, 2004.
[3] Secretary's Advisory Committee on Genetics, Health and Society. "Toward a Vision of the Integration of Genetics in Health and Society." Genetic Discrimination Issue Brief. Draft. June 2004. http://www4.od.nih.gov/oba/SACGHS/meetings/June2004/Draft_SACGHSvisionreport.pdf

## IN THE SOCIETIES

**ETHNOGRAPHIC RESEARCH REDEFINED**

In an effort to protect clinical trial patients, the federal government has adopted a set of rules governing human research, the "Federal Policy for the Protection of Human Subjects." Through standardized use and broad acceptance, the regulations have become known as "The Common Rule." Ethnographic studies, like many other areas of research, have historically been brought under the scope of these regulations. However, that practice was challenged last year when the U.S. Office of Human Research Protections ruled that oral history of the kind collected in ethnographic studies did not constitute research as defined by the regulations. Other scholarly fields have begun to question the requirement that ethnographic projects undergo evaluation by an IRB. One society, the American Anthropological Association, has recently responded by developing an official statement on Ethnography and IRBs.

The statement, released on June 4, 2004, is intended to be an educational document defining ethnographic methods, assessing the risks and benefits of ethnographic research, and emphasizing the importance of protecting study participants. It begins by stressing that the process of weighing risks with benefits should involve several parties. Participation from the researcher, study participants, and all other stakeholders is necessary to ensure responsible conduct.

The AAA document provides an explanation of ethnographic research, in which the long-term nature of the research, researcher emersion, and subject trust are critical to effective studies. In reference to IRBs, the guidance stresses that ethnographic research is still subject to the "Common Rule." According to the statement, every project should be reviewed on a case-by-case basis by some outside party. The document does, however, denote several instances in which projects may be completely exempt from IRB review.

The AAA statement also provides guidelines for risk assessment and informed consent, noting that careful consideration of cultural and social environments is critical for assessing all studies. For example, investigators conducting research within largely illiterate populations may need to ratify means other than written informed consent. Researchers studying persons engaged in illegal activity may also have special considerations of subject risk not prevalent in other forms of research. Taking careful note of such concerns, the new statement attempts to disentangle ethnographic research from traditional biomedical research, while still emphasizing the vital importance of IRBs. **CM*

## ANNOUNCEMENTS

**Town Hall Meetings** – The **Genetics and Public Policy Center** is sponsoring a series of Genetic Town Halls in six cities across the country: Sacramento (June 29), Seattle (July 1), Kalamazoo (July 19), Fort Worth (July 31), New York City (August 2), and Nashville (August 4). Each meeting is free and open to the public, and will focus on reproductive genetic technologies. More information is available at http://www.dnapolicy.org.

**Call for Papers** – The ***Journal of International Technology and Information Management*** is accepting papers for a special issue on ethical issues of international and intercultural information management. The first submission deadline is July 1, 2004. Publication is expected in December 2004/January 2005. More information is available at http://www.iima.org.

**Conference** – The **Australian Association for Professional and Applied Ethics** and is holding its 11th annual conference from September 29-October 1, 2004 in Richmond, New South Wales, Australia. More information about the conference is available at http://www.arts.unsw.edu.au/aapae/.

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# Professional Ethics Report

Scientific Freedom, Responsibility and Law Program
American Association for the Advancement of Science
1200 New York Avenue, NW, Washington, DC 20005

(**Announcements** continued from page 7)

**Funding opportunities** – The next deadline for the **National Science Foundation's** societal dimensions program is August 1, 2004. The program is designed for researchers studying the interactions of engineering, science, technology and society. More information is located at http://www.nsf.gov/sbe/ses/sdest. Also, applications for the Faculty Early Career Development (CAREER) Program are being accepted until July 22, 2004. The program recognizes and supports the development of teachers/scholars interested in ethics, values or policy aspects of engineering, science, technology and society at the beginning of their careers. Information on applications and qualifications for the CAREER is located at http://www.nsf.gov/career.

**Conference** – On October 8-10, 2004, the **Center for Academic Integrity** will hold its International Conference, "Academic Integrity, Moral Development, and Demands of Citizenship." Session proposals are being accepted through July 15, 2004. Possible topics include cheating and technology, campus partnerships that promote integrity, and academic integrity and the law, among others. For more information, visit http://www.academicintegrity.org/2004_Conference/program_calls.asp.

**Call for Papers** – The **Society for Ethics Across the Curriculum** is hosting its sixth International Conference on "Ethics Across the Curriculum" at Oregon State University, Corvallis, Oregon, October 14-16, 2004. The overarching theme is "Ethics and Organizations." Submissions should be sent to Dr. Stephen Scales, Department of Philosophy & Religious Studies, Towson University, 8000 York Road, Towson, MD 21252, sscales@towson.edu. The deadline is August 9, 2004.

**Pilot Project** -- The **Council of Graduate Schools** has received a contract from the Office of Research Integrity to engage its member institutions in collaborative research project into the responsible conduct of research in behavioral and biomedical sciences. Ten institutions will receive $15,000 to generate and test innovative interventions and assessment strategies for promoting responsible research conduct. Applications for the award are due August 20, 2004. For more information, contact Paul Tate, ptate@cgs.nche.edu.

**Call for Papers** – The ***Journal of Information, Communication and Ethics in Society (ICES)***, an interdisciplinary publication focusing on the impacts of new media and communication technologies on society, organizations, individuals and the environment has issued a call for papers. More information about submission guidelines is located at http://www.troubador.co.uk/ices/submissions.asp.

**Conference video** – The Medical College of Wisconsin has released the entire 25th Anniversary of the Belmont Report Symposium on DVD/Video and online. The symposium was held on May 14, 2004. For more information, visit http://www.mcw.edu/belmont.

**Call for Papers** – ***IEEE Technology and Society*** is inviting submissions for the coming year on the ethical, social and policy implications of such topics as biomedical engineering, homeland security, nuclear weapons proliferation and robotics, among others. More information is available at http://www.njcc.com/~techsoc/.

**New Research Center** — Duke University's Fuqua School of Business (in collaboration with the Duke Athletics Department, and Kenan Institute for Ethics at Duke University) has established the **Fuqua/Coach K Center of Leadership & Ethics (COLE)** to advance the fields of leadership and ethics through research and education. As a global think tank, COLE will convene leading scholars and corporate leaders world-wide to advance key leadership and ethics issues. COLE will also develop new leadership and ethics-related resources for Fuqua's MBA and executive students. For more information, visit www.leadershipandethics.org.

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American Anthropological Association
American Association of University Professors
American Political Science Association
American Psychological Association
American Psychological Society
American Society for Engineering Education
American Sociological Association
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