

PROFESSIONAL ETHICS REPORT

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Cover Story

Fostering Research on Research Integrity

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2001 marks an anniversary for research integrity. Twenty years ago, on March 31, 1981, Congress opened the first of a number of investigations into misconduct in research in response to reports of several episodes of what appeared to be egregiously improper research conduct. In the years following the first hearings on *Fraud in Biomedical Research*, dozens of meetings and reports as well as several thousand publications, both popular and scholarly, have grappled with the problem of misconduct in research. During this time, however, surprisingly little research has been done on the central topic under discussion—research integrity.

In an effort to improve our understanding about research integrity issues, the Office of Research Integrity (ORI), Department of Health and Human Service (DHHS), has recently launched two new RRI (research on research integrity) initiatives. The first supported a research conference on research integrity, held in Bethesda, MD. The second will fund new research on research integrity, with the first awards being announced on the ORI website (<http://ori.dhhs.gov>) in July 2001. Together, these initiatives have two primary goals. First, they are conscious efforts to encourage the development of an RI research community. Second, they are part of a broader effort to provide a firmer evidentiary base for understanding research integrity issues and their potential impact on research institutions, the community of scientists, federal agencies, and the general public.

1. *Research on Research Integrity*. Professional societies and universities have published numerous handbooks, codes, guidelines and policies outlining the ideal standards researchers should seek to attain. There is, in addition, widespread agreement that some research behaviors, generally defined as "falsification, fabrication, and plagiarism" or FFP, constitute misconduct. In combination, the ideal standards and the behaviors identified in misconduct policies establish limits for "good" and "bad" behavior in research. They delineate what researchers *should* and *should not* do. They do little, however, to bring practical meaning to the term "research integrity" since most researchers do not work at the extremes, either good or bad.

As a professional activity, research must have standards that define responsible behavior. Is simply avoiding misconduct all that is required to be a responsible researcher? Or must someone meet every ideal for responsible conduct in order to have integrity? Where on the spectrum between the ideal and forbidden should research behavior be located to qualify as having integrity? And, most importantly, where on the research integrity spectrum (fig. 1) do current research practices fall? Answers to questions such as these are vitally important to providing a sound evidentiary base for responding to research integrity concerns and identifying ways to foster the adoption of high standards and to discourage misconduct in federally supported research.



Fig. 1. Research Integrity Spectrum

That most research behaviors fall between the poles of the research integrity spectrum is becoming more and more evident as the research literature on research integrity grows (see the background document for the November 2000 conference for a summary of this literature: <http://ori.dhhs.gov/html/news/researchconf.asp>) While there is still no evidence to suggest that behaviors that fall under the official definition of "research misconduct" are widespread, there is growing evidence that they may not be as "rare" as sometimes claimed. Surveys of researchers' knowledge of research misconduct and data audits consistently report significant problems at rates approaching or perhaps exceeding .1% or even 1%. If one adds to these findings studies that suggest that many researchers do not report misconduct when they become aware of it, it is clear that confirmed cases of misconduct in research do not equal actual cases. Just how serious the under-reporting is remains to be determined.

Equally as important is the growing body of evidence on research practices that do not meet federal or local definitions of research misconduct but that nonetheless fall short of the ideal standards for good research practices set by the research community. This work is beginning to provide hard evidence to support what most researchers already instinctively know, namely that research is subject to the same ethical corner-cutting as any other human activity. Some researchers do inappropriately put their names on research papers, publish data in different places without proper referencing, fail to disclose conflicts of interest, let personal biases interfere with peer review, fail to report negative findings or adverse events in human experimentation, and neglect supervisory or mentoring responsibilities. However, simply confirming that research is a human activity is not sufficient. To provide a scientific basis to permit institutions, scientists, and others to establish sensible policies and develop effective education programs, one needs to know not only that "questionable research practices" exist, but also to learn about their extent and impact. This is one expected outcome of ORI's RRI agenda.

2. *ORI Research Conference on Research Integrity.* As a logical first step toward building an RRI community and fostering research, ORI convened a Research Conference on Research Integrity in Bethesda, MD on November 18-20, 2000. The Conference was co-sponsored by the American Association for the Advancement of Science, the Association of American Medical Colleges, the National Institutes of Health, and the National Science Foundation. A call for papers issued in January 2000 drew an unexpectedly strong response, with 85 proposals for plenary, concurrent, and poster presentations ultimately being accepted for the day-and-a-half conference. Sessions included:

- Emerging issues
- Research practices and ideals
- Conflict of Interest
- Integrity and biomedical ethics
- Social science and methodological perspectives
- Institutions and professional societies
- Publication practices
- Tools for measuring research integrity
- International concerns
- Research ethics training

Roughly half of the presentations were subsequently expanded into papers, which will be published in the conference proceedings, *Investigating Research Integrity: Proceedings of the First ORI Research Conference on Research Integrity*. A preprint version of the proceedings will be available on the web in August 2001. When published, the web version can be found on the ORI webpage: <http://ori.dhhs.gov/html/publications/conference.asp>.

Plans are currently underway to hold a second RRI Conference in the Washington D.C. area in November 2002. It is hoped that the second RRI conference will build on work discussed during the first Conference, explore new approaches to learning about research practices, and have stronger international representation. Long term, this effort to build a research community and define key research questions should become a self-sustaining effort that will still depend on the government, private organizations, and professional societies for support but gain its inspiration and direction from the scholars engaged in this crucial field of research.

3. *Research on Research Integrity Grant Program.* New fields of research need to be nurtured, particularly if the benefits of the research are not immediately apparent. In an effort to gather the information it needs to understand research integrity issues and their impact on the scientific community, ORI requested and received approval to spend \$1M annually (\$500k for the first year) to support RRI, beginning with the 2001 budget year. With strong administrative support and intellectual commitment from the National Institutes of Neurological Diseases and Stroke (NINDS), NIH, the new grant program was officially announced on August 14, 2000, with the due date for applications set for December 15, 2000, less than a month after the ORI's Research Conference on Research Integrity.

Engaging in research in a new field requires a considerable effort and some chance taking on the part of researchers. For RRI, there are some unique intellectual and methodological challenges as well. The RRI RFA provides a practical working definition for "research integrity":

For the purposes of this RFA, "research" is defined broadly to include societal, institutional and individual aspects of the enterprise. "Integrity" is understood as "adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms."

The goal of the program as set out in the most recent RFA (2002) is:

to foster empirical research on the institutions, processes, and values that affect integrity in research. The sponsoring agencies are particularly interested in studies that will inform policy making at DHHS, NIH, and research institutions, with the goal of fostering appropriate attention to integrity in publicly funded research programs.

The challenge researchers face is developing proposals that are methodologically sound, practical, and mindful of the unique characteristics of different fields of research. Meeting this challenge requires interdisciplinary research that is sensitive to the unique demands of physical or biological science, social science, and humanities research.

The 25 proposals submitted for the first round of funding far exceeded initial expectations. The \$100k/year cap for proposals (direct costs) means that current funds are only sufficient to support three to five projects, yielding a 20% success rate at best. Moreover, \$100k/year also appears to be a bare minimum budget figure for some of the work that was supposed, much of which relied on survey research. Therefore, as the RRI grant program heads into round two, with the application deadline set for November 19, 2001 (<http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-02-005.html>), efforts are underway to identify co-sponsors who are willing to fund RRI that is relevant to particular fields of interest. Initial reports on the first round grants will be presented at the 2002 ORI RRI Conference. Details will be announced here and on the ORI website.

In the News

Proposed Congressional Legislation to Prohibit Human Cloning

The 107th Congress is witnessing a new wave of proposed cloning legislation in response to announcements by a group of international fertility specialists and members of a Canadian religious cult that each intend to clone a human by the end of the year. Legislators introducing bills cite an array of moral and ethical concerns regarding the groups' announcements, as well as practical concerns about legal issues and the safety of the current state of somatic cell nuclear transfer cloning technology.

Seven bills reflecting these concerns have been submitted that would place limitations on human cloning. The least restrictive bill, Rep. Cliff Stearns' Human Cloning Research Prohibition Act (HR 1372), would prohibit federal funding for research on human somatic cell nuclear transfer techniques and urge other nations to follow suit with similar legislation. The bill also calls for a National Research Council study to review the impact of restricting funding and make recommendations for future legislation in a report that would be submitted within five years of the signing of the bill. Stearns' legislation would not affect human cloning conducted with private funds, but would prevent recipients of federal funding from working with the products of human cloning acquired from other sources.

None of the proposed bills would restrict the cloning of fragments of human DNA or cloning to produce non-embryonic human cells. However, each of the other six bills would criminalize aspects of the cloning of human embryos. House and Senate versions of bills sponsored by Rep. Dave Weldon and Sen. Sam Brownback (HR 1644 and S 790, respectively) would ban the use of human somatic cell nuclear transfers for any reason and prohibit the importation or shipping of the products of such human cloning techniques. Violators would face up to ten years in prison, as well as a minimum one million dollar fine for violations committed in pursuit of pecuniary gain. Additionally, the bill includes language encouraging other nations to pass similar legislation, and calls for a report to be given by the National Bioethics Advisory Commission within five years on whether there may be medical justifications for some human embryonic cloning.

Rep. Vernon Ehlers has introduced a similar bill (HR 1608) which would prohibit human somatic cell nuclear transfer procedures, but would make an exception for cases in which modifications are made prior to nuclear transfer which prevent the creation of an embryo capable of full fetal development. Violations would be punishable by a fine and up to two years in prison.

Sen. Ben Nighthorse Campbell and Rep. Brian Kerns have submitted more permissive bills, which would allow the cloning of human embryos for research and medical purposes. Campbell's bill (S 704) would make only human cloning for reproductive purposes illegal, but would prohibit embryo splitting for this purpose in addition to nuclear transfer. Kern's bill (HR 1260) would prohibit only human somatic cell nuclear transfer techniques for the purpose of reproduction. Campbell's bill provides for a ten million dollar fine, up to 10 years in prison, and automatic ineligibility to receive federal funds for 15 years for violators, whereas Kerns' bill provides for a much smaller fine and up to five years in prison for violators.

The bill submitted by Rep. James Greenwood (HR 2172) would also allow the cloning of human embryos for non-reproductive purposes. Greenwood's bill proposes to ban only human somatic cell nuclear transfers for the purpose of initiating a pregnancy and the transportation of the cellular products of human somatic cell

nuclear transfer technologies to knowingly facilitate the initiation of a pregnancy. The penalty for violations would be up to 10 years imprisonment and a fine of no more than one million dollars or twice the amount of any financial gain resulting from the violation. The bill would also require that all parties using human somatic cell nuclear transfer techniques register with the Secretary of Health and Human Services. Finally, Rep. Greenwood's bill calls for a study to be conducted to evaluate the clinical prospects of human stem cells, which could potentially be derived from the cloning of human embryos. The bill is unique among cloning bills before Congress in that ten years after the bill's enactment, the restrictions it would put in place would expire.

It is difficult to predict the probability that any of the bills will make it beyond committee review. Common sentiment is that of the bills currently under consideration, the Weldon-Brownback bill, which has been endorsed by the President, and the Greenwood bill, which is backed by the Biotechnology Industry Organization, are the primary contenders for passage. A similar wave of anti-cloning bills in 1998 failed to result in the enactment of any legislation. *BJK

Huntingdon Life Sciences Fights Back

Huntingdon Life Sciences (HLS), a leading research contractor in the UK that conducts studies for pharmaceutical, biotechnology and chemical industries, has been the target of an aggressive 18 month campaign by the animal-rights group SHAC ("Stop Huntingdon Animal Cruelty") to halt the use of animal testing. To date, SHAC activities have included demonstrations, email and website disruption, abusive phone calls, destruction of property, stealing of lab animals, distribution of propaganda, and protests against stakeholders from financial institutions to customers and suppliers. Violent acts attributed to SHAC have included physical attacks on the Director of Marketing and Communications for HLS and its Managing Director, who suffered a head wound and arm injuries when assaulted by a group of masked individuals wielding baseball bats outside his home. Three men have been arrested in the UK on suspicion of the latter assault.

The successes of this targeted campaign are undeniable. HLS nearly shut down in January when the Royal Bank of Scotland pulled its financial support after repeated demonstrations against them. Charles Schwab stopped dealing in Huntingdon shares after a number of employees were personally threatened and harassed by protesters, and HLS stock has plummeted since 1999.

HLS, however, insists it will not bow to intimidation and has made progress in fighting back. A lawsuit has been filed by HLS's U.S. subsidiary and one of its major shareholders that seeks injunctive relief from violence and intimidation and an award for monetary damages for "losses incurred as a result of the defendants' unlawful conduct." In the wake of the SHAC campaign, other organizations with a stake in animal research have begun preventative measures. A recent issue of *Nature* (411, 7; 2001) cites an example by the Association of Medical Research Charities (AMRC), which moved its bank account out of one of the world's largest banking and financial organizations, London-based HSBC. Apparently the bank failed to assure AMRC that it would not give in to campaigns of animal rights groups by abandoning investments in animal research. Similar actions have been threatened or taken by organizations such as the Association of the British Pharmaceutical Industry (ABPI), the BioIndustry Association (an umbrella group for UK charities including Cancer Research and the British Heart Foundation), and Seriously Ill for Medical Research.

With regard to the charges made against HLS by SHAC, in 1997 an undercover researcher did film HLS lab staff engaged in mistreatment of animals, including punching an uncooperative beagle. Two employees were subsequently convicted of animal cruelty, and HLS was required to institute a 16-point improvement program for renewal of their license to work with animals. *AC

Moratorium on the Use of Genetic Test Results

On May 1, UK's Human Genetics Commission (HGC) recommended an immediate moratorium on the use of genetic tests by insurance companies. Currently, the UK Government permits life insurers to use the results

of genetic tests for Huntington's disease, and is considering the use of genetic test results for early onset Alzheimer's disease, in setting premiums (see *PER*, Volume XIII, No, 4 or <http://www.aaas.org/spp/sfrl/per/per23.htm#Genetic>). According to HGC, the moratorium is based on the importance of establishing a "clear and defensible regulatory system" that "not only balances the interests of insurers, insured persons, and the broader community but also enjoys the confidence of the public."

HGC has been reviewing the wider social and ethical implications of the use of genetic information in insurance and made its recommendations based on four conclusions: 1) the existing system of self-regulation has failed; 2) there is much disagreement and uncertainty about the interpretation of many genetic tests; 3) there needs to be effective regulation of this area; and 4) public trust in genetic testing is essential. HGC recommends several features that the moratorium should include. For example, it should last for a period not less than three years; not affect the current ability of insurance companies to take into account favorable results of any genetic test results that the applicant has chosen to disclose; and no insurance company should require disclosure of adverse results of any genetic tests, or use such results in determining the availability or terms of all classes of insurance.

Current debate in the UK on the use of genetic information in insurance stems from reports of the House of Commons' Science and Technology Committee (STC) and the Human Genetics Advisory Committee (HGAC) in 1997. HGAC, the commission that preceded HGC, suggested a two-year moratorium on the insurance industry's practice of including genetic test results into decisions on whether to provide insurance coverage. This recommendation was not accepted, but a voluntary system of regulation was put forward by the Association of British Insurers (ABI), which published a Code of Conduct to be observed by all members of the Association, and the Government formed the Genetics and Insurance Committee.

In evaluating the current system of self-regulation, STC found that insurance companies have been testing for conditions such as breast or ovarian cancer and gave the results "a predictive significance that cannot at present be justified." The Committee further concluded that insurers were "more interested in establishing their future rights to the use of genetic test results in assessing premiums, than in whether or not they are reliable or accurate." HGC is currently convinced that there is no satisfactory means of monitoring and enforcing the code, hence the moratorium.

Alan Milburn, Health Secretary in Tony Blair's cabinet, said he would support a moratorium to make sure that "citizens can choose to take genetic tests free from the fear that should they test positive they will face an enormous bill for insurance or treatment." (T. Reid, "Britain Moves to Ban Insurance Tests," *The Washington Post*, April 30, 2001; Pg. A11.)

Several European countries, including Austria, Belgium, Denmark, France, Norway and the Netherlands, have either banned genetic tests or put a moratorium on their use. A number of US states have banned or limited genetic testing by insurance companies, and federal legislation is under consideration by Congress.

For more information on HGC and their recommendations, see <http://www.hgc.gov.uk> *RJG

AAUP Releases Recommendation: Professors Should Assume Central Role in Creating Academic Conflict-of-Interest Policy

The American Association of University Professors released a list of recommendations in the May/June issue of the AAUP publication *Academe* to address the growing need for policy to prevent conflicts-of-interest in academic research. The prevalence of funding from corporations, currently the fastest growing source of funding for research on university campuses, is causing concern that research integrity could be compromised by commercial interests. To limit corporate interference with the publication of research findings and industrial pressures that could inappropriately influence the direction and outcome of research, the AAUP has urged university faculty to play an active part in formulating and implementing conflict-of-interest policies. The recommendations, approved by the AAUP's Committee A on Academic Freedom and Tenure and included in the "Statement on Corporate Funding of Academic Research," are listed below (the full report can be viewed at <http://www.aaup.org/repcorf.htm>).

1. Consistent with principles of sound academic governance, the faculty should have a major role not only in formulating the institution's policy with respect to research undertaken in collaboration with

industry, but also in developing the institution's plan for assessing the effectiveness of the policy. The policy and the plan should be distributed regularly to all faculty, who should inform students and staff members associated with them of their contents.

2. The faculty should work to ensure that the university's plan for monitoring the institution's conflict-of-interest policy is consistent with principles of academic freedom. There should be emphasis on ensuring that the source and purpose of all corporate-funded research contracts can be publicly disclosed. Such contracts should explicitly provide for the open communication of research results, not subject to the sponsor's permission for publication.
3. The faculty should call for, and participate in, the periodic review of the impact of industrially sponsored research on the education of students, and on the recruitment and evaluation of researchers (whether or not they hold regular faculty appointments) and postdoctoral fellows.
4. The faculty should insist that regular procedures be in place to deal with alleged violations by an individual of the university's conflict-of-interest policy. Should disciplinary action be contemplated, it is essential that safeguards of academic due process be respected.
5. Because research relationships with industry are not static, the faculty, in order to ensure that the assessment of conflict-of-interest policies is responsive to changing needs, should regularly review the policies themselves as well as the instruments for conducting the assessment. *BJK

Researchers File Suit for Academic Freedom

In June, a computer science group brought the first legal challenge to the Digital Millennium Copyright Act's (DMCA) criminal provisions by filing a lawsuit against the Recording Industry Association of America (RIAA) and the U.S. Department of Justice (DOJ).

The suit is the latest development in the two months tangle between the recording industry and a team of researchers led by Princeton professor Edward Felten. In April, the latter had developed an approach to breaking digital watermarks as part of a contest sponsored by the Secure Digital Music Initiative (SDMI). The challenge was to "strip" music files coded with digital watermarks. However, instead of accepting the prize money, an action that would prevent the group from publicizing the results, it decided to publish its findings at a major conference. Soon after, the researchers received a letter from the SDMI threatening legal action.

The industry based its argument on the DMCA. A criminal section of the Act prohibits distribution of any technology that "is primarily designed or produced for the purpose of circumventing a technological measure" and the "intentional removal or alteration of copyright management information" such as watermarks. It argued that without the DMCA, piracy will thrive online and the recording artists will no longer be compensated.

The letter stopped Felten's group from presenting the paper at the conference. Although the recording industry followed with a statement that it "does not - nor did it ever - intend to bring any legal action against Prof. Felten or his co-authors," Felten and his group felt that RIAA had threatened the scientific process. They cited the research and publication process as fundamental to scientific progress and academic freedom and alleged that the recording industry's interpretation of the DMCA would stymie scientific progress. Felten and his team then decided to present the paper at the Usenix Association's 10th security symposium in August. Rather than negotiating with the industry groups, they filed suit.

The lawsuit, filed in a New Jersey federal district court, sought immunity for the researchers from prosecution under the DMCA when they present their findings. The researchers also asked the court to prevent enforcement of the provision against researchers by the DOJ. The suit names the RIAA, the SDMI, Attorney General John Ashcroft and the watermarking company Verance as defendants. *SS

Database to List Industry-Funded Researchers

In an effort to lift the "veil of secrecy" that surrounds the corporate funding of research, the Washington D.C. based Center for Science in the Public Interest has created a searchable database listing scientists and non-profit organizations that conduct industry sponsored research. The site can be viewed at <http://integrityinscience.org> and currently lists over 1000 scientists. Information for the site was compiled from a variety of sources, including résumés, scholarly publications, and corporate and university web sites. Plans to expand the database to make it more complete include the filing of Freedom of Information Act requests with universities and government agencies.

The stated purpose of the database is to serve as a resource for "journalists, activists, policymakers, and the public" to contextualize and provide better understanding of statements made by scientists and organizations. Information provided on the database web site stresses that the receipt of corporate funding by no means indicates impropriety, but that "the public interest is best served by the free flow of information."

Concern over the database, however, has been inspired more by the information that the site does not include than by the information it discloses. Scientists listed in the database have stressed the importance of the context in which funding is received in determining whether industry is likely to have inappropriately influenced research. Some worry that the list format, which provides no information about the particulars of funding, will prompt automatic assumptions of wrongdoing, even though most industry-funded research is conducted appropriately. The Center for Science in the Public Interest explains that the database is intended to serve as a starting point for those investigating industry's ties to research, rather than a final word on the presence or absence of bias or impropriety. The simple list of researchers, projects, and sponsors provided by the database makes no distinctions with respect to the appropriateness of funding, leaving users of the database to draw their own conclusions. *BJK

NBAC Issues Report on International Research

On April 30, the National Bioethics Advisory Commission (<http://www.bioethics.gov>) published its fifth report, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*. The report examines the appropriateness of existing U.S. regulations in conducting clinical trials abroad and recommends ethical requirements for ensuring that the participants of these studies are adequately protected. The report is in response to increasing interest in research ethics, the increasing number of clinical trials conducted by US companies in developing countries, and the growing number international collaborations between researchers in the U.S. and those from host countries.

The report contains 23 recommendations that address research design, ethics review, and post-trial access to research products by the participants and members of the host country at large. First and foremost among the recommendations is the limitation of the number of trials to those studies that are responsive to the health needs of the host country. Consequently, researchers should consult with the community and involve representatives from the potential participant population in the research design and implementation process.

NBAC also recommends that researchers and sponsors make "reasonable good faith efforts before the initiation of a trial to secure continued access for all participants to proven effective experimental intervention for the study population." Furthermore, proposals submitted for review by an ethics committee should account for how any drugs proven to be effective from the trial will become accessible by the host country population at large. Another recommendation advises that researchers consult with community representatives to develop ways to ensure participant understanding of the information in the consent process.

The report elicited responses from patient health advocates, who consider some of the recommendations inadequate. Among the latter is health-care watchdog group, Public Citizen (<http://www.citizen.org>), based in Washington, DC. The group found the ethical standards set forth in the NBAC recommendations to be lower than those expressed in the World Medical Association's Declaration of Helsinki, thereby leading to potential loopholes for exploitation. In particular, it contends that the recommendations will allow researchers to bypass the "best current" therapy standard by providing therapies that are locally available for patients during clinical trials. It also raises issue with the lack of guarantee that interventions proven effective in the course of the trial will become available to the host country. The group also raises issue with the recommendation that allows for only one review by the host country, as opposed to requiring US review as well, if the human subject protection system in the former is determined to be adequate by the U.S. Office of Human Research

Protections. * SS

German Bioethics Council Created Amid Controversy

In a controversial move, German Chancellor Gerhard Schröder launched a national bioethics council in Munich on May 2 to advise the government on issues that are currently fueling a heated nationwide debate. The 23 council members, who represent ecclesiastical, scientific, legal, and industrial areas of expertise, are expected to address such issues as stem cell research, cloning, pre-implantation embryonic genetic diagnosis, and embryo protection.

Many in the German Parliament have voiced opposition to the council, noting that Germany already has two advisory bodies that report on issues pertaining to bioethics: the Health Ministry's Ethics Council and the Parliamentary Commission on the Law and Ethics of Modern Medicine. Some have speculated that the new council, which is not expected to make any recommendations until after next year's general election, was created to postpone meaningful action on issues that have divided Schröder's Social Democratic party.

Foremost among these issues is the German Embryo Protection Act of 1990, which bans all testing and research on human embryos that is not directly beneficial to the embryo. Deutsche Forschungsgemeinschaft (DFG), Germany's primary research funding institution, has led opposition to the law, and has found a sympathetic ear in Chancellor Schröder. Schröder has cautiously expressed openness to the prospect of making the law less prohibitive, citing potential medical advances and the economic benefits of a thriving biotech industry.

Support for the law is led by German President Johannes Rau, a fellow member of Schröder's Social Democratic party. The German President serves a largely ceremonial role, but has considerable public influence on issues pertaining to morality. Rau has vehemently criticized Schröder's pragmatic approach to embryo research, accusing the Chancellor of willingness to sacrifice human dignity for the sake of economics. Rau warned that failing to protect human embryos amounts to distinguishing between human life which is worthy of living and human life which is not, an assertion that has inspired strong emotions in a nation haunted by its 20th century history.

Amidst the political controversy created by its inception and a public debate fueled by intimate familiarity with the consequences of a failed bioethics policy, the newly formed German bioethics council will face the daunting task of making recommendations that will have a potentially profound impact on the future of biotechnology and medical research in Germany. *BJK

In the Societies

PSEG Hosts Meeting on Animals in Research

Scientists who use animals are now encountering a growing number of challenges, including an uncertain funding future, a burdensome regulatory environment, and rising ethical concerns. To examine the topic, the AAAS Professional Society Ethics Group hosted a meeting on May 21, 2001. Speakers addressed the changing direction of biomedical research and its impact on animal research, practical problems encountered by research institutions in the field, and oversight mechanisms. The meeting featured presentations by J.R. Haywood, Department of Pharmacology, University of Texas Health Science Center at San Antonio; Barbara Rich, Executive Vice President, National Association for Biomedical Research (NABR); and Kathryn Bayne, Associate Director, Association for the Assessment and Accreditation of Laboratory Animal Research, International (AAALAC).

Haywood's presentation examined the shifting focus of biomedical research in the past few years to molecular biology, genomics, and proteomics, noting the shift as a cause of the changing landscape of animal research. As the focus of research shifts away from whole animal studies and organ and tissue studies, fewer students understand "the big picture," or the context in which genes and proteins function. Inevitably, research will require returning to the study the whole animal as an integrated biological system. Hence, another shift is now occurring to move the knowledge gained from molecular genetics into the animal laboratory. Haywood also dispelled some common myths regarding the use of animals in research, asserting that good science leads to good animal care, oversight in animal research is extensive, and alternative approaches are often supplementary but cannot replace studies of living organisms.

Rich spoke about the pending regulations for animal care and their impact on research institutions. Currently, the U.S. Department of Agriculture (USDA), which has oversight responsibility for laboratory animals, is

considering modifying the system it uses to classify pain and distress in animals, as well as creating a new definition for the word "distress."

There is also consideration of a change in policy to include rats, mice and birds in the Animal Welfare Act (AWA) regulations. Precipitating this change are actions taken by the animal rights movement. Animal rights activists have influenced the legal and regulatory landscape as well as the biotechnology industry and public attitudes toward research. They work to make research more cumbersome and difficult by promoting measures that will increase costs and add regulatory burdens. Because the goal of some animal rights organizations is not only to reduce, refine or replace animals, but to end all animal research, scientists and their societies and institutions find that constructive dialogue and compromise are difficult, if not impossible. Rich suggested looking to the United Kingdom as a harbinger of animal rights activism to come. Despite having the strictest laws and regulations governing animal research in the world, the UK still faces extreme harassment and violence from the animal rights community, illustrating her point that the animal rights movement will not be satisfied with "tougher" rules.

Bayne's presentation focused on oversight mechanisms, citing as an example, AAALAC, International, which has a voluntary accreditation service that focuses on peer review and conducts site visits every three years. AAALAC monitors public and private institutions and advises laboratories on correcting deficiencies. Its membership includes scientific and medical societies, and educational organizations such as AAAS. Other ethical guidelines of note are those adopted by the National Aeronautics and Space Administration (NASA), including respect for life, societal benefit, and nonmaleficence, and the American Psychological Association's Guidelines for Ethical Conduct in the Care and Use of Animals. Bayne also stressed the importance of self-monitoring in animal care, encompassing the principles of trust and vigilance, as well as the need for sufficient resources. A good example of such a resource is the *Guide for the Care and Use of Laboratory Animals*, the accepted primary reference on animal care and use, provided by the Office of Laboratory Animal Welfare, Office of Extramural Research, National Institutes of Health. *MH

Announcements

Research Grants-The Office of Research Integrity (ORI, DHHS), the National Institute of Neurological Disorders and Stroke and the National Institute of Nursing Research invite applications to support research on research integrity. "Integrity" in this context is understood as "adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms." The proposed grant program is intended to foster empirical research on the institutions, processes and values that influence integrity in research. The grant application deadline is November 19, 2001. The ORI intends to commit approximately \$500,000 in FY 2002 to fund three to five new grants with project periods of up to two years and a direct cost budget up to \$100,000 per year. WWW <http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-02-005.html>

Fellowships-The University Center for Human Values at Princeton University invites applications from all disciplines for its Laurance S. Rockefeller Visiting Fellowships. These fellowships will be awarded for the academic year 2002-03 to outstanding scholars and teachers interested in devoting a year in residence at Princeton writing about ethics and human values. A central activity for the Fellows is participation with University Center faculty members in a Fellows Seminar to discuss work in progress. Fellows also participate in other activities, including seminars, colloquia, and public lectures. The major part of their time is devoted to research and writing about ethics and human values. Applicants typically have a doctorate or a professional post-graduate degree and cannot be in the process of writing a dissertation. Deadline for applications for fellowships beginning September 2002 is December 5, 2001. Contact Amy Gutmann, University Center for Human Values, 304 Louis Marx Hall, Princeton University, Princeton, New Jersey 08544-1006, (609) 258-4798, Email values@princeton.edu. WWW <http://www.princeton.edu/values>

Fellowships-The National Cancer Institute (NCI) and the Cancer Prevention Fellowship Program (CPFP) are pleased to announce a new postdoctoral fellowship track in the Ethics of Public Health and Prevention. This program will provide an opportunity for ethicists, philosophers, physicians and scientists to study ethical issues in cancer prevention research and their application in public health and clinical medical practice. Fellows will receive a Master of Public Health degree and will undertake mentored research at the NCI, the NIH Clinical Center's Department of Clinical Bioethics, the DHHS Office of Research Integrity, and at local universities, including but not limited to: Johns Hopkins University and Georgetown University's Kennedy Institute of Ethics. Additional coursework will be provided in bioethics, ethics, and philosophy or in biology, epidemiology, biostatistics, clinical trials, or health policy as needed. General categories of research topics could include: moral reasoning and ethical theory, concepts and methods of moral decision-making, IRBs and

informed consent, confidentiality and privacy, equipoise and the conduct of prevention trials, concepts of cause and prevention, uncertainty and scientific inference, scientific evidence and the ethics of intervention, professional ethics, scientific misconduct, autonomy and the public good, genetic markers and the ethics of early detection, and the ethics of primary prevention, and issues of justice and health disparities. Fellows are accepted for up to five years of training beginning in July. Applications are due September 1 for entry into the program the following July 1. Applicants must have a doctorate degree, and must also be either a citizen of the U.S. or a resident alien eligible for citizenship within four years. Contact Cancer Prevention Fellowship Program, National Cancer Institute, 6120 Executive Boulevard (EPS), Suite T-41, MSC 7105, Bethesda, MD 20892-7105, (301) 496-8640, Fax (301) 402-4863, E-mail br24v@nih.gov. WWW <http://dcp.nci.nih.gov/pob>

Call for Papers/Conference-**The Society for Ethics Across the Curriculum** is holding its 3rd annual conference January 30-February 3, 2002, at the University of Florida. To meet submission deadlines, papers or abstracts must be postmarked or emailed by September 1, 2001. Accepted papers may be submitted for publication in the Society's journal, *Teaching Ethics*. Submissions should be sent to the Secretary-Treasurer of the Society, Steven Scales, Department of Philosophy & Religious Studies, Towson University, 8000 York Road, Towson, MD 21252, Email sscales@towson.edu. WWW <http://www.rit.edu/ethics/seac>

Fellowships-**The Center for Ethics and the Professions at Harvard University** invites applications for Faculty Fellowships in Ethics 2002-2003. The resident Fellowships support outstanding teachers and scholars who wish to develop their ability to address questions of moral choice in such areas as business, education, government, law, and medicine. Fellows participate in the weekly seminar of the Center, which discusses problems of teaching and research in ethics. They enjoy access to a wide range of activities in all of the professional schools at Harvard, including opportunities to participate in courses, colloquia, curricular development, collaborative research, study groups, casewriting workshops, and clinical programs. A significant part of their time is devoted to conducting their own research in ethics. Applicants should hold a doctorate in philosophy, political theory, theology or related disciplines; or a professional degree in business, education, public policy, law, or medicine. Preference will be given to applicants at an early stage of their careers, normally no more than ten years from the terminal degree in their field. The Faculty Fellowships are open to all, regardless of citizenship. The deadline date for receipt of applications is December 1, 2001, for Fellowships beginning September 2002. Contact Center for Ethics and the Professions, Harvard University, 79 John F. Kennedy Street, Cambridge, MA 02138, (617) 495-1336, Fax (617) 496-6104, Email ethics@harvard.edu. WWW <http://www.ethics.harvard.edu>

Conference-The conference "**Beyond Cloning: Protecting Humanity from Species-Altering Experiments**," sponsored by the Health Law Department of Boston University School of Public Health, will be held September 21-22, 2001, at Boston University. This conference addresses the need for policies to prevent the alteration of the human species through genetic engineering. It will discuss where lines should be drawn, lessons learned from existing policies and procedures, and new national and international approaches and mechanisms for proscribing species-altering experiments. Contact Evelyne Shuster, Conference Director, Email EvelyneShuster1@msn.com.

Call for Papers/Conference-The conference "**The End of Natural Motherhood? The Artificial Womb and Designer Babies**" will be held in Tulsa, Oklahoma, February 22-23, 2002 and is sponsored by the Ethics Center at Oklahoma State University. Paper submissions are invited for presentation at the conference, on the topics of ectogenesis/artificial womb technology, genetic engineering, and the impact of reproductive technologies on social relationships and values. Essays on the topic of ectogenesis/artificial womb technology are strongly encouraged. The e-mail and postmark deadline for submissions is November 1, 2001. Contact Scott Gelfand, Philosophy Department, 308 Hanner Hall, Oklahoma State University, Stillwater, OK 74078-5064, (405) 744-9238 Fax (405) 744-4635, Email gelfand@okstate.edu. WWW <http://philosophy.okstate.edu/ethicscenter.htm>

Meeting--**PRIM&R and ARENA** are pleased to announce their 2001 annual IRB meetings, to be held December 1-4, 2001 in Boston, Massachusetts at the Sheraton Boston Hotel. December 1: IRB 101 - Educational Training Program for IRB Newcomers and Investigators & RCR 101 - Teaching Responsible Conduct of Research: Tools and Methods. December 2: The 15th Annual Meeting of The Applied Research Ethics National Association. December 3-4: IRBs and New Approaches: Assessing, Evaluating, Discarding and Moving Forward. Complete program information and online registration will be available in August through the PRIM&R Web site at <http://www.primr.org>.

Call For Papers/Conference-**The International Development Ethics Association (IDEA) Sixth**

International Conference on Ethics and International Development, "Impunity, Justice, And Development: Ethics And Policy" will be held Jan. 17-20, 2002, at the National Autonomous University of Honduras, Tegucigalpa, Honduras. It is sponsored by IDEA, a cross-cultural group of philosophers, social scientists, and practitioners who apply ethical reflection to development goals and strategies and to North/South relations, and the Citizens Forum, an Honduran civil society group that promotes democratic development since 1996. The Conference organizers invite proposals for individual papers and multidisciplinary panels from members of its sponsoring bodies and others engaged in the theory and practice of ethically-based development. Abstracts and papers may be in either Spanish or English. Deadline for receipt of paper proposals (200 words) and panel proposals is May 31, 2001 (early) and October 31 (later). Contact David A. Crocker, Institute for Philosophy & Public Policy, School of Public Affairs, University of Maryland, College Park, MD 20742, (301)405-4763, Fax (301)314-9346, Email: dc134@umail.umd.edu.