

Volume XII, Number 3, Summer 1999

- [Cover Story](#)
- [In the News](#)
- [Ethics, Law and Public Policy](#)
- [Resources](#)
- [Announcements](#)

Publication of the AAAS Scientific Freedom, Responsibility and Law Program, in collaboration with the Committee on Scientific Freedom and Responsibility Professional Society Ethics Group

Editor: Mark S. Frankel

Deputy/Managing Editor: Sanyin Siang

Contributing Editors: Michele Garfinkel, Rachel Gray, Tamany Vinson

ISSN: 1045-8808

URL: <http://www.aaas.org/spp/sfrl/sfrl.htm>

Stem Cell Controversy

by Michele Garfinkel

Michele Garfinkel is a student in the George Washington University Science, Technology, and Public Policy Graduate program. She received her doctorate in microbiology from the University of Washington. Dr. Garfinkel is also a staff member of the American Association for the Advancement of Science.

In November of 1998, two groups reported that they had successfully cultured human stem cells and demonstrated that these cells could differentiate into cells from each of the three developmental germ layers. Although similar experiments had been done for many years using tissue from other animals, this unequivocal demonstration of the pluripotency (ability of the cell to give rise to virtually any tissue type, but not to a functional organism) of the equivalent human cells caused great excitement and great concern. The excitement arises from the potential therapeutic applications of these cells, and from the promise of learning about human development at a level that could only be imagined before. The worries arise from the sources of the cells, and from concern about how they will be used and how the fruits of this research may further strain access to health care.

Issues

The stem cells used in research and potentially for therapies can be derived from several sources. Many mature tissues have stem cells that are responsible for replacing tissue over the life of an organism. One example of these so-called adult stem cells is the hematopoietic stem cell that can give rise to blood cells. Though somewhat crude, therapies using these stem cells are already successfully employed (frequently following chemo- or radiation therapies for cancer, where the patient's blood-generating compartment is frequently destroyed). But regeneration of tissues from other adult stem cells is now being researched⁽¹⁾ and at least one product is in early clinical trials. But it is the stem cells isolated from embryos or fetuses hold the most promise for therapies. The source of the cells is thus the source of most of the controversy. For those who believe that it is permissible to use human embryonic or fetal tissue in research, there is the proximal question of how to do this in a way that is ethical and respectful of the donors. But another interesting question then arises. If these cells truly are special in some way, and there is agreement about the high moral status of the source, then what does this mean for eventual uses of these cells?

Because there is as yet no federal funding of this research, everything that is known specifically about human embryonic or fetal stem cells is the result of private investments. This fact precipitates several immediate concerns. The first concern is oversight. The vast majority of research scientists carry out their research in ways that adhere strictly to all the commonly accepted tenets of professional ethics, and would do so even without oversight. But some public uneasiness over what goes on "behind closed doors" does exist. The argument is that federal funding will assure the public that most research is being conducted in an ethical manner. The other concern, perhaps the more important one (and not necessarily specific to stem cell research), is whether and how public good can be drawn from private research. If research is not publicly funded, there can be no reasonable expectation that technologies (in this case, for example, stem cell generated tissue transplants) will be available beyond those who can pay out-of-pocket (or perhaps via insurance). These and related issues have been studied and publicly discussed by several groups.

Diverse approaches to studying complex policy issues

Because of the enormity of these issues, including the debate over whether this research should be federally funded, national-level bodies have been engaged in discussion over the disposition of this research. These groups have taken different approaches to considering the problems. The National Institutes of Health (NIH) is the major public funder in the United States of basic biomedical research. Federal funds can be used for research on material taken from non-living fetuses, but researchers are sometimes hesitant to use federal funds for such experiments. For example, at his testimony before the subcommittee on Labor, Health and Human Services, and Education on January 12th, 1999, Harold Varmus, Director of the NIH, testified that John Gearhart's research of human embryonic germ cells would have been eligible for funding under current law. In other testimony, the NIH, supported by some members of Congress, wants this to change so that federally-funded researchers are not excluded from participating in this research.

Although it is impossible to know at this time exactly how the NIH guidelines will read, based on discussions at the public meeting and on the President's endorsement of the NIH approach (see below), it seems likely that federal funding will be recommended only for use of embryonic stem cells that have been isolated without federal funding, and that there will be some mechanism to ensure that federally-funded researchers can obtain the cells in an ethical manner. How many "layers" between the publicly-funded research and the privately funded isolation there will be, and how complex the oversight of the actual experiments will be, remain to be seen upon publication in the Federal Register of the suggested guidelines.

Using a strict legal definition, Harriet Rabb, General Counsel, U.S. Department of Health and Human Services, determined that federally-funded researchers could carry out experiments on human pluripotent stem cells, because the cells themselves are not human embryos.⁽²⁾ This ruling precludes researchers from obtaining the cells themselves. The NIH has decided not to fund any research using human pluripotent stem cells until guidelines have been developed and can be distributed to the research community. This led to the formation of a Stem Cell Working Group as part of the Advisory Committee to the NIH director, which drafted guidelines and, following a public comment period, held a public meeting on April 8th, 1999. Taking public commentary into account, NIH is in the process of revising its guidelines, at which time they will again be posted for public comment.

The National Bioethics Advisory Commission (established by Executive Order in 1995) has released its report, "Ethical Issues in Human Stem Cell Research."³ Reflecting its mission and its charge ("In November 1998, President Clinton charged the National Bioethics Advisory Commission with the task of conducting a thorough review of the issues associated with human stem cell research, balancing all ethical and medical considerations."), the Commission has generated a comprehensive report, with special emphasis on bioethics issues.⁽³⁾ Following complex ethical arguments, the Commission concluded that federal funding could be used not only for experiments using embryonic or fetal stem cells that had already been isolated, but also for the isolation of such cells.

Even before the formal release of the report this finding stoked heated discussion and criticisms, including from the White House.⁽⁴⁾ In this early statement, the Administration declared that the NIH guidelines and oversight (yet to be published) would be sufficient, and that "...[n]o other legal actions are necessary at this time, because it appears that human embryonic stem cells will be available from the private sector." The statement released following the actual delivery of the report ⁽⁵⁾ did not refer specifically to any recommendations, but rather referred to the promise of stem cell therapies, and thanked the Commissioners for their thoroughness in the execution of the report, and in their efforts to seek the views of "virtually every segment of our society."

Equally notable are NBAC's recommendations concerning oversight, calling for local and national level oversight and review (including the creation of a new body specifically for the national level oversight), as "...the public and the Congress must be assured that oversight can be accomplished efficiently, constructively, and in a timely fashion, with sufficient attention to the relevant ethical considerations."⁽⁶⁾ Paul Berg, speaking for the American Society for Cell Biology, has called the oversight recommendations "bureaucratic," ⁽⁷⁾ but perhaps necessary to provide the promise to the public and to various government agencies that this research will be carried out ethically.

The American Association for the Advancement of Science and Institute for Civil Society also initiated a project on stem cell research. AAAS/ICS organized a working group of experts who, over a period of several months, advised on various aspects of the ethical, moral, religious, legal, and public policy issues that are germane to stem cell research.

The Working Group members are not the authors of the report, but rather advised AAAS and ICS in its preparation. The final report will be completed shortly; preliminary Findings and Recommendations were publicly released (WWW <http://www.aaas.org/spp/sfirl/projects/stem/main.htm>) prior to a public forum held on August 25th.

Much of the public discussion at the meeting concerned the ethics of using tissue obtained from embryonic or fetal sources. The AAAS/ICS recommendation on the public funding of derivation of stem cells is in agreement with the presumptive NIH view (that is, public funding for isolation of stem cells should be prohibited). In contrast to NBAC's recommendation, AAAS/ICS found no reason for the time being to establish a new body to oversee this research, and recommends using established bodies for approval of research protocols. This would include local review at the level of Institutional Review Boards, review by normal NIH study sections, and, as necessary, review by, for example, the Recombinant DNA Advisory Committee, whose mandate could easily be expanded to include stem cell research protocols. This recommendation should be of great interest to scientists, and to those who make science policy.

REFERENCES

1. Pittenger, M.F., Mackay, A.M., Beck, S. C., Jaiswal, R.K., Douglas, R., Josca, J., Moorman, M., Simonetti, D., Craig, S., and Marshak, D.R. 1999. Multilineage potential of mesenchymal stem cells. *Science* 284: 143-147.
2. Rabb, Harriet S. 15 January 1999. Letter to Harold Varmus. "Federal Funding for Research Involving Human Pluripotent Stem Cells."
3. An Executive Summary of the NBAC report is available on line (http://bioethics.gov/stemcell_exec_intro.htm). The full report is available from NBAC (<http://bioethics.gov/pubs.html>).
4. 14 July 1999. Statement by the Press Secretary (<http://www.pub.whitehouse.gov/urires/I2R?urn:pdi://oma.eop.gov.us/1999/7/15/3.text.1>)
5. 13 September 1999. Statement by the President. (<http://www.pub.whitehouse.gov/urires/I2R?urn:pdi://oma.eop.gov.us/1999/9/13/8.text.1>)
6. Ethical Issues in Human Stem Cell Research, Executive Summary.
7. Quoted in Marshall, E. 1999. Ethicists Back Stem Cell Research, White House Treads Cautiously. *Science* 285: 502.

IN THE NEWS

UK BIOINDUSTRY ORGANIZATION ISSUES DRAFT CODE

The British biotechnology industry has decided on a stringent course of action with regard to the relationship between companies in the medical and life sciences sectors and their shareholders. In July 1999, BioIndustry Association (BIA), an organization prominent in the UK's biotech industry, issued a nine-principle draft code. The code seeks to provide a best practices benchmark for public review of company activities relating to the exchange of commercial and regulatory information and aims to manage the flow of scientific information to the financial community in a way that does not mislead or oversell the implications of research findings, nor falsely raise expectations from patients' groups.

Additionally, the code's provisions also include ensuring that companies have access to independent scientific (and where relevant, external regulatory and clinical) advice and expertise in handling scientific information; ensuring that information to investors is accurate and provides a fair presentation of a product's prospects, including its manufacturing and marketing potential; and ensuring that information released to the public is as transparent and as easy to understand as possible.

Enforcement of the code will require that BIA member companies listed on the Stock Exchange comment on their compliance or reasons for non-compliance in their annual reports. The identities of companies that do not comply will be made public. BIA will also establish a subcommittee to review complaints, and to take appropriate action. Such action could range from advice, to public censure, to expulsion from the BIA, in the event of a serious breach.

"The Code is not prescriptive, but provides a set of principles and supporting provisions which companies should apply to their activities," commented John Sime, Chief Executive of the BIA. "We anticipate that it will quickly become recognized by companies and their shareholders as the standard by which companies can be judged."

The code was drafted in the aftermath of the British Biotech Company scandal. The company was censured by the London Stock Exchange and the US Securities and Exchange Commission for the inaccuracy of statements about the company's main anticancer drug. The code will be formally adopted by the BIA in October of this year.

ADVISORIES ON THE USE OF MEDICAL WEBSITES ISSUED

In July 1999, the American Telemedicine Association (ATA) issued a set of advisories for consumers on the appropriate use of the Internet to obtain health information and medical services. The Association is a leading organization promoting and guiding the deployment of telemedicine.

Recent years have witnessed a proliferation of the amount of health and medical information over the Internet and the number of people who use it. While the ATA recognizes the potential of the Internet for facilitating the exchange of medical information among medical providers and between patients and their healthcare providers, it is also fully aware of the potential for abuse in the provision of health information and treatment over the Internet.

The advisories are as follows:

1. Consumers should make sure that Web sites used to obtain information about health and medicine are provided by a reliable and credible source such as recognized and credentialed healthcare providers, and use sources that are based on qualified authorities. The source of the information should be clearly labeled and annotated. The ATA endorses the concept of professional societies accrediting Web sites that provide consumers health and medical information.
2. In some cases commercial interests such as a drug manufacturer may sponsor or contribute information to a Web site. Consumers should look for assurances that the information provided in these cases is objective and does not favor the sponsor's products.
3. At this time consumers should exercise caution in using Web sites that offer online diagnosis of an individual's medical condition and prescribed treatment and medication for the diagnosed condition. There are currently no recognized accreditation or regulatory authorities overseeing the operation of these sites.
4. It is a widely recognized conflict of interest for health professionals that prescribe medicines to have any direct financial relationship with an entity that sells those medications. Therefore, consumers are cautioned against obtaining prescribed medicines from Web sites that offer both diagnosis of condition and direct sales of the prescribed medicine.
5. Medical professionals in almost all developed nations are required to obtain credentials from a recognized authority in order to practice medicine. For example, health professionals in the United States are issued a license to practice medicine by individual state authorities. Consumers seeking medical treatment from health professionals over the Internet should receive clear assurances that they will be interacting with a qualified professional holding the appropriate credentials and that the professional is able to legally practice medicine in the consumer's location.
6. Clinical consultation over the Web by credentialed providers should include procedures that protect the patient including: Informed consent; Information security and privacy protection measures; and Documentation of the clinical encounter.

Additionally, the ATA encourages specialty medical societies to develop guidelines to ensure that clinical consultations provided over the Internet are consistent with accepted medical practices.

The advisories appeared prior to the publication of a paper in the August 1999 issue of *Cancer* by University of Michigan researchers. The study which analyzed 371 Web sites for accuracy of information regarding a particular form of bone cancer found close to a third of the references erroneous and lacking any indication that they had undergo the process of peer review. Since most people lack the expertise to assess the validity of what they find, the study suggests that erroneous information can pose potential hazards in several ways. When the information conflicts with recommendations from physicians, it may affect the patients' decision making process, resulting in a delay of treatment or inappropriate choice of therapies. Patients may also lose confidence in their physicians, leading to a possible compromise in their willingness to accept and endure necessary treatments.

SWEDISH STANDARDS SET FOR USE OF GENETIC 'BIOBANKS'

The Swedish Medical Research Council's (MRC) ethics committee has developed and published Europe's fullest set of ethical guidelines on the use and control of 'biobanks' — tissue and health science information banks that can be used for genetic research. The publication of the guidelines follows the founding of a private gene-broking company called UmanGenomics, based in Northern Sweden. UmanGenomics has exclusive rights to generate and sell genetic information from blood samples stored in a 15-year-old Medical Bank based on samples from 60% of the geographically isolated population of the town of Västerbotten.

The guidelines, which define biobanks as any banks storing biological samples or information that may be linked to an individual, stress the importance of protecting individual data. The committee advises that biobanks containing linking data to individuals should be kept within a public institution (such as a university), and that all access to stored material should be granted and controlled by the ethics committee. The guidelines propose that the quality of the material stored and the rules for selecting material to be stored, should be strictly controlled. Additionally, research projects that might exhaust any part of the biobanks should not normally be approved.

According to the guidelines, informed consent should be sought from donors for every new use of their biological samples on a project-by-project basis. The ethics committee will decide whether or not a research proposal involves a new use, or a use that does not differ from that for which informed consent has already been obtained.

However, when an important, high-quality project addressing a prevalent disease with presumed minimum harm to the participants is proposed, the guidelines recommend a series of newspaper advertisements offering the opportunity for individuals to opt out might be appropriate. Whether informed consent should be secured from relatives who might be affected by the results of a genetic study will also be determined by the committee.

UmanGenomics has been accepted by the community because it conforms with these guidelines, according to Gisela Dalquist, who chairs the MRC's ethics committee. Sune Rosell, temporary chairman of Uman Genomics, observes that this differs from the situation in Iceland because "there is control at the individual level through informed consent, at the social level through the regional ethics committees that screen all research proposals, and at the population level, since local politicians sit as non-voting members on the boards of both the company and the Medical Bank." It is not just the sensitivity to ethical issues that underlies the positive local response to the company. UmanGenomics has promised to bring high-tech jobs to the area ensuring that research contracts are carried out locally.

OPRR CRACKS DOWN ON HUMAN SUBJECTS RESEARCH

The U.S. Office for Protection from Research Risks (OPRR) continues to investigate universities throughout the country and enforce guidelines pertaining to human subjects research. The agency, charged with oversight of all federally funded human subjects research, recently shut down 1,000 human research projects at the University of Illinois at Chicago and investigated the IRB at the University of South Florida.

In late August, the University of Illinois was blocked from initiating new research projects involving human subjects due to inadequate oversight and safety procedures. The agency cited 28 violations of federal guidelines including the failure of the university's Institutional Review Boards (IRBs) to review some proposed research projects and its approval of research protocols despite insufficient information. This included the IRB's failure to follow special procedures for research projects involving children and prisoners, and inadequate monitoring of research involving students in the university's psychology departments. Furthermore, the board inappropriately expedited approvals for some studies and did not always ensure that research participants received clear, understandable forms to secure their informed consent.

OPRR noted that the violations resulted from insufficient professional support, working space and computer resources. The restrictions will continue until the university improves training for its IRB members and their support staff, and supplies the more complete documentation that is required for approval of research projects.

Concurrently, in July, OPRR investigated the IRB of the University of South Florida and reviewed several materials.

After reviewing a February report regarding a project titled, "Water Handling and ADH Regulation in Moderately-High Altitude Natives," OPRR sent a memo to the University, noting the brevity of the research protocol and its amendments and commented that the IRB might lack sufficient information to make the determinations required for approval of research under HHS regulations.

The IRB appears to have reviewed only minimal information regarding procedures for minimizing risks and maximizing benefits to subjects, subject recruitment and enrollment, and the equitable selection of subjects. For example, the IRB approved the informed consent form that lacked an appropriate description of a potentially serious complication that can result from the implementation of a section of the research protocol. The IRB also approved protocol changes that significantly exceeded the limitation of minor changes. No records exist for the recruitment of subjects. Changes in the number of human subjects occurred without IRB approval, and the IRB failed to recognize the deviation from the original protocol in its annual review.

OPRR's actions appear to be infectious. In late September, the U.S. Food and Drug Administration, another government agency that enforces regulations on human subject protection, ordered the University of Colorado Health Sciences Center to suspend enrollment of new subjects in clinical trials involving drugs or devices regulated by the FDA due to improper maintenance of research records. This was the FDA's first suspension or limitation of research in at least three years. Following the directive, the University of Colorado decided to halt all clinical research. Concurrently, OPRR issued a separate letter that requested the university to suspend all federally financed clinical research.

ETHICS, LAW AND PUBLIC POLICY

AUTHORSHIP IN PHYSICS ACCORDING TO POSTDOCS

by Eugen Tarnow

Eugen Tarnow is the owner of Avabiz.com, a software business in New York City. He obtained his PhD in physics from MIT in 1989 and worked as a postdoc at Xerox PARC and Los Alamos National Laboratory before leaving the field. He can be reached at etarnow@avabiz.com.

Introduction

One of the attractions of the scientific community, and possibly the reason for its success, is the ethical ideal it seems to offer: the egalitarian opportunity for positive feedback to its workers in the form of a public listing as authors on scientific papers. Because this reward can have a significant impact on the careers of the scientists involved, the important ethical issue is how accurate is the process of assigning authorship credit? Is credit given when and only when it is due?

This paper is one of the first inquiries into how authorship is distributed in everyday research collaborations. It will focus on perhaps the most important class of all research collaborations: junior scientists in non-permanent positions (postdoctoral associates or "postdocs") supervised by senior scientists.

The scientific work on the designation of authorship is limited.(1-5) Among these, Swazey, Anderson and Lewis,(3) studied self-reported exposure to a variety of types of misconduct among university professors and graduate students.(3) The authors found that the rates of plagiarism and inappropriate authorship were reported to be similar by both faculty and students, that is, student reports of faculty violations were similar to faculty reports of faculty violations and vice versa. This suggests that while the current study only considers the postdoc side of the story, the supervisor point of view might not be substantially different. The present contribution attempts to obtain a quantitative count of inappropriate authorship, where "inappropriate" is defined by physics postdocs' interpretation of authorship violating the existing ethical statement of the American Physical Society (APS). A survey was mailed out to 191 postdoctoral workers in physics, about 35% of the postdocs returned complete questionnaires. I believe that the results presented represent the most precise count of any ethical misconduct in any science to date.

Results

The APS ethical guidelines relating to requirements for authorship states: Authorship should be limited to those who have made a significant contribution to the concept, design, execution and interpretation of the research study.

The survey results indicate that 26% of respondents have seen the ethical statement above, while the majority has not. There is sometimes little agreement among respondents as to what the APS ethical statement means, as revealed by the answer to the question:

Do you consider, according to the ethical statement above, that obtaining grants and other funding for a project qualifies as a 'significant contribution' that warrants authorship?"

49% of the respondents answer affirmatively, while the rest are of the opposite opinion. Indeed, the ethical statement allows for both views, the "significant contribution" is not required to be "intellectual" (also, somewhat surprisingly, the statement does not state that contributions be "original").

Guided by the APS ethical guidelines, in 14% of papers with the supervisor as an author, respondents indicated that the supervisor should not have been listed as an author. The supervisor was an author on 92% of all papers the survey respondents authored. Similarly, in 33% of papers with authors in addition to the supervisor or the postdoc, one or more authors, other than the postdoc or the supervisor, should not have been listed as authors. 46% of all postdocs answering the question reported that at least one paper on which he or she was an author had at least one inappropriate author; 22% of postdocs answering the question reported that at least one paper had the supervisor as an inappropriate author. Respondents reported that in 1% of all papers, they were themselves inappropriate authors.

In 75% of postdoc-supervisor relationships, authorship criteria had never been discussed: in 61% of relationships the criteria for the postdoc's authorship were not "clearly agreed upon," and in 70% of the relationships the criteria for designating others as authors were not "clearly agreed upon."

Reasons reported for inappropriate authorship fell into four groups:

- Explicit concern for relationships both by postdoc and supervisor. For example, the postdocs need letters of recommendation from their supervisors and want to keep in their good graces. Relationships with other scientists in the field are also perceived to be enhanced by giving them authorship. Sometimes the postdoc and the supervisor hope to gain prestige or expedite the publication of their work by adding a well-known name.
- Minor contributions were made (more appropriate for acknowledgement than authorship)
- Previous work in the field or expected contributions that did not materialize
- Crediting staff that are socially close; for example, part of the same research group

The Dilemma

The physics discipline is not alone in its lack of a consistently applied, well-defined public procedure for assignment of authorship. A similar situation in psychology was found by Vasta,(2) and in biomedical sciences by Eastwood, Derish, Leash, and Ordway.(5) Since these scientific disciplines' sole purpose is to define nature and people, and since authorship is so important to everybody in the disciplines, not being able to define authorship must strike any observer as a strange aberration.

Within a research collaboration, a desire to avoid conflicts may make the parties involved reluctant to talk about authorship. It may be particularly important for the postdocs not to challenge the authorship of supervisors since we also found in our survey that postdocs believe their supervisors' recommendation letters are very important for future job prospects (in fact, as important as their publications.)

On the level of science policy makers, (from the leadership at the departmental level to university, scientific association, and governmental levels), however, the reluctance to aggressively address the issue of authorship cannot be explained by intra research group conflicts. In fact, there are at least two obvious options to make the assignment of authorship more meaningful, which completely removes such conflicts between members of a research collaboration. One option is to follow the patent authorship model and have an attorney, or another disinterested party, inquire into

the research work and, according to existing legal standards for patent authorship, write down the list of authors. A second option would be to assign authorship more accurately by adding an authorship section at the end of each paper giving each author an opportunity to explain what he or she contributed.

The reluctance to address the issue on the discipline level may be explained by the fact that the scientific disciplines consist of two groups of actors with different interests and different powers. The likely victims of misappropriation of authorship are the more junior scientists with no power to legislate the rules of authorship. The power to legislate is in the hands of more senior scientists, a group, in my experience, with little interest in accurate assignment of authorship. Senior scientists may no longer perceive the issue as important—for example, no supervisor exists who can easily appropriate authorship from them, or they may also see “honorary” authorship as an entitlement of their senior status. Undefined authorship may also be a symptom of the much larger issue of science financing. Senior scientists are dependent upon a financial system that forces them to spend so much time looking for grant money and marketing their research, they may have little time for substantial intellectual contributions to scientific work.

Acknowledgement

I would like to extend my gratitude for the time given to me by the survey respondents; for a critical reading of the manuscript by Michele Fine, and for the contribution of others who shall remain anonymous.

Bibliography

1. Tarnow, E. (1999) the Authorship List in Science: Junior Physicists' Perceptions of Who Appears and Why, *Science and Engineering Ethics* 5, p.73-88.
2. Vasta, R. (1981) The Matter of Publication Credit: a Survey of APA Members, *Journal Supplement Abstract Service Catalog of Selected Documents in Psychology* 11:2-3
3. Swazey, Judith P., Anderson, Melissa S., Lewis, Karen Seashore, (1993) Ethical Problems in Academic Research, *American Scientist* 81: 542-554.
4. Kalichman, M., Friedman, P., (1992) A Pilot Study of Biomedical Trainees Perceptions Concerning Research Ethics, *Academic Medicine* 67:767-773.
5. Eastwood, S., Derish, P., Leash, E., Ordway, S. (1996) Ethical Issues in Biomedical Research: Perceptions and Practices of Postdoctoral Research Fellows Responding to a Survey, *Science and Engineering Ethics* 2:89-114.

RESOURCES

Beyond Regulations: Ethics in Human Subjects Research, edited by Nancy M.P. King, Gail E. Henderson, and Jane Stein (Chapel Hill, NC: the University of North Carolina Press, 1999; \$18.95 plus s/h). To order call 1-800-848-6224; Fax 1-800-272-6817.

This book is a collection of essays commenting on a range of ethical issues in human subject research. The opening keynote essay by Ruth Macklin addresses how ethics transcends national borders, which is followed by an analysis of six specific case studies. Each case concentrates on a different type of community introduced to the reader by a background essay, and then two opinion papers evaluate the ethical dilemma involved.

Case one addresses the issue of contracts between researchers and communities that give the community control over what information obtained from a study is published. It moves from there to the effect and efficacy of community advisory boards, and then to the ethical issues involved in corporate funding of research and the influence of society on these issues. A few of the essays address the concept of consent and whether the individual informed consent process can or cannot be applied internationally. Legal issues are also discussed, with respect to their effects on the structure of human subject research and on the outcome of the data collected. The closing essay calls for new approaches to the ethical dilemmas by creating new relationship paradigms, such as those between the researchers, the research subjects, and the communities.

Ethics of Research with Human Subjects: Selected Policies and Resources, edited by Jeremy Sugarman, Anna C. Mastroianni, and Jeffrey P. Kahn (Frederick, MD: University Publishing Group Inc., 1998; \$19.95 plus s/h). To order, call 1-800-654-8188; Fax 301-582-2408; email orders@UPG-books.com

This collection of policies and resources dealing with the ethics of research using human subjects is intended to guide a researcher through the different and evolving international and national policies on human research.

The book is divided into three sections: landmark documents, major policies, and a selected bibliography. The first section discusses three of the most well known and prominent ethical policies to date on human subjects research: the Nuremberg Code, the Belmont Report, and the World Medical Association's Declaration of Helsinki. The second section discusses federal policies, specific population policies, policies in prison settings and the international arena, and waivers of informed consent. The final section is an extensive bibliography containing more than a hundred suggested sources for further information. It follows the organization of the previous parts of the book, with additional sections where major policies do not exist. The authors chose the selections based on what they had found was useful in their research, and also on their searches of the Bioethicsline database.

For convenience, the book also contains three "finder tools" that enable a reader to locate a category, title or citation. The first "finder tool" aids the reader in locating documents and policies referenced in the volume. The second "finder tool" lists policies by the federal agency or department that issued the policy. The final "finder tool" lists policies by citations from the *Code of Federal Regulations*.

ANNOUNCEMENTS

Applied Research Ethics National Association ARENA and Public Responsibility in Medicine and Research (PRIM&R)'s 1999 Annual IRB Conferences and 25th Anniversary Gala will take place on December 5-7, 1999. ARENA will hold its annual meeting on December 5, 1999 in Boston, MA. This year's meeting will focus on practical and creative solutions for managing IRBs in the new millennium, including coping with increased workloads and responsibilities and new ways to evaluate and improve the IRB review process. PRIM&R will hold its commemorative IRB conference on December 6 and 7, 1999. The meeting will feature presentations by a diverse faculty of experienced researchers, IRB administrators, ethicists, federal officials, and others involved with human subjects research programs.

The annual IRB conference on December 6 and 7 will be a unique and celebratory event, as it marks PRIM&R's 25th Anniversary. Through the Looking Glass: Where We Have Been, Where We Are, and Where We Are Going will feature five panels: "What is 'Old' and Still Unresolved?"; "What is 'New' and Really New?"; "What is 'Old', Was Reasonably Resolved, but Now in Need of Revisiting?"; "Origins: The Commission and Other Ethical Antecedents of IRBs;" and "Research Subjects in Their Own Words." In addition, there will be a panel of research subjects discussing their experiences of and attitudes toward participating in research. A broad range of cutting-edge problems will be discussed, such as international research, research with special populations, multi-center trials, compliance concerns, privacy and confidentiality, genetic research, the role of central review boards (CRBs), IRB education, and the ongoing search for a new paradigm of partnership between the IRB, Principal Investigator (PI), research participant and sponsor. Contact Joan Rachlin, PRIM&R and ARENA, 132 Boylston Street, 4th Floor, Boston, MA 02116; (617) 423-4112; Fax (617) 423-1185; Email prmr@aol.com; WWW <http://www.aamc.org/research/primr>

The **Center for Urban Bioethics** at the New York Academy of Medicine presents Bioethics in the Urban Context: A National Symposium, on December 2-3, 1999 in New York City. The field of urban ethics seeks to apply bioethical analysis to a cluster of problems that arise in the urban setting, and to create a new conceptualization of bioethics, with more emphasis on context, social reality, and the contributions of diverse disciplines. Conference topics include the Social Determinants of Health in the Urban Environment, The Nature of Urban Bioethics, The Impact of Urbanicity on Health, Cultural Diversity and the Clinical Transaction, The Social Responsibilities of Medicine and Bioethics, and Health Care Delivery and the Urban Safety Net. Contact Department of Medical Education, The New York Academy of Medicine, 1216 Fifth Avenue, New York, NY 10029; (212) 822-7273; Email: bioethicsymposium@nyam.org

The **Sixth National Communication Ethics Conference** will be held May 11-14, 2000 on the shores of Gull Lake, near Kalamazoo, Michigan. Hosted by Western Michigan University and Duquesne University, the conference's purpose is to promote research and teaching relating to ethical issues and standards in all aspects of human communication, encourage the development of academic programs in communication ethics, and to facilitate the collaboration of colleagues who have a significant interest in communication ethics. This is a residential conference, which allows scholars and teachers to interact both formally and informally.

New this year, graduate students are invited to submit papers for the Duquesne University Graduate Student Fellowship in Communication Ethics competition. As many as four student authors will be chosen as fellows and will have their registration fees, housing, and meals for the conference paid by the contribution of the Department of Communication at Duquesne University. Submissions may include competitive research papers, position papers, case studies with commentary, round table proposals, or program proposals.

Papers on any topic relevant to communication ethics are welcome, including communication ethics within various areas of the discipline; history of communication ethics, freedom of speech, ethical issues regarding pluralism and diversity; moral development theories, theory and practice; studies of ethics centers, instructional resources, teaching methodologies, and curriculum. Deadline for submissions is December 15, 1999. Contact James A. Gilchrist, National Communication Ethics Conference, Department of Communication, 309 Sprau Tower, Western Michigan University, Kalamazoo, MI 49008; (616) 387-3130; fax (616) 387-3990 Email james.gilchrist@wmich.edu; WWW <http://www.wmich.edu/communication/ethics.html>.

The **Information Resources Management Association (IRMA) International Conference** is seeking submissions for its Social Responsibility in the Information Age track. The conference will take place on May 21-24, 2000 at the Anchorage Hilton Hotel in Anchorage Alaska. Recommended topics include aspects of information security in modern organizations, computer abuse and crime, ethics in cyberspace, regulating the World Wide Web and legal issues in global information security management. The deadline for submissions is October 8, 1999. Contact Gurpreet Dhillon, College of Business, Box 456009, University of Nevada Las Vegas, Las Vegas, NV 89154; Email Dhillon@cmail.nevada.edu; WWW <http://www.irma-international.org>

The **Ninth Annual Conference of the Center for Academic Integrity** will take place on October 15-17, 1999 in Durham, North Carolina. Program highlights include 3 pre-conference workshops on assessing your academic integrity program; how to lead good small group discussions; and can the CAI address the cheating problem in high schools? Concurrent Sessions will include Academic Integrity and the Internet; Structuring Exams and Assignments to Encourage Academic Honesty; What To Do When Lawyers Get Involved in Academic Integrity Cases; Brainstorming Ideas for Research on Academic Integrity; and Keeping Faculty Involved in a Vibrant Academic Integrity System. See WWW <http://www.academicintegrity.org>.

The **Ohio University Student Conference on Applied and Professional Ethics** will convene on November 6, 1999. The conference will provide an informal setting for graduate and undergraduate students to present their work, to meet, and to exchange ideas with a prominent representative of the discipline. Deborah Johnson, Director of the Program in Philosophy, Science, & Technology at the Georgia Institute of Technology School of Public Policy, will present the keynote address on "Is Forbidden Knowledge Possible in Modern Science?" Contact Student Conference, Philosophy Dept., Ohio University, Athens, OH 45701; Email jape@www.ohio.edu

With funding from the National Science Foundation, the **Center for the Study of Ethics in the Professions (CSEP)** at Illinois Institute of Technology has posted its comprehensive collection of codes of ethics online. This database is a resource for students, scholars, and professionals in all the professions. An *Introduction, Users Guide, Bibliography* (in process), an index and other search tools, and a report on constructing codes by a student who participated in entering codes provide guidance and aids for study. CSEP is committed to maintaining and improving this database. Additions of new codes, suggestions for making the site more useful, and information about any "bugs" that users find are therefore welcome. WWW <http://csep.iit.edu/codes>.

A course on **Ethical Issues in Occupational Health Research** will convene on October 29-30, 1999 at the University of Texas-Houston Health Science Center in Houston, TX. The course will examine the ethical, social and legal

problems surrounding occupational health research, more specifically, the balance between the need to protect the rights and welfare of human subjects, and the necessity to conduct research into the hazards that workers are exposed to in the workplace. It will provide a forum for industry, workers, occupational health physicians, and institutional review board members and their regulators. Jurists and philosophers will help to guide the debate of these research issues and aid in the formulation of solutions. Topics include: informed consent, dissemination of research findings, union/worker interest, creative solutions to recognized problems, and intellectual freedom. Contact Paula Knudson, ORSC, PO box 20036, JFB G.700, Houston, TX 77225; (713) 500-5827; Fax: (713) 500-5830.

The **1999 Brunel Centre for Organisational and Professional Ethics Workshop** on “The Ethics of Trust and Responsibility” will be held on December 3, 1999 at Buckinghamshire Chilterns University College in the UK. ‘Trust’ is generally defined as a resting on the integrity of another; of moral obligation within a relationship of reliance. ‘Responsibility’ suggests moral accountability. These concepts are rapidly becoming germane to the discourse of debate concerning the ethical premises of public and private organizations within a context of change and fluctuation. Papers are invited which explore the linkages between the concepts of trust and responsibility, and demonstrate their relevance to current ethical challenges. Papers might, for example, explore the role of trust within the virtual organization; the responsibilities inherent in new systems of policing; the ethical obligations of stakeholding. Contact Claire Cohen, Email claire.cohen@brunel.ac.uk or Anne Mills, Email amills01@buckscol.ac.uk.

The **American Association for the Advancement of Science** and the **U.S. Office of Research Integrity** are accepting abstracts for a conference on “The Role and Activities of Scientific Societies in Promoting Research Integrity.” Examples of the issues likely to be explored at the conference include: What ethics standards and policies are currently in place in professional societies and how do the societies communicate these standards to members and students? What range of professional conduct is covered by the standards? How do/should members use the standards or policies in their work? In training new or future members? What support structures (e.g., ethics committees, hotlines) do/should professional societies employ to promote research integrity? How effective are the standards and support structures? What factors (e.g., law, resources, internal pressures) constrain or facilitate action by societies? Abstracts must include (1) a summary of the proposed presentation (including a bibliography) of no more than 1,000 words, and (2) a resume or biographical sketch not to exceed 100 words. Submissions by e-mail is strongly encouraged; if mailed, please submit 6 copies. The deadline for receipt of abstracts is December 21, 1999. Successful applicants will be notified by January 31, 2000. Contact Sanyin Siang, AAAS, 1200 New York Avenue, NW, Washington, DC 20005; Fax (202) 289-4950; Email societies@aaas.org