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How (Not) to Regulate Social and Behavioral Research[1]

By Joan E. Sieber,[2] Stuart Plattner,[3] and Philip Rubin[4]

Suppose that you were attempting to drive to a place that you had not been to before, and had to rely on road signs to get there. Suppose further that the road signs, if properly interpreted, were *accurate*, but were written in such a way that most people misinterpreted them. The delays, extra expenses, spoiled trips, and missed opportunities would be enormous, especially if this were a national highway on which many people traveled.

Such is the dilemma of social and behavioral scientists whose research is governed by their Institutional Review Boards' (IRB) interpretations of the federal regulations of human research. Unfortunately, it has become more common in recent years for IRBs to interpret the regulations in ways that are more restrictive than contemplated by the authors of the federal regulations and inappropriate for the social sciences. The results can be bad for social and behavioral research. For example:

- A linguist seeking to study language development in a pre-literate tribe was instructed to have them read and sign a consent form.[5]
- An experimental economist seeking to do a laboratory-based study of betting choices in college seniors was held up for many months while their IRB considered and reconsidered the risks inherent in a study whose only real danger was boredom.
- A political scientist purchased appropriate names for a survey of voting behavior (of people who had consented to such participation) and was initially required by their IRB to get the written informed consent from subjects before mailing them the survey.
- A Caucasian Ph.D. student, seeking to study career expectations in relation to ethnicity, was told by the IRB that African-American PhD students could not be interviewed because it might be traumatic for them to be interviewed by the student.
- Faculty who employ routine classroom exercises for pedagogical purposes, in which students are asked to make judgments and discuss their reasons are required by their IRBs to obtain the students' signed informed consent. The consent form includes the proviso that students may choose not to participate and warns of non-existent risks. (No data are collected; no research is performed. The only purpose of the exercise is to educate the students.)
- Anonymity of subjects has been required for oral histories in which a single individual is interviewed about a historically significant event in which he or she was a key participant.

How could such "mis-regulation" occur? IRB members in previous years usually employed appropriate judgment in these sorts of matters. What happened? What are the philosophical, regulatory or political foundations of this overly broad and strict application of research regulation? Why would IRBs, which have already overworked and understaffed, frequently create such needless, time-consuming, and counter-productive work for themselves and others? Why do they not allocate a larger proportion of their time to overseeing high-risk research?

Some History

The federal regulations were developed based on the ethical principles set forth in the Belmont Report. This report, the capstone document prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,[6] sets forth the following ethical principles governing human research: respect for persons, beneficence, and justice.[7] Respect for persons is upheld primarily by communicating to potential subjects the information a rational person would want in order to decide whether to participate. The information should be in language the person can readily understand, and brief enough that the individual will actually attend to it. Although university attorneys may recommend several pages of informed consent verbiage, participants in simple social or behavioral studies tend to respond to such a lengthy consent document by signing without reading it. It is just such conflicting mandates – between common sense interpretation of the regulations and Belmont principles versus the self-protective and self-defeating requests of university lawyers – that have placed IRBs between the rock and the hard place. What is it about the federal regulations and the current regulatory environment that has caused this unfortunate state of affairs?

Interpreting the Belmont Report into Federal Regulations

The current regulations, 45 CFR 46, Subpart A (known as the Common Rule) were written to interpret the "Belmont principles" into regulations of human research funded by HHS (then HEW). The source of greatest risk to human subjects is biomedical research, which is mainly sponsored by HHS. Hence the federal regulations of human research were written primarily with biomedical research in mind. There was some debate concerning whether to have a separate set of regulations for social and behavioral research. The authorities decided to have just one set of regulations. To accommodate social and behavioral research (which is often but not always of minimal risk) under the same regulations, IRBs were given the prerogative of formally exempting some research from the regulations, of conducting expedited review, and of waiving the requirement of signed consent under certain reasonable circumstances (45 CFR 46.116(c), 117(c)). However, these provisions are not particularly easy to interpret. The analogy to diffi-

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cult-to-interpret road signs is germane. For those who wrote the regulations or who regularly interpret them, the interpretations are simple and obvious. For everyone else they are highly confusing.

The biomedical focus of the regulations has always posed problems for social scientists since biomedical (especially clinical) research requires standards that are often inappropriate for social and behavioral research. Although problems existed in the 1970s through the 1990s, it seems that more flexibility prevailed during these years. IRBs tended to interpret the regulations in ways that were not unduly restrictive of social and behavioral research. More IRBs exercised their prerogative to exempt research, conduct expedited review, or waive the requirement of a signed consent form as permitted under the regulations, when appropriate.[8] For example, paragraph (2) of 46.117(c) states that the IRB may waive the requirement for a signed consent form

...if the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context."

Much if not most social and behavioral research presents no more than minimal risk. The regulations also permit IRBs to exempt specified categories of research and to conduct expedited review. These alternative provisions, buried far into the regulations, and difficult to interpret, posed no problem for IRBs in the first decades of regulation. The IRBs simply used common sense, which produced results consistent with the regulations.

Subpart A of 45 CFR 46 has now been incorporated into the regulatory structure of 17 federal agencies.[9] Subpart A, known as the Common Rule, as well as the rest of 45 CFR 46 (Subparts B, C and D) may be found at http://ohrp.osophs.dhhs.gov/ under Policy Guidance. The Common Rule sets forth the role and operation of the IRB, the required elements of the research protocol and the informed consent, and general criteria for IRB review and approval.

The diverse agencies that now operate under the Common Rule perform or fund a range of research, including biomedical, social, behavioral, product and drug testing research. However, some of the IRBs that were created to review the social and behavioral research done by or funded by these agencies interpret the requirements of the Common Rule in a manner more appropriate to high risk biomedical research, ignoring the flexibility available to them in the Common Rule. They impose requirements more appropriate to risky clinical than to minimal risk social-behavioral research. For example many IRBs, in their effort to "go by the book," routinely require a signed consent form even when this would not attain any of the Belmont goals and would be inappropriate (i.e., in low risk survey research).

Within mainstream Western culture, Singer[10] and Trice[11] have found that a significant number of subjects refuse to participate in surveys, or in studies and experiments, respectively, if required to sign a consent form, but would gladly participate otherwise. Among subjects who willingly sign documents, most sign the consent form without reading it.

After all, why bother when comprehending the consent form might be the most difficult and challenging part of participation in otherwise innocuous or enjoyable research ? Some cultures consider it insulting to sign an agreement, as though one's word were not to be trusted. Other cultures, such as Native Americans, have had bad experiences, e.g., loss of land, as a result of signing documents, and might gladly participate in a study but refuse to sign a consent form. Although informed consent (in the form of clear, appropriate communication) is a critical requirement, the way in which this requirement is sometimes enforced at present (e.g., as a legalistic, incomprehensible, long consent form) raises instead of minimizes problems. In an effort to get a signed consent form, some IRBs have prevented the research from going forward or demanded a form which actually created the anxiety the form is supposed to ameliorate.

The Current Regulatory Climate

In recent years, the HHS Office for Protection from Research Risks (OPRR) and its successor, the Office for Human Research Protection (OHRP), have suspended the federally funded research of entire institutions for lack of compliance with federal regulations. While the events that triggered such suspensions typically consisted of a continuing pattern of neglect of the rights and welfare of human subjects, the offenses that could be proven or documented often consisted of inadequate paperwork practices of the IRB. These highly publicized and costly sanctions against research institutions had the effect of creating a climate of anxiety in the human subjects enterprise. Institutions and IRBs often adopted a highly conservative approach, rather than reaching reasonable decisions. There has been a growing tendency to follow what is felt to be the letter of the basic regulations rather than the spirit of the Belmont principles.

More recently, several tragic cases of deaths of human subjects of biomedical research were in the news.[12] These cases, and the aggressively reported shut-downs of entire research programs, heightened the interest of the public and the fear of IRBs. New interpretations sprang into the IRB culture. For example, the "secondary subject" requirement arose in some IRBs, which routinely deemed it necessary for the researcher to obtain the informed consent of any person about whom the primary subject was asked for information of a private nature. This interpretation would endanger the "primary subjects" of research on domestic violence, and made it difficult to do epidemiological research. Other effects of this new regulatory climate include much bureaucratic iteration before a protocol is approved, disapproval of minimal risk student research, and IRB interference with normal (non-research) classroom instruction. If IRB oversight is to protect human subjects, its major focus should be elsewhere — on high risk research.

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In the current regulatory climate, many IRBs treat all social and behavioral research as if it were very risky. They interpret the Common Rule as literally as possible, ignoring any cultural or procedural inappropriateness this may entail, and generating an extensive paper trail to prove that they have done what they construe the Common Rule to require. Inappropriate demands are placed on researchers and subjects that do not address what should be the focus on the enterprise: the protection of participants in research activities. Some results of this environment of fear include (a) a self-defeating quest for entirely risk-free research in a world where nothing is entirely risk free, (b) long delays in approving protocols, and (c) extremely bureaucratic interpretations of the requirement of informed consent. These three problems are intertwined. The focus on very minor or unlikely risks has resulted in lengthy negotiations between IRBs and investigators, and overly detailed, insultingly paternalistic informed consent procedures. This practice is ultimately abusive to subjects, the researcher, the institution, and the public interest. Fortunately, IRBs and researchers can return to true interpretation of the Belmont Report under the Common Rule, if they make use of the flexibility it offers for reasonable interpretation of its requirements.[13]

Flexible Interpretations of the Common Rule

Various groups have sought to develop interpretations of the Common Rule that are reasonable for the social sciences. For example, the National Science Foundation (NSF) has developed a set of FAQs (frequently asked questions) about the Common Rule, which appear on the NSF website (*http://www.nsf.gov/bfa/cpo/policy/hsfaqs.htm*). Such interpretations are based on a few basic principles such as the following:

IRBs should balance level of oversight with level of risk.

Informed consent should take the form of an open, easily understood communication process.[14]

All subjects should receive enough easily understood information to judge whether the risk-such as it exists in the project- is at a level they can accept.

When the subject can readily refuse to participate by hanging up the phone or tossing out a mailed survey, the informed consent can be extremely brief.

The cultural norms and life-styles of subjects should be considered in deciding how to approach informed consent. Protocols for research on such populations should show evidence that the researcher is informed about the culture of the intended research population and has arranged the informed consent and other research procedures accordingly.

In some situations, it may be desirable for the researcher to consult with community representatives or leaders first, in order to enhance respect for and well being of individual research subjects.

Some research cannot validly be conducted if all details are disclosed at the outset. Alternatives are to (a) obtain permission to provide only a description of what the subject will experience, with an agreement that the full details of the study will be disclosed afterward; (b) obtain permission to engage in concealment or deception with the understanding that peers of the subject do not find such concealment or deception objectionable and that a full explanation will follow participation, (c) to explain that the subject might be enrolled in one of several possible conditions as in placebo research.

In certain circumstances, persons are not in a position to decide whether to consent until after their participation. This includes brief sidewalk interviews which persons are likely to welcome. Deferred consent is an option.

Principles such as these have been set forth, and explained and described more fully in various contexts such as the National Science Foundation's FAQs. Will IRBs begin to use them?

We hope so.

References

[1] The material in this article is the personal opinion of the authors and does not necessarily represent the policy of their organizations.

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[5] Each of these cases was reported to the authors by researchers. Details such as names of persons and institutions are omitted to protect privacy.

[6] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report (Washington, D.C., 1979.

[7] *Beneficence* requires that the projected benefits of the research, such as they may be, outweigh the risks. *Justice* requires fairness of procedures and fair distribution of risks and benefits among those affected by the research.

[8] The Common Rule states that the following kinds of research projects are exempt: research in educational settings involving educational practices, and research involving educational tests (cognitive, diagnostic, aptitude, achievement) surveys, interviews, or observations of public behavior. However, the exemption does not apply if specific individual human subjects can be identified (i.e., their names, phone numbers, or other unique identifiers are recorded in the data and if disclosure of their identity could place them at risk of criminal/civil liability, or damage to their financial standing, employability or reputation. When subjects are public officials or candidates for office, the research is exempt even when identifiers are included or disclosure might be harmful.

[9] Upon becoming part of the code of one of the other 16 agencies, the DHHS code is replaced by the code of the other agency. Thus HHS' 45 CFR 46 becomes 45 CFR 690 for NSF, 34 CFR 97 for Education, etc. The text remains the same.

[10] Eleanor Singer, "Informed consent: Consequences for response rate and response quality in social surveys," *American Sociological Review,* 43, 144-162 (1978).

[11] T. R. Trice, "Informed Consent. VII. Biasing of Sensitive Self-report Data by Both Consent and Information," *Journal of Social Behavior and Personality* 2, 369-374 (1987).

[12] A (relatively ill) young man named Jesse Gelsinger died while involved in research at the University of Pennsylvania; a (healthy) young woman named Ellen Roche died while involved in research at The Johns Hopkins University hospital.

[13] See above for the regulatory provisions that grant these prerogatives.

[14] This could take many forms. For example, if conducting a housing study of elderly people at a retirement community, the PI should be mindful of the safety needs of elders, and of possible memory, auditory and visual impairment. They might begin by holding a meeting at the community's meeting center to explain the purpose of the interviews and answer any questions. They might arrange with the management to have the discussion written up in the community's newsletter, with photos of the interviewers, to be distributed to all residents. In preparation for the interview, the interviewers might then make initial contact with individual households by phone or letter. Upon arriving, they might bring along the article so that the elderly residents could ascertain that they are admitting bona fide interviewers and not con artists. The interviewers might then provide a brief summary of their purpose, confidentiality and other pertinent elements of consent, obtain the verbal consent

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of respondants and proceed.

In other cases, venues such as focus groups, group discussions or other kinds of gatherings might serve as the most effective way to gain potential subjects' interest and attention, provide details and answer questions. The actual recruitment and consent or declination could occur at a later time after the details have been carefully considered. In still other cases, as among homeless or other wary groups, meeting with informal leaders or gatekeepers of the group can serve as a first step in getting word to potential subjects about the nature and purpose of the research and what it would entail. This might then be followed up with other meetings, and finally with recruitment and individual informed consent or declination.

In still other kinds of research, especially when the research procedures are lengthy and complex, brochures, videotapes, simulations, and discussion with prior subjects may be the effective ways to begin communication with prospective subjects.

IN THE NEWS

DOJ WEIGHS IN ON CLONING DEBATES

On May 15, 2002 the Attorney General's Office for the Department of Justice (DOJ) submitted a recommendation to the House subcommittee on Criminal Justice Drug Policy and Reform proposing a ban on embryonic cell cloning. The testimony of Daniel J. Bryant, Assistant Attorney General to the Office of Legislative Affairs, called for an outright ban to all cloning activity, citing the difficulties with law enforcement. Mr. Bryant argues, *inter alia,* that it would be difficult to ascertain the true intent of scientists if the ban is only in place for the "purpose of creating a cloned human being."

Intent, or *mens rea,* is a requisite element for any criminal offense. If the intent is lacking or ambiguous, it would be exceedingly difficult for law enforcement authorities to establish that those performing a clonal implantation did so with the requisite *mens rea* at the time the procedure was performed. Additionally, Mr. Bryant argues that the cloned embryos could be exported abroad and used to produce cloned human beings. Mr. Bryant states, "once a pregnancy were established, any government-directed attempt to terminate a cloned embryo in utero would create problems enormous and complex."

The Department of Justice is for obvious reasons more concerned with the law enforcement problems surrounding cloning, than in the benefits and advancement of science. Mr. Bryant acknowledges that in-vitro fertilization is a lawful means of conception. This however, poses a problem for government prosecutors interested in preventing cloned embryos from entering the uterus since there does not seem to be "any reliable means for determining the difference between a fertilized embryo and a cloned embryo."

There are currently two bills pending before Congress on "human cloning." Although both bills propose a ban on human cloning, there are important distinctions between the two that could have significant ramifications on the ability to conduct scientific research. Senator Brownback has sponsored a bill (S. 1899) that defines human cloning as introducing genetic material from one of more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism that is genetically virtually identical to an existing or previously existing human organism. Senators Specter, Feinstein, and Kennedy have introduced comparative legislation (S. 2439) that bans implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus for the purposes of producing a human clone.

The difference between the bills lies in the distinction that S.1899 defines human cloning as the transfer of genetic material into an oocyte, a fertilized egg, rather than the implantation of the fertilized material into a uterus, as S.2439 does. The distinction is important because the former prevents the growing and culturing of human embryos, that is a fertilized egg past its initial stages when the cells begin splitting. Whereas the latter specifically prevents the transfer of the egg into a uterus that could lead to a human life.

Proponents of S.1899 argue that once embryos are grown and cultured there is no way to keep track of where they go or how they are used. Specifically, they contend that once a "living organism" is produced by genetic manipulation, the embryos could be frozen in time, or sold abroad to produce human beings at a latter time. The opponents of the bill suggest that embryonic human cell cloning is not the same as growing and cultivating a human being, and could accelerate possible medical breakthroughs. As *Professional Ethics Report* went to press debates on the two bills were stalled in the Senate.

The legislation recommended by the DOJ (S.1899) would impose a threat to scientific research by levying criminal and civil sanctions on scientists who attempt to clone human cells for the purpose of scientific research. Proposed criminal penalties include fines or imprisonment for not more than 10 years. Civil penalties for violations that involve a pecuniary gain carry fines of a minimum of $1,000,000. The "criminalization" of scientific research and scrutiny by government officials might severely limit the scope of existing stem cell research if scientists and their institutions are intimidated by the threat of imprisonment or stiff fines. *IK*

REMODELING OHRP

On April 17, Greg Koski, director of the Office for Human Research Protections (OHRP), announced a new "Quality Improvement (QI) Program" that will be offered voluntarily to institutions and independent Institutional Review Boards (IRBs) to improve human research protections.

The QI Program aims to increase the operation and efficiency of human subjects protection programs provided by IRBs and institutions that conduct biomedical, behavioral and social research by offering consultation and support. The Program will assist IRBs and institutions to ensure compliance with federal regulations, as well as assist in preparing institutions to attain accreditation of their human protection programs by private accrediting bodies.

The QI Program contains three stages: quality assurance, quality improvement, and continuous quality improvement. The first stage will assess an institution's human subjects protection program and offer guidance to instruct the institution on how to conduct future assessments by means of a quality self-assessment tool developed by OHRP. Essentially, the quality self-assessment tool is a form designed to assess and gauge the compliance of an institution or IRB with federal regulations.

The second stage identifies an institution's strengths and weaknesses as well as other mechanisms to help improve the functioning of an institution's human subjects research protection program. The quality improvement stage fosters a network of sharing best practices and procedures between institutions, but on a voluntary basis. The third and final stage offers guidance to the institution to develop its own quality improvement program to ensure

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continued quality, performance and efficiency.

OHRP is currently scheduling QI consultations on a voluntarily basis, while waiting for final approval of the quality self-assessment tool by the federal Office of Management and Budget (OMB). Information voluntarily provided to the QI Program may be considered exempt from the Freedom of Information Act (FOIA), but exempt status is dependent upon approval by OHRP FOIA officials.

The move from a system based on regulatory compliance to a system based on prevention from harm reflects the commitment of OHRP to transform human research protections to meet the ever-changing ethics associated with advances in science and technology.

For further information about the Quality Improvement Program, visit the OHRP website at http://ohrp.osophs.dhhs.gov. *KA*

NSF CHANGES RESEARCH MISCONDUCT POLICY

On March 18, the *Federal Register* published the National Science Foundation's (NSF) final rule outlining changes to 45 CFR Part 689, which covers research misconduct.

The changes implement the scientific misconduct guidelines for federally funded research found in the federal policy on research misconduct, issued by the President's Office of Science and Technology Policy.[1]

The following changes outline the elements required for a finding of research misconduct: "A finding of research misconduct requires that – (1) There be a significant departure from accepted practices of the relevant research community; and (2) The research misconduct be committed intentionally, or knowingly, or recklessly; and (3) The allegation be proven by a preponderance of evidence."[2] A noteworthy portion of (1) is the "significant departure" language. Because the definition of "research misconduct" is "fabrication, falsification, or plagiarism…"[3] (FFP[4]), the first step leading to a finding of research misconduct demands that the FFP advance to the point of "significant departure."

Additionally, concerns regarding the standard of proof in (3) were addressed in response to comments to both the federal policy and to NSF's proposed rule. The federal policy and NSF adopt the "preponderance of the evidence" standard as the level of proof that must be established for a finding of research misconduct. As "clear and convincing evidence" and "beyond a reasonable doubt" are more demanding standards, some commenters suggested that one of them be implemented. Those raising the issue were concerned that the adopted preponderance standard, because of its leniency, would increase the likelihood of false findings of research misconduct. However, the preamble to the federal policy[5] explains that "preponderance of the evidence" is the standard for most civil fraud cases as well as many federal administrative proceedings (including debarment). *HL*

[1] 65 FR 76260-76264.
[2] 45 CFR 689.2 (c).
[3] 45 CFR 689.1 (a).
[4] *Science*, October 15, 1999, p. 391.
[5] 65 FR 76262.

MINORITIES UNDERREPRESENTED IN CLINICAL TRIALS

According to a recent study published in the May 2 issue of the *New England Journal of Medicine*, non-Hispanic blacks and Hispanics are less likely than non-Hispanic whites to participate in HIV-related research trials or to receive experimental HIV treatment. The study, led by Allen L. Gifford, M.D., of the Veterans Affairs San Diego Healthcare System, is the first to analyze nationally representative data in order to examine such racial disparities.

While researchers estimate that 14 percent of the 231,400 HIV-infected adults receiving care in the United States in 1996 participated in a medication trial and 24 percent received experimental medications through a trial or expanded-access program, study results indicate distinct racial and ethnic disparities in accessing such experimental treatments. In 1996, blacks constituted 37 percent of patients with AIDS whose cases were reported to the CDC. Yet blacks accounted for only 33 percent of patients reported as receiving care for HIV infection and only 23 percent of those who participated in treatment trials. White patients, making up 44 percent of reported HIV cases, represented 49 percent of those receiving care for HIV infection and 62 percent of patients enrolled in clinical trials.

The study also reports that 8 percent of HIV-infected patients tried and failed to receive treatment and that those patients who were white, who possessed a higher level of education, or who had a higher income were more likely to obtain experimental medications. Additionally, 77 percent of white patients seeking experimental medications were able to acquire them, whereas only 69 percent of black patients were able to do so.

In addition to race, the research team found that other factors had considerable influence on the extent to which participants would participate in medication trials. Those patients who had received less than a high school education, possessed private insurance through an HMO, and sought primary care eight miles or more from a major clinical trial center "were each associated with a reduction of about 50 percent in the likelihood of participating in a medication trial." Like the black patients looked at in the study, these patients were more likely to withdraw from or terminate participation in clinical trials.

Of particular concern is the extent to which minority groups are being underrepresented in HIV treatment studies and the implications of such disparities in applying clinical research to the general patient population. What's more, the lack of minorities in clinical HIV treatment studies prevents such groups from accessing new and potentially beneficial treatments. In the case of HIV, for which there are few options for conventional treatment, experimental therapies are often the only means by which patients can obtain effective medication. The research team suggests that "innovative and culturally sensitive methods of communicating the benefits and risks of research to minority-group patients could be helpful, and consideration should be given to expanding such efforts."

Researchers studied a nationally representative sample of 2864 persons, interviewing subjects three times between 1996 and 1998. The full report can be found in the May 2 issue of the New England Journal of Medicine, Vol. 346, No. 18. *DG*

ETHICS, LAW AND PUBLIC POLICY

PETA UNDER SCRUTINY

By Deborah Runkle and Parisa Morris

Non-profit organizations typically do not steal trade secrets, encourage arson, physically harass business executives, or support terrorists. However, these are some of the activities attributed to People for the Ethical Treatment of Animals (PETA) in a 12-page complaint to Charles O.

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Rossotti, Commissioner of the Internal Revenue Service (IRS), from the Center for the Defense of Free Enterprise (CDFE). *(1)* In its letter to Rossotti, the non-partisan group documents more than a decade of questionable charitable activity, illustrated by arrests of PETA members for acts of criminal mischief, burglary, criminal impersonation, disorderly conduct, and trespassing. The CDFE urges the IRS to revoke PETA's status as a 501(c)(3) tax-exempt organization. In support of its argument, CDFE cites a 1980 decision from the Fourth Circuit Court of Appeals, *Bob Jones University v. United States*, to the effect that in order to merit a charitable exemption an organization's actions must not be in violation of public policy.

Founded in 1980, PETA's underlying principle is that "animals are not ours to eat, wear, experiment on, or use for entertainment." *(2)* PETA's co-founder and president, Ingrid Newkirk, is perhaps best known for her statement that "[S]ix million people died in concentration camps, but six billion broiler chickens will die this year in slaughterhouses." *(3)* Since its founding, PETA has used a variety of in-your-face methods to promote its cause, not least of which are tasteless ad campaigns. *(4)* Commenting on fires set in research laboratories, Newkirk says, "I wish we all would get up and go into the labs and … burn them down," and claims that she would join the arsonists if she had "more guts." Other top PETA directors have openly promoted illegal acts, such as burglary, arson and property damage, as acceptable means to advocate for animal rights. Indeed, one PETA official, Bruce Friedrich, responded to animal rights activist Freeman Wicklund's call for non-violence by labeling it "obscene." Friedrich again: "Of course we're going to be blowing things up and smashing windows….I think it's a great way to bring about animal liberation….Hallelujah to the people who are willing to do it."

In today's climate, however, attention has focused on PETA's relationships with two groups that have been named by the FBI as major domestic terrorist threats, the Animal Liberation Front (ALF) and the North American Earth Liberation Front (ELF). PETA has provided over $100,000 in legal funds to ALF members arrested in connection with a 1986 raid at the University of Oregon and the destruction of a lab at Michigan State University in 1995. In addition, PETA has served as an information conduit for ALF, providing statements to the press on behalf of the underground group. ALF has admitted to over 130 criminal acts in 2001 alone, labeling 43 of them as "major." *(5)* In fact, ALF boasts of these activities.

PETA also has ties to ELF, the eco-terrorist sister group to ALF. For example, the release of PETA's Form 990 for FY 2001 shows a payment of $1,500 to ELF, which has recently joined forces with ALF. PETA spokeswoman Lisa Lange claims the money was used for an ELF project of habitat protection, while PETA attorney Jeffrey Kerr says the money was used to assist in the legal defense of ALF spokesman, Craig Rosebraugh. In any case, PETA contends that none of this money was used for illegal purposes. According to the FBI, ELF has committed more than 600 criminal acts, causing over $43 million of damage since 1996. *(6)* ELF's website shows a building engulfed in flames, followed by pages listing numerous acts of arson and property damage claimed by the terrorist group, as well as how-to articles on setting fires and on what to do when questioned by federal investigators. *(6)*

The House of Representatives is also paying attention to ALF/ELF and their links to PETA. On February 12, 2002, the House Subcommittee on Forests and Forest Health, chaired by Representative Scott McInnis (R-CO), held an oversight hearing on Eco-terrorism and Lawlessness on the National Forests. In testimony at the hearing, FBI counterterrorism chief James Jarboe identified ALF as "a terrorist group, whose purpose is to bring about social and political change through the use of force and violence." McInnis stated his view that ELF and ALF are dangerous groups that use violence to promote a radical agenda, and he warned that not only were the FBI and other law enforcement agencies watching these groups, but Congress was no longer going to ignore their actions. And while no human life has been lost to date in an ALF or ELF attacks, Jarboe and McInnis are not optimistic for the future and fear that if the terrorist activities increase, the loss of a human life is inevitable. ELF's Rosebraugh was also called to testify but, invoking the Fifth Amendment, answered only a few questions. In a later ALF/ELF press release, Rosebraugh said "the United States government is the most extreme terrorist organization in planetary history."

Following the hearing, and with the discovery of PETA's link to ALF and ELF, Rep. McInnis sent a letter to Newkirk asking her to respond to seven specific questions concerning these links. In his letter McInnis said "PETA has a responsi-bility to explain the full extent of its involvement with and contributions to environmental terror groups like ELF and ALF." *(7)* PETA has charged McInnis with engaging in a "new McCarthyism." Further, in responding on behalf of Newkirk, attorney Kerr denied that PETA assisted any terrorist organization, saying that "[a]ny suggestion to the contrary is simply wrong, defamatory, and the product of lobbyists, public relations consultants and other paid spokespeople for animal-exploitive industries."

McInnis is awaiting further action by the IRS before planning next steps.

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3. DeWeese, Tom. "PETA, Sharks, and a Cure for Cancer." CNSNews.com Commentary. September 6, 2001.
4. Examples include ads implying that former New York City Mayor Rudy Guiliani contracted prostate cancer from drinking milk, urging people to drink beer rather than milk, and implying that injuries to humans from sharks are deserved.
5. Moran, Ken. "Stopping Animal Rights Radicals." New York Post. March 8, 2002.
6. http://www.earthliberationfront.com
7. Jarboe, James F. Statement before the House Resources Committee Subcommittee on Forests and Forest Health. February 12, 2002. http://resourcescommittee.house.gove/107cong/forests/2002feb12/jarboe.html.
8. McInnis, Scott. Letter to Ingrid Newkirk. March 4, 2002.

IN THE SOCIETIES

AAAS HOSTS LEON KASS

Leon R. Kass, chairman of the President's Council on Bioethics, spoke on April 23 at a meeting of the Professional Society Ethics Group (PSEG), sponsored by the Scientific Freedom, Responsibility and Law Program at AAAS. Comprised of participants from numerous government agencies, academic institutions and professional societies, PSEG serves as a forum for discussing ideas relating to professional ethics.

Kass began by providing insight about the charge of the President's Council on Bioethics, which is to advise the President on bioethical issues raised by advances in biomedical science and technology. The Council consists of seventeen leading ethicists,

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(**SOCIETIES** continued from page 6)
philosophers, theologians, physicians, and scientists. Members are charged with the short-term goal of exploring the issue of human cloning and experimentation of cloned human embryos, as well as the long-term goal of providing guidance to the President and developing terms of discourse on matters of how to approach and do bioethics.

The President's Council, in Kass's view, is not a council of bioethicists but a council on bioethics. It is a heterogeneous group of individuals from various disciplines and backgrounds who recognize the importance of the ethical issues that arise from the intersection of biology, biotechnology, and life as humanly lived. Moreover, the posture of the Council is neither reactive nor regulatory, but rather seeks to undertake fundamental inquiry into the full moral significance of developments in biomedical and behavioral science and technology. The culmination of its inquiries will be the Council's reports to the President.

In seeking to develop an understanding of all moral positions, Kass emphasized that Council members are not required to reach a consensus. Rather, members develop and present intelligent arguments to allow deeper reflection on the complex issues at hand and defend those arguments against competing moral positions. One can envisage the Council as a microcosm of the pluralistic and often competing moral viewpoints representative of American democracy. Kass noted that all meetings are open to the public and that all viewpoints are welcome.

For additional information on Council members, transcripts of past meetings, and future meeting times and places, see http://www.bioethics.gov/.

For further information on PSEG and the SFR&L program, see http://www.aaas.org/spp/dspp/sfrl/SFRL.htm. *KA*

RESOURCES

UTOPIA, DYSTOPIA, OR JUST THE NEXT STEP?

Redesigning Humans: Our Inevitable Genetic Future &
Our Posthuman Future: Consequences of the Biotechnology Revolution

When you turned 13, your parents told you that it is time you "had a little talk." Not the bird and the bees, nobody is getting divorced, it is not even that you are adopted. Instead, it is that you are a clone—genetically identical to your long-deceased great-grandfather Howard, who both your mother and father loved madly.How do you feel about this news? Are you an identical twin, separated in time? A victim, robbed of your individual genetic identity?

These questions, and others like them, are increasingly being posed in the public sphere as biotechnological innovations offer a glimpse into a world where we might modify our own biology (and that of our offspring) for a variety of purposes, including better health, longer life, and disease resistance. We may also choose to modify our children's intelligence, clone a lost child, or select among a number of possible embryos for that one which best fits our own needs.

Two recent books have addressed the questions raised by biotechnologies head on, albeit from very different perspectives. Gregory Stock's new book, *Redesigning Humans: Our Inevitable Genetic Future*, takes a generally pro-enhancement position, while recognizing the need for some caution. Stock enthusiastically endorses the development of technology and knowledge that would ultimately allow people to enhance and modify their own capabilities and abilities to an unprecedented degree. Frank Fukuyama, on the other hand, takes a more skeptical view, expressing great concern that the "biotechnology revolution" holds substantial risks for humanity, and should be tightly regulated at the national, if not international, levels. Fukuyama's book, *Our Posthuman Future: Consequences of the Biotechnology Revolution*, raises the question of who and what we are if we are "enhanced" by biotechnological means.

Both Stock and Fukuyama raise interesting questions about the future and acceptable uses of "enhancement technologies," and are likely, at least in the immediate future, to drive the debate on the issue. Their approaches to the topic are very different, with Stock focusing much more on the technologies and their potentials from a science perspective, while Fukuyama looks more at the possible impact on culture and society from a policy perspective. Both authors make cogent and sensitive arguments, and it is clear that they were in contact while writing the books (each acknowledges and thanks the other in their respective books).

There are a number of tensions between the two perspectives of the authors that are worth noting, as they serve to give a sense of the scope of the inquiry. Among the tensions:

- the effects and potentials of enhancements on individuals (Stock) v. the political and societal results (Fukuyama);
- a focus on scientific developments and potentials (Stock) v. a focus on moral and ethical questions regarding human nature and what it means to "enhance" (Fukuyama);
- a call for scientific freedom and a somewhat laissez faire attitude towards enhancement (Stock) v. a call for strict and comprehensive regulation (Fukuyama);
- and finally, a fundamental difference in the potential outcome of the "biotechnology revolution"–an unlimited possible benefit (Stock) v. a massive risk of the commodification of people, with a resultant loss of humanity and diminishment of "human nature" (Fukuyama).

The two books, taken together, offer a more full perspective than either does alone. Stock stakes out a position that could be described as "it's inevitable, so let's get the greatest possible benefit." Fukuyama, on the other hand, draws an analogy to the awesome power of atomic weaponry, an "inevitable" technology that we have chosen to tightly regulate and control in order to keep the world a safer place. The difference between these two positions serves to reflect the two modes of thought currently dominant in the public discourse, and are important reading for anyone interested in the ethical challenges currently posed by biotechnology.

Bibliography
Fukuyama, Francis, *Our Posthuman Future: Consequences of the Biotechnology Revolution*, New York: Farrar, Strauss, Giroux, 2002. US$25.00

Stock, Gregory, *Redesigning Humans: Our Inevitable Genetic Future*, Boston: Houghton Mifflin, 2002. US$24.00. *BG*

ANNOUNCEMENTS

Conference – The **Association of American Medical Colleges (AAMC), Office for Human Research Protections (OHRP), and Office of Research Integrity (ORI)** are co-sponsoring "Fostering Integrity in Clini

(Announcements continue on page 8)

Professional Ethics Report

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(**Announcements** continued from page 7)
cal Research at Academic Medical Centers" on September 9-10, 2002 at the Radisson Plaza Hotel near the Inner Harbor in Baltimore, MD. This conference will help institutions plan coherent activities for addressing integrity issues in clinical research. Speakers will discuss improved protocol design, oversight mechanisms, educational techniques and practical approaches to running well-managed clinical research trials. Anyone who is responsible for overseeing the collection and handling of clinical research data would benefit from attending this meeting. Dr. Eve E. Slater, Assistant Secretary for Health, will give the keynote address. For more information about the agenda or to obtain registration materials, contact Ms. Tracy Morgan, phone 301-443-5330, fax 301-594-0039, or email tmorgan@osophs.dhhs.gov.

Workshop – The **Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), Department of Veteran Affairs, and North Shore-Long Island Jewish Health System** will host "Protecting Human Research Subjects: Whose Responsibility is it Anyway?" from July 10-12, 2002 in Garden City, Long Island. The workshop aims to educate those responsible for conducting clinical research in regulatory and ethical issues in order to enhance the integrity of research programs. For registration and information, see WWW *http://www.northshorelij.com/cme/IRB*.

Call for Funding Applications – The **Office of Research Integrity (ORI, DHHS),National Institute of Neurological Disorders and Stroke (NINDS, NIH), National Institute on Drug Abuse (NIDA, NIH), and National Institute of Nursing Research (NINR, NIH)** invite applications to support research on research integrity. The proposed grant program intends to promote empirical research on the institutions, processes, and values that affect integrity in research. The application deadline is Friday, November 15, 2002. Those in the social sciences are encouraged to apply. The latest announcement and application details can be found on the NIH website:
WWW *http://grants1.nih.gov/grants/guide/rfa-files/RFA-NS-03-001.html*.

Conference – The **Office of Research Integrity (ORI)** is sponsoring a conference entitled "The Role of Institutional Rules, Guidelines, and Education in Promoting the Responsible Conduct of Research" on September 23-24 in Philadelphia, PA. The conference is part of a threefold effort to stimulate thinking and discussion about the usefulness of research guidelines in preventing misconduct and promoting the responsible conduct of research, and is a followup to the report Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components. This effort will include the development of a resource document for developing effective guidelines that will be based, to some extent, on the completed analysis of the medical school research guidelines. Registration must be submitted by September 13, 2002. The fee is $130. For more information, please see the conference website at WWW *http://www.rowsciences.com/ORIconference/home.html*.

Support From the Following Societies and Organizations is Gratefully Acknowledged:

American Anthropological Association
American Association of University Professors
American Political Science Association
American Psychological Association
American Psychological Society
American Society for Engineering Education
American Society for Microbiology
American Statistical Association
Botanical Society of America
National Society of Professional Engineers

Call for Proposals – The **Association for Politics and the Life Sciences (APLS)** will hold its annual meeting from August 11-14, 2002 in Montreal, Canada. Panels are being formed on a range of topics in the categories of: Evolution and Social Behavior; Environment and Population; Bio-ethics; Life Sciences, Health, and Public Policy; Bio-terrorism; and Bio-technology. For more information about the Meet ing and registration, visit WWW *http://www.aplsnet.org* and click on the APLS 2002 logo.

Workshop – The **University of Minnesota Center for Bioethics and The Hastings Center** are co-sponsoring "Exploring Ethics and Public Health: An Intensive Workshop," from July 14-17, 2002. The workshop will provide an opportunity for intensive study and discussion of approaches and frameworks for ethical issues in public health, including: Responses to Bioterrorism; Infection Disease Control; Genetics – Screening Programs and Individual Testing; Research and Practice – Domestic and International Settings; and Teaching Ethics and Public Health. For more information, contact the Center for Bioethics, University of Minnesota, 410 Church St. SE, N504 Boyton, Minneapolis, MN 55455-0346; (612) 624-9440; fax (612) 624-9108; Email bioethx@umn.edu, WWW *http://www.bioethics.umn.edu*.

Conference – An **International Conference** entitled "Between Technology and Humanity: The Impact of New Technologies on Health Ethics" will be held from October 18-19, 2002 in Brussels, Belgium. The conference will analyze the interaction between technology and humanity in care practices, beginning with a philosophical-ethical reflection about the possibilities and dangers of new technologies in health care and welfare work and moving to concrete examples that consider ways to integrate these technologies in a care context that is directed to humanity. For more information, contact Caritas Vlaanderen, Guimardstraat 1, 1040 Brussel, Belgium; +32 2 507 01 11; fax +32 2 512 01 18; Email post@caritas.be. *DG*