PROTECTING HUMAN SUBJECTS

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Protecting Human Subjects
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http://www.science.doe.gov/ober/humsubj/newslett.html

FOCUS ON BELMONT REPORT

The December 2003 Public Responsibility in Medicine and Research (PRIM&R) meeting held in Washington D.C. focused on the Belmont Report and ways the research community can fulfill the report's vision for how human subjects should be treated. This issue of *Protecting Human Subjects* reports on some of the discussion at the meeting, which we hope will be useful to those who could not attend.

We hope that by providing this account of issues discussed at the last meeting, it will highlight some of the continuing concerns that will be brought back to the table when PRIM&R meets in San Diego in October 2004.

When the Belmont Report was released 30 years ago by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, it outlined the ethical principles that the Commission believed should govern the conduct of human subjects research. The Belmont Report provides the moral framework that would be applied to the Commission's other reports.

The legacy and the future

30 years after the Belmont Report, Beauchamp sets the record straight

Tom Beauchamp, one of the principal authors of the influential Belmont Report, was the keynote speaker at the annual PRIM&R meeting. This synopsis of his address focuses on the history and effects of the 1978 report, which has strongly influenced the standard of conduct for human subjects research in the United States.

Beauchamp is Professor of Philosophy and a Senior Research Scholar at Georgetown University and the Kennedy Institute of Ethics. In 1976 he joined the staff of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, where he wrote the bulk of the report.

The Commission came into existence in the aftermath of public outrage and Congressional uncertainty over the Tuskeegee syphilis experiments and other questionable uses of human subjects in research.


Tom Beauchamp

The law creating the Commission specified that no more than five of the Commission's eleven members could be research investigators—because there was a great deal of suspicion about the system, which at the time was largely not controlled by regulation. Responsibility for the protection of human subjects was largely left up to individual investigators.

The Belmont Report is best known for its framework of three basic ethical principles: respect for persons, beneficence, and justice. Respect for persons applies to

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informed consent. Beneficence applies to risk–benefit assessment. Justice applies to the selection of subjects. We thought of these principles as universal truths; that is to say, we couldn't imagine that research could be conducted responsibly without following these principles.

Autonomous persons
By the first of these, the Commission demanded, first, that the choices of autonomous persons not be overridden or otherwise disrespected. Second, persons who are not adequately autonomous must be protected by the consent of an authorized third party who is likely to appreciate the subject's circum-stances and who will look after his or her best interests.

The principle of beneficence is an abstract norm with several subrules: do no harm, maximize possible benefits, minimize possible harms, and balance benefits against risk. This principle was thought by the Commission to be satisfied in the research context by refraining from intentional causation of injury and by ensuring that risks stand in reasonable relationship to possible benefits.

The principle of justice has been deeply misunderstood in some writings about the Belmont Report, which did not seek to present a broad theory of justice.

The principle of justice has been deeply misunderstood in some writings about the Belmont Report, which did not seek to present a broad theory of justice. Instead, it is an attempt to protect very vulnerable research subjects.

The principle of justice demands fairness in the distribution of what the Commission conceived of as the burden of research. So it then demands that researchers seek healthy persons best prepared to bear the burdens of research, rather than focus on those groups that have been repeatedly targeted.

A great deal of discussion by the Commission focused on the repeated use of mentally retarded children. Historically, the burdens of research were placed heavily on the economically disadvantaged and the very sick and vulnerable, owing to their ready availability.

The Commission wanted to express the deepest moral concern about this unjustified overutilization of readily available, but often compromised segments of the U.S. population.

For the public good
The theme of justice and proper selection of subjects was Belmont's way of saying that because medical research is a social enterprise for the public good, it must be carried out in a broadly inclusive and participatory way. If participation in research falls on a narrow spectrum of citizens because of their ready availability, then it is unwarranted. Similarly, the Commission recommended that persons who were already burdened by disability or institutionalization not be asked to accept the burdens of research.

By invoking these three principles, the Commission had no ambition to be specific and practical for institutions that conduct research. The practical objectives were to be initiated from the other sixteen reports.

Creating the Belmont Report was a three-stage process: first the very general philosophical underpinnings; then the intermediate documents, many of which were written into federal law; and then the other responsibilities passed on to people who are actually engaged in the practice, whether on Institutional Review Boards (IRBs), in government agencies, or in other forums.

I also want to say something about weaknesses, deficiencies, and unclarities in this report, which you have to remember is very short and leaves a lot of things unanswered.

The principles, in certain respects, run together. There is a little bit of beneficence in respect for persons. Justice, as discussed in the report, is a very truncated notion of justice. Many people who refer to the respect for persons mistakenly construe this principle merely as respect for autonomy. That is really not the way the Commission saw it at all.

A question often raised is whether the Commission too readily used a utilitarian justification of research. We thought a great deal about this problem, about how research should be justified, whether that basis had a utilitarian foundation or other foundations. We concluded that while it could not have a completely utilitarian foundations, some of that justification was necessary to serve the public interest.

The report attempts to do two things. First, serve people who must be protected as research subjects. Second, protect the public's interest for research to be done. Whether or not we succeeded, I don't know. In fact, I don't know whether anybody has ever succeeded in addressing the question of how you protect both of these interests in a very vigorous way.

A possible defect

The report has been criticized as not being utilitarian enough in the sense of not taking sufficient account of research interests. This criticism first emerged during the debates among AIDS activists who did not see research as a burden but rather as an opportunity. This inadequacy is something that I believe was never seriously considered by the Commission. It may be a defect both in Belmont and other documents that don't address this issue.

The enduring legacy of the report is that it has influenced almost every sphere of activity in bioethics; moral theory; and general standards of research, government regulatory activity, bioethics consultation, and even medical practice. Its influence is arguably as extensive in practice as it has been in theory, perhaps more so.

A near canonical role

In federal regulatory oversight and law, the Belmont Report has at times assumed a near canonical role. The Advisory Committee on Human Radiation Experiments noted in 1995 that Belmont provided the framework "for the regulation of the use of human subjects and federally funded research that is the basis for today's system in the United States."

The legacy of the Belmont Report may be most enduring in areas of practice. Federal regulations require that all institutions receiving federal funds for research espouse a statement of principles for the protection of human subjects. Virtually all such institutions have subscribed to the Belmont principles as the basis of their efforts.

Doctor-patient relationship

Professional associations, too, have widely recognized the authority and the historical significance of the Belmont principles. It has been argued that the Belmont principles were a significant force in a broad cultural shift in medicine toward reworking the relationship between the doctor and the patient.

Nevertheless, whatever influence the Belmont Report has had, it is not clear to me that scientists involved in research using human subjects are any more familiar with the actual Belmont principles and the report than their predecessors of several decades ago were with documents such as the Nuremburg Code.

To some, the system seems today caught in a notably similar state of disrepair.

When the Commission deliberated, it seemed that the system of protecting human subjects was in need of serious repair. It was thought that research investigators were not educated about research ethics and that subjects were not adequately protected. To some, the system today seems caught in a notably similar state of disrepair.

Still defective

From 1997 to 2002, a large number of hearings, bills, and reports by official, prestigious government bodies and government-mandated bodies argued that the system of IRB review and practices of informed consent—the core of research ethics we attempted to establish at the Commission—are still seriously defective.

Thus, although the report may have succeeded in resolving some major problems and bringing oversight to the research context, the fix may have been only a temporary and time-bound one. Today the Belmont principles may be more revered than they are actually practiced and understood.Δ

"Today the Belmont principles may be more revered than they are actually practiced and understood."

Susan Rose

The longtime director of DOE's Protecting Human Subjects Program leaves D.C. for the University of Southern California

Susan Rose, who for many years directed the U.S. Department of Energy's (DOE's) Human Subjects Protection Program, accepted a new position as Executive Director of the University of Southern California Office for the Protection of Research Subjects. She began the new position at USC in February.


Susan Rose

During her tenure, Rose was on the committee that drafted the "Common Rule" and set DOE's regulations for protecting human subjects. In the process she organized and established the department's entire nationwide human protection system.

Catalyst for change

Serving on various national committees, she also made DOE's protection program a catalyst for change in other agencies and institutions. During her tenure in the office, she was the only person at DOE Headquarters whose sole focus was protecting human research subjects.

As the program developed, so did her interest in establishing systematic protections designed to prevent recurrences of the kind of research abuses that occurred previously in government-sponsored research. But her main focus was on education, community member outreach, and a DOE-wide working group.

Policies and orders

Rose spent years putting in place the system of policies and orders that today attempt to govern human subjects research at DOE.

Among the most effective parts of the system she established was her emphasis on education.

She organized meetings and panel sessions; developed workshops; established this newsletter; and created publications, brochures, and reports.

She was also a featured speaker at human subjects-related meetings throughout the country.

An important element of the educational effort was her creation of DOE's Protecting Human Subjects Web site (**http://www.science.doe.gov/ober/humsubj/**), which has served as the source for information about the program and related resources.

Rose was also a strong leader in promoting the use of community members on IRBs. To further this, she instituted a Web site (**http://www.orau.gov/communityirb/**) and listserv for issues related to community members. She organized and sponsored a 2002 conference, "The Community IRB Member: Neighbor & Partner."

Those who worked with her say she focused her considerable will on developing a multifaceted approach to disseminating information and sparking discussion.

An important facet of the program that Rose sheperded for more than two decades was establishment of the Human Subjects Working Group (HSWG), a semiformal collection of people directly involved in IRBs, research, and management, and as community members.

All of this was designed to ensure that investigators, IRB members, management, research subjects, and communities took seriously the obligation of protecting human subjects.

The group's purpose was to ensure broad-based support for the program by facilitating communication among the various and disparate elements.

Taking it seriously

All of these efforts were designed to ensure that investigators, IRB members, managers, research subjects, and communities took seriously the obligation of protecting human subjects.

Her longtime friend and colleague, consultant Charles Pietri, said the first time he heard about

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Rose and her program was in 1987 when he got an urgent call for assistance.

She had been given the impossible task of preparing a DOE Policy and Order for the program in two weeks. Pietri and Edward Cumesty, Assistant Manager for Laboratory Management, at the Chicago Operations Office, met with her to talk about codifying in DOE what was already accepted "good practice" in the form of a DOE directive.

Most important contributions

Pietri said her most important contributions included the system of regulations, along with establishment of the HSWG, and her focus on the educational aspects of human subjects research.

But the program really thrived, he said, "because of her enthusiasm, perseverance, creativity, and direction."

Another friend and colleague, Paula Knudson, at the University of Texas Health Science Center's Office of Research Support, said she thinks the program's success was Rose's "unerring capacity to think outside the box and to astonish those of us with more pedestrian approaches to solving problems."

It also helps, she said, that Rose is "not awed by those in authority whose infatuation with power overrides their sense of the possible, and she never lets go of an idea that should be pursued."

Reformulating ideas

Knudson, a member of the HSWG, said she has for many years observed the development of Rose's program.

She said she believes one of the reasons it has worked well is that when her ideas are not received well, "she quickly reformulates the idea and goes at it again and again until she's eventually successful."Δ

News notes

Protecting Human Subjects newsletter wins merit award for design achievement

The DOE newsletter, *Protecting Human Subjects*, was cited for design and editorial achievement in a merit award from the professional association, Society for Technical Communication, East Tennessee Chapter.

The newsletter, published since 1992, has a primary circulation of more than 5,000.

More than 300 entries competed in this year's publication competition. Past issues are available on the Web at **http://www.science.doe.gov/ober/humsubj/newslett.html**.

Renewing federalwide assurances

All Federalwide Assurances (FWAs) expire three years after their approval date. Updates to FWAs should be submitted throughout the three years whenever there are changes in the information provided on the approved FWA.

To check your institution's FWA expiration date, go to the OHRP Web site at **http://ohrp.cit.nih.gov/search/asearch.asp#ASUR**.

To renew an FWA, follow the instructions at **http://www.hhs.gov/ohrp/humansubjects/assurance/renwfwa.htm**, and fax the completed form to OHRP at (301) 402-0438.

If you have any questions, see the staff assignments at **http://www.hhs.gov/ohrp/daqi-staff.html#DC** (bottom of page). You may call the staff person at (866) 447-4777.

ORAU's Hawkins graduates with management degree

Becky Hawkins, the IRB administrator for Oak Ridge Associated Universities in Tennessee, was awarded an Associate of Applied Science Degree in Contemporary Management.

She graduated from Roane State Community College in May 2004 after two years of classes while working full time in her position as administrator of the Oak Ridge Site-wide IRB and the Central Beryllium IRB.

During the same time, Hawkins was studying for and passed her National Association of IRB Managers certification.Δ

Alexander Capron, Director of Ethics and Health at the World Health Organization (WHO) in Geneva, delivered a keynote address at the PRIM&R meeting. He is the author of *Law, Science, Medicine* and *A Treatise on Health Care Law*. He served as the Executive Director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The following is an edited version of his talk.

More issues than ever

WHO's director of ethics says we've come a long way since the horrors of earlier times, but not as far as we like to think

The Belmont Report was published 25 years ago, and although we have come a long way from the horrors that underlie that first attempt in modern times to develop international rules for research ethics, it is neither as far as we think we have come nor as far as we need to go.

We need, for example, to attend both to implementing what we already know we should do and to the problems raised by premises that have not been adequately examined.

Alexander Capron

Historical stages

The conventional view is that the story of protecting human subjects is the story of the IRB's stages of historical development. The first stage was notable for its absence of any meaningful review. The second stage was peer review and review by others. The third was defined by the 1974 National Research Act requiring institutions to establish IRBs.

I thought that IRBs would mean that there would be effective oversight. Instead, during the next 25 years, IRBs came to feel that they were being buried in rules, to very little effect. The fourth stage was adoption of the Common Rule in 1991 and formation of the Office for Human Research Protections (OHRP).

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Have those changes succeeded? Yes, but we are now told that the rules are being over-applied.

The crisis in research

A very useful article was written last year by a team headed by Ezekiel Emanuel, Chair of the Department of Clinical Bioethics at the Warren G. Magnuson Clinical Center at the National Institutes of Health. The article can be viewed at **http://www.bioethics.gov/background/emanuelpaper.html**. It provided a review of what the authors called "The Crisis in Human Participants Research," along with some proposed solutions.

They pointed out that not all research is covered by the regulations. There is an absence of adequate resources for IRBs and a lack of attention to institutional conflicts of interest.

These deficiencies resulted largely because IRBs are inherently in a position of having to make decisions that are not always in the interest of their institution, which can lead to compromises in protecting human subjects.

Emanuel's list also noted the lack of adequate education of clinical investigators and IRB members, as well as the problems of competitive review, particularly for multicenter trials. The team raised questions about whether the research ethics review process is principally aimed at protecting institutions or at letting the community know what goes on.

African village

When you go into a village in Africa and want to do research, you have to sit down with the community. You have to talk to people about what the research enterprise is. You've got to understand what they think research is and what the role of investigators is, vis a vis the role of the physicians. You also have to be clear about what the role of subjects are vis a vis their role as patients.

This communication can lead to a much more defensible research ethics process. In the coming years we need to decide whether some of the inherent problems with our research ethics review process could be addressed in ways that borrow usefully from models developed elsewhere in the world.

Too much focus on consent forms
Emanuel's team also argued that the review process itself focuses excessively on informed consent forms and focuses too little on the real communication that we would like to see in informed consent. Deficiencies also exist in monitoring the execution of protocols and in continuing review.

Finally, they found a set of problems in performance assessment, such as insufficient evaluation of IRB effectiveness and the absence of systematic collection and dissemination of performance data.

This situation puts IRBs in sharp contrast to most other parts of the health care system, which for a full decade now have tried to orient their activities around exactly these kinds of feedback mechanisms.

What are IRBs?
What are IRBs? Are they part of the research enterprise? Are they an administrative process to ensure adherence to rules?

More is needed. IRBs should be a force to ensure that research ethics are fully developed and adhered to in reality. They are great repositories of knowledge and commitment, and I think IRB members should set their sights high.

The review process focuses too little on the real communication that we would like to see in informed consent.

Three sets of problems must be addressed. The first is what is meant by justice, the most neglected of the Belmont principles. The second is taking seriously obligations to the community and to those who participate in research. Finally, we must acknowledge the inherent tension or conflict in all research and implement appropriate protections.

The question of justice is first. Only 10% of biomedical research addresses the health needs of 90% of the world's population. I think justice requires that we address the health needs of the people being used for research.

Further, what happens when the research ends? Do the subjects continue to receive an intervention if it has been helpful, even though that intervention has perhaps not yet proven beneficial?

Obligations of research sponsors
When a drug trial ends, what are the obligations of the research sponsors to people who are benefiting from the drug? What is owed to the communities in which the research takes place? How many people enroll in research because it is their only way of getting care?

Only 10% of biomedical research addresses the health needs of 90% of the world's population.

I think IRBs should reject research projects where no attempt has been made to work out these issues in a prior arrangement with the local community and with the potential participants.

One basic question speaks to the inherent tensions and conflicts of research: what are the limits of sacrificing the interests of some for the potential benefit of others, whether that is the broader community, future patients, or the amorphous notion of a public good deriving from scientific knowledge?

Do no harm
The Hippocratic injunction "Do no harm" is an injunction not to act when you don't know enough. And yet research is predicated on the need to act when we don't know for sure.

The U.S. government issued the first guidance about protecting human subjects fewer than a hundred years ago. It followed a particularly egregious case in which a physician in a clinic intentionally injected prostitutes with venereal diseases taken from infected persons to study the effect of the infection.

Those first rules were not so different from current federal regulations. Yet now, many years later, we have a series of reports from the General Accounting Office showing deficiencies in the IRB process. We have scandals at major research institutions: Penn, Duke, Johns Hopkins, UCLA. Does this mean we are on a downward trajectory?

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When the Nazi doctors were tried and most of them found guilty at Nuremberg following World War II, the court stated the ten principles that we now call the Nuremberg Code.

The first, voluntary consent, is so clear that you would think there would never have been any question afterwards.

IRB members and administrators can and should take a leading role. No one has a deeper commitment.

But of course we are still struggling with the meaning of voluntary consent. The court was very clear, saying the subject should have the legal capacity to give consent and should be able to exercise choice free from force, fraud, deceit, duress, or any ulterior form of constraint or coercion.

Applicable to all research

This principle is applicable to all forms of research in which one person uses another to gain knowledge. But how often do IRBs insist on consent monitors? How often do they insist that the research involves enough complexity and enough risk that it is inappropriate to go forward without the additional burden and expense to the research of ensuring a separate attending physician for the patient, a physician not in any way involved in the research?

Think of the inherent tensions that exist with HIV vaccine research as an example, where a conflict exists between the needs of the researchers and the well being of subjects.

This tension does not mean that such research should not go forward. But it should not proceed without everyone involved recognizing the risk of the therapeutic misconception, which is a problem for patients who want to benefit from their involvement in research, as well as for the researchers, who often are convinced of the study's therapeutic value.

All of us are subject to this therapeutic misconception because it is so difficult for us to knowingly ask someone to take a risk so that others may benefit. This is particularly difficult in the medical profession, which is guided by the admonition to, above all, do no harm.

IRBs should lead

We have come a long way, a very long way. Yet we must also address the practical problems of the review process. We must be willing to go back to the underlying issues and address the premises of research with human beings.

I think IRB members and administrators can and should take a leading role. No one has a deeper commitment. No one ought to have a greater stake, and few have greater knowledge.Δ

Web Sites

Belmont Report
http://history.nih.gov/history/laws/belmont.html

National Cancer Institute: A guide to understanding informed consent
http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide

Bioethics and the National Institutes of Health (NIH)
http://www.nih.gov/sigs/bioethics/withinnih.html

NIH National Human Genome Research Institute, Ethical, Legal and Social Implications Research Program
http://www.nhgri.nih.gov/10001618

Centers for Disease Control & Prevention
http://www.cdc.gov/OD/ads/

The President's Council on Bioethics
http://www.bioethics.gov/

Office for Human Research Protection
http://www.hhs.gov/ohrp/

Department of Health and Human Services (HHS) Office of Research Integrity
http://ori.dhhs.gov/

HHS Office of Research on Women's Health
http://www4.od.nih.gov/orwh/

Below is a synopsis of parts of one of the panel discussions held during the PRIM&R meeting.

James F. Childress is a Professor of Ethics and Professor of Medical Education at the University of Virginia, where he teaches in the Department of Religious Studies and directs the Institute for Practical Ethics and Public Life. He is the author of *Principles of Biomedical Ethics* (with Tom L. Beauchamp) and several other texts. He has served on numerous biomedical task forces and committees, including the National Bioethics Advisory Commission.

Steven Joffe is an attending physician in pediatric hematology and oncology and an ethicist at the Dana-Farber Cancer Institute and Children's Hospital, Boston. He is also an instructor in Pediatrics at Harvard Medical School. He has written on physicians' attitudes to clinical research, ethical aspects of the patient-doctor relationship, and the role of empirical research in medical ethics.

Jeremy Sugarman is the Harvey M. Meyerhoff Professor of Bioethics and Medicine at Johns Hopkins University. He served as Senior Policy and Research Analyst for the White House Advisory Committee on Human Radiation Experiments and as a consultant to the National Bioethics Advisory Commission for its project on international research ethics. He has edited or coedited several books related to research ethics, including *Beyond Consent: Seeking Justice in Research* and *Ethics in Primary Care*. He is a contributing editor for *IRB*, and serves on the editorial boards of several other journals, as well as the IRB for Family Health International.

Belmont & respect for persons

Panelists discuss informed consent, dignity, and respect

JEREMY SUGARMAN: Honoring the Belmont requirements for informed consent demands that there be adequate decision-making capacity.

For the vulnerable and those with diminished capacity, however, the need to take special care presents very difficult challenges.


James Childress


Jeremy Sugarman


Steven Joffe

I served on the Advisory Committee for Human Radiation Experiments, which looked into thousands of U.S. government experiments done during the Cold War, most of them conducted without the subject's consent. They did such things as feed radioactive oatmeal to retarded children.

When we talked to people who had been subjects in these experiments, the most powerful message that came through was that they trusted the doctors and the institutions: "Surely they wouldn't have me do this if it wasn't going to help me." This is what we refer to as the therapeutic misconception.

The advisory committee also looked at how good a job IRBs have been doing recently. The results were disappointing: they were doing a good job on minimal risk research, but not so good with higher risk research, especially those using subjects of questionable decision-making capacity.

For example, many studies appeared not to offer any direct benefits to the subjects. Four studies involved diagnostic imaging with cognizably impaired persons, such as those with Alzheimer's. People would be anesthetized to restrict movement during imaging, yet there was no discussion in the consent forms of the implications of these potentially anxiety-provoking conditions. Nor was there discussion of the subject's capacity to consent or provision for appropriate decision makers to give permission for the subject's participation.

By contrast, regulations for children require that if you were going to anesthetize before putting them in a scanner, there would have to be an expected benefit and the child would have to assent. We don't have the same thing for the elderly or the demented.

We also looked at the experience and motivation of proxies who have made decisions regarding research participation by patients with dementia. Most proxies reported that decisions were partially or wholly made by the patients, that the proxy signed the consent form as a mere formality.

Another concern is that consent sometimes isn't required in areas for which it should be. For example, sometimes we get stem cells from

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Bernard Schwetz is Director of the Office for Human Research Protections of the Department of Health and Human Sciences. He is a Distinguished Scientist at the University of Maryland. He has previously served as Acting Principal Deputy Commissioner of the FDA, Director of the FDA's National Center for Toxicological Research, and Acting Director of the Environmental Toxicology Program at NIH's National Institute of Environmental Health Sciences (NIEHS). The following is a report of his talk.

Focus on public trust

OHRP's Schwetz says more information needed before making wide-ranging changes in human subjects protection

Before changing the human research enterprise in an effort to improve it, it would be helpful to know more about the enterprise's disparate components, Bernard Schwetz said during an address to PRIM&R.

Bernard Schwetz

Director of the Office for Human Research Protection (OHRP) of the Department of Health and Human Services (HHS), Schwetz believes that too little is known about basic elements of the enterprise, including how many IRBs are operating, how many human subjects there are, and how they are classified by gender, age, race, and so forth.

"Neither do we have much information about the number of studies, their sources, or what they are trying to do," he said. "We also don't have a very good sense of adverse events, and we don't have an accessible list of studies that have failed."

Without this and other information, he argues, it is hard to deduce how well the enterprise is operating.

Knowing more details

"We can talk about a few cases of this or that, but without knowing more details about the enterprise in its entirety, it's very hard to figure out where the problems are and how to make improvements."

This lack of information is related to the lack of uniformity in the way IRBs work, he said. "The diversity in operating procedures suggests that there may be reason to revisit the question of clearly defining both the legal requirements and the real role for IRBs."

It would be a mistake, he added, to focus on IRBs as the source of most difficulties in the research enterprise. There are many other parts of the enterprise that should be examined. For example, without a list of studies that have failed and an understanding for why they failed, "is there an unacceptable risk we may recruit people into studies that have already failed once and may predictably fail again?"

In a wide-ranging talk about OHRP's activities and directions he would like to focus on, Schwetz said one of the most productive activities has been development of the HHS Secretary's Advisory Committee for Human Research Protections.

Prisoners, children, accreditation

"The committee is moving ahead very effectively with a huge amount of activity, especially by three active subcommittees—one on prisoners, another on children, the third on accreditation."

Issues related to prisoners are troublesome, he said, because the status of prisoners in the world today is different from what it was 20 years ago. The committee on children, he said, is seeking ways to make the process of funding approval more formal and more transparent. Accreditation is a difficult matter because there is uncertainty about incentives for seeking accreditation and the ultimate impact of accreditation.

"We can talk about a few cases of this or that, but without knowing more details about the enterprise in its entirety, it's very hard to figure out where the problems are and how to make improvements."

Keeping trust
Any endeavor to improve the enterprise must focus primarily on keeping the trust of the public, Schwetz said. "We can do this mostly by understanding that the key to success is protecting human subjects."

This is easily confounded, however, by the changing nature of the enterprise and the way we think about it. "For example, research is moving from academic health centers to community sites, largely because the big centers are slow-moving and costly. As research moves out into the community, it is leaving behind the advantage the big centers have, which is an emphasis on education, training, and tracking. This may inevitably cause problems, including in areas such as tracking adverse events."

None of these problems are insurmountable, Schwetz said, "so long as we keep the focus on public trust and protecting human subjects."Δ

DOE's accreditation workshop

Day-long Human Subjects Working Group session outlines how to prepare for and survive the process

Winning strategies
The strategies necessary for winning accreditation for research institutions were outlined in a day-long workshop sponsored by DOE that was held at the end of the PRIM&R meeting.

Participants at the workshop were primarily representatives of DOE, DOE national laboratories, and various invited organizations.

Arranged by DOE's Susan Rose and conducted by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), the workshop included sessions covering the range of requirements for accreditation.

Led by Jeffrey Cooper, AAHRPP deputy director, and Marjorie Speers, AAHRPP executive director (see photos on page 19), the program included an overview of AAHRPP, the goals of accreditation, and its foundation as an educationally based process. The AAHRPP-driven requirements employ standards based on federal regulations, good clinical practice, and stakeholder input.

How the process works
Workshop participants were provided a detailed account of how the process works, beginning with self-assessment, moving to on-site evaluation by expert visitors, and concluding with a determination by the AAHRPP Council on Accreditation.

The section on self-evaluation covered ways to assess strengths and weaknesses, ways to improve policies and procedures, and the use of AAHRPP evaluation instruments.

It was suggested that self-assessment should encompass the entire organization seeking accreditation; responsibility should not be limited to the IRB. Also discussed was the range of documentation needed to meet the requirements and ways to utilize documentation to enhance human subjects protection.

After covering the details of submitting the application and documentation, the workshop outlined the site visit process and ways to ensure that it goes well.

The typical site visit lasts 2–4 days and is conducted by 2–6 site reviewers. They may include stakeholder representatives and people involved as investigators, ethicists, regulators, and participants.

Site interviews
The site reviewers hold interviews with management, as well as those involved on the front line of the process, including IRB members. They also analyze records, including protocol files, IRB records, contracts, training records, site agreements, study logs, noncompliance, conflicts of interest, and scientific review.

The site reviewers hold an exit briefing at the end of the visit, during which they provide an overview of findings and recommendations. A written report is subsequently prepared including findings that are intended to be objective, specific, and educational. It also notes recommendations for changes.

The organization seeking accreditation has 30 days to respond. Its response is evaluated by the site visit team, which provides its evaluation to the AAHRPP Council on Accreditation.

For more information about accreditation, see **http://www.aahrpp.org/**.Δ

David A. Lepay serves as Senior Advisor for Clinical Science and Director of Good Clinical Practice (GCP) programs within FDA's Office of the Commissioner and its Office for Science and Health Coordination. In this position, he has responsibilities for GCP policy and initiatives at FDA, in the coordination of FDA's Bioresearch Monitoring program of on-site inspections for human clinical trials, in international GCP and human subject protection activities, and in GCP education and outreach. Below is a report on his PRIM&R address.

FDA focus: vulnerable populations

Stronger safety monitoring promised

More focus is being applied by the U.S. Food and Drug Administration (FDA) on protecting vulnerable populations, including the issue of informed consent for non-English-speaking research subjects.

David Lepay, Senior Advisor for FDA's Clinical Science and Director of its Good Clinical Practice (GCP) programs, said that because vulnerable populations are subject to greater risk, working with them requires more time, attention, and resources.

"This is a fundamental tenet of risk management," he said, "and this focus will permeate all of what the agency does in dealing with human subjects."

In his discussion of initiatives and plans, Lepay noted that FDA is developing new approaches to safety monitoring and to pharmaceutical vigilance. Increasing resources are being assigned to improving the system designed to protect those who are often most at risk and least able to protect themselves.

Protecting vulnerable populations, he said, involves more than a signature on an informed consent document. It includes determining the best way to explain a protocol and its risks. The explanation must be provided in language that can be understood by each research subject. In addition, the language should be culturally sensitive.

The document must be properly understood, he added, but "there must be a process in place to ensure that information is conveyed, comprehended, and updated. A short summary may be more informative to the subject than a massive informed consent document. Less can be more.

"And as we look at issues relating to informed consent, we must also ask how we can be more consistent between FDA and other government agencies that regulate clinical research."

A thorny area for researchers and IRBs is pediatrics, he said. "It is important to do pediatric studies if products will ultimately be used in children." He said FDA has therefore adopted regulations to provide additional protections for children participating in medical research.

Reducing inconsistency

Further, in developing these new regulations, FDA harmonized closely with the DHHS Office for Human Research Protections to reduce inconsistencies in interpretation.

FDA is also looking at other vulnerable populations—including pregnant women and the decisionally impaired. "They, too, are users of FDA-regulated products," he said, "and we must better understand how metabolism, toxicities, and use might vary in these groups so products can be properly and appropriately labeled."Δ

New FDA regulation proposed for accepting foreign clinical studies

The FDA is proposing to revise its regulations on acceptance of foreign clinical studies not conducted under an investigational new drug (IND) application.

The revision would replace the current narrow requirement that such studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki, with a more comprehensive requirement that the studies be conducted in accordance with good clinical practice (GCP) standards, including review and approval by an Independent Ethics Committee.

The FDA said the proposed rule is intended to update the standards for the acceptance of non-IND foreign studies and to help ensure the quality and integrity of data obtained from such studies.

For more information, including deadlines for comments, see: **http://www.fda.gov/OHRMS/DOCKETS/98fr/04-13063.htm**.Δ

Carl Schneider holds the Chauncey Stillman Professorship for Ethics, Morality, and the Practice of Law and is a Professor of Internal Medicine at the University of Michigan Law School (where he was Editor-in-Chief of the *Michigan Law Review*). He served as Law Clerk to Justice Potter Stewart of the United States Supreme Court. He is the author of *The Practice of Autonomy: Patients, Doctors, and Medical Decisions*. The following is a synopsis of some of his PRIM&R talk.

Autonomy: theory & the real world

Ethics and law professor says that when he's sick, he does what his wife tells him and doesn't worry about empowerment

I have been researching how the legal principle of autonomy actually works itself out in real life.

The law is moving toward an increasingly strong view of autonomy. But in areas other than the law we have an increasing sense of discouragement about how well our hopes for autonomy might be put into action.


Carl Schneider

When I say an increasingly strong view of autonomy, I mean, first, that we are moving toward an increasingly rigorous sense of what it takes for people to make decisions that are truly autonomous.

Second, there is increasingly a view that autonomy is not optional, that autonomy is something that people are obliged to undertake for themselves; that in the particular context of medical decisions, people are not just free to be autonomous, but are obliged to take up the gift of freedom and make their own medical decisions.

Broader legal doctrine

Now, at the same time that the legal doctrine of informed consent gets broader and broader, and more and more things are brought under the umbrella of matters that doctors are required to disclose to patients, I think we have an increasing sense of failure about doctrines like informed consent.

I recently co-authored an article* arguing that the policy of living wills is a failure and most always will be a failure. Although there are occasions when individuals might benefit from a living will, the attempt to adopt them virtually universally cannot work for a wide variety of reasons, and indeed the research suggests that they do not affect patient care. Why is this?

*Angela Fagerlin and Carl Schneider, "Enough: The Failure of the Living Will," *Hastings Center Report* 34, no. 2 (2004): 30–42.

There is another problem, which is that when you're sick, empowerment is not necessarily what you seek most. The authority to make your own medical decisions is not necessarily what you want most.

When I'm sick I crawl into bed and do what my wife tells me, and that has worked brilliantly well. It also correlates well with research we're beginning to see that finds a substantial number of people who do not want to make their own medical decisions.

These are not foolish people or people who are afraid of taking on difficult tasks. They do tend to be older and sicker people, which means that the unfortunate consequence is that the decisions likely to be the most consequential are often being made by the same people who reject the gift of autonomy.

When people are sick

Part of the problem is that the information patients need to understand is often very complicated. The most serious difficulty, however, is that when people are sick, the questions they are asking are not about medical decisions.

Instead, they are asking the most troubling questions: What has my life meant? How can I make the remaining moments useful and happy? Or they are thinking about the everyday logistical questions: How can I get to the dialysis clinic three times a week?

So there is enormous uncertainty about how we should respond to this dilemma. Even asking people in advance how much of a role they want to take in making decisions doesn't help us much. My advice is to try to expand people's authority over their lives, but proceed prudently, cautiously, with humility and modesty when you think about doing this through institutions and laws.Δ

C. Kristina Gunsalus is one of the nation's foremost experts on handling research misconduct. She is a Special Counsel in the Office of University Counsel and Adjunct Profession in the College of Law at the University of Illinois at Urbana-Champaign. She served on the Committee on Research Integrity of the Association of the American Medical Colleges and as chair of the American Association for the Advancement of Science Committee on Scientific Freedom and Responsibility. This is a synopsis of her talk at the PRIM&R meeting.

Who are we protecting, and why?

Expert on handling research misconduct says we need to know more about our intentions: 'Protecting from what?'

How do we make the protection systems better? How do all our well-meaning, well-intentioned people who are hoping to make things better for human subjects and to be ethical actually make it work in our system?

This practical issue is the one that most engages me.

C. Kristina Gunsalus

How, for example, do we make protections work in nonbiomedical areas, such as journalism, history and oral history, English, anthropology, psychology, education, and so on?

Many of the problems in those disciplines fall in the category of what I call 'two people talking.' How do we figure out whether it is research when two people are talking with each other.

First Amendment & prior restraint

First Amendment and prior restraint issues also are beginning to arise, particularly if you look at disciplines like journalism.

Does it become research when I'm talking to someone? Does it become research when I start to write about it? Does it become research when I plan to write about it? Does it become research when I actually publish something about it? What is a human subject?

If I write an essay for the *Chronicle* talking about my experiences as an administrator at the University of Illinois and interacting with people over time and I do it for publication and I start making generalizations, does that make each human being with whom I've spoken a subject?

The biomedical model doesn't always fit the methods or goals in other disciplines, including the social sciences and humanities. The Belmont principles and the system of regulation in this country is deeply rooted in biomedical research.

There also are academic freedom issues that are becoming more troublesome. First Amendment and prior restraint issues are beginning to arise, particularly in two-people-talking arenas such as journalism and oral history.

OHRP determined that most oral history projects are not subject to the regulations protecting human subjects and so can be excluded from IRB oversight. This was because they do not involve research as defined by HHS regulations. The problem is that if you read the regulations carefully, they don't really define research.

This imprecise terminology and lack of specificity in what we want to do, for whom, and why is leading to mission creep. When the Belmont Report was issued, the biomedical research community was relatively small. Terminology can be more imprecise when it is for a small, homogeneous community that knows what the terms mean.

Conflicting demands on IRBs

Now, however, the imprecision is becoming troublesome. We're seeing a proliferation of conflicting demands on IRBs. When we began trying to collect data about the problem, it became apparent that the data aren't there on how our systems operate.

I am suggesting several steps. Clarify the domain of covered research involving human subjects. Clarify standards in terms of real dangers rather than hypothetical worst cases—especially in non-biomedical areas. Provide multiple pathways for review. Allow for varied intensity of reviews. There are circumstances where prior review should always be required, circumstances where expedited review is reasonable, and circumstances that should be exempt from review. Make clear which is which.Δ

Community members: "more training"

David Bernardt's Delaware Valley survey suggests IRB members need to know why community representatives can be a benefit to scientific research projects

David Bernhardt, retired director of research administration at Philadelphia's Albert Einstein Medical Center and now a community member on five IRBs, says a survey he is close to completing suggests that IRBs could benefit significantly by focusing more training on an often-overlooked aspect of IRB dynamics.

"The scientific and other members of IRBs tend to have no idea at all what to do with the community members," he said. "They don't really know what they're there for or how the community member should function. On bigger boards, the scientists and physicians sometimes don't even know the names of the community members."

Harvesting knowledge

Bernhardt said the key to harvesting the knowledge and understanding that community members bring to the discussion is to teach the other members why the community view is both important and helpful.

"It's not that the scientists and physicians don't want that outside view," Bernhardt said. "Most of them do. There are a few who might be too arrogant or too paternalistic, but most are trying their very best to do good work.

"They just need to be educated about why community members are on the board. It would also help to implement a process that ensures the community view is a central aspect of the discussion."

Bernhardt's ideas grow out of his past experience as research director, his years as an IRB community member, and his recent survey of other community members.

Bernhardt's survey is a small sampling of about 25 community members serving on six IRBs in the Delaware Valley. He asked community members what they were told when they were being recruited, what training they received, what resources were provided for them, what they think their function is, and how they think they are seen by other IRB members.

Uniform results

The results, he said, are almost unanimous. "They're not told much about why they're on the board or how they're supposed to function. Few received any kind of orientation. They make their way into the process as best they can."

Bernhardt said most of those surveyed do not feel that they are disrespected, but neither are they made to feel that they are peers. "Some IRBs do better than others," he said, "largely depending upon the leadership shown by the chair or the administrator."

> *In the Netherlands, IRBs by law must be 51% community members. Isn't it interesting to see the difference in approach?*

Community members will be valued, he said, to the extent that the IRB sees their participation as an advantage. "That may be an idealistic hope," he said, "and, if so, the only way to solve the problem is by regulation, which isn't what I'd prefer.

"In at least one nation, the Netherlands, IRBs by law must be 51 percent community members. That's not going to happen here, but isn't it interesting to see the difference in approach?"Δ

"The key to harvesting the knowledge and understanding that community members bring to the discussion is to teach the other members why the community view is both important and helpful."

Childress, Sugarman, Joffe on autonomy (Continued from page 9)

umbilical cord blood and placentas, yet consent isn't required for harvesting from either of these. We have tended to view them as things we discard.

For people from the Philippines, the placenta is an amulet worn around the neck of the child for the first six months. In parts of Asia, the placenta is made into a tea to be drunk after delivery. In other places, such as Northern Vietnam, the placenta is cooked and eaten as a replenishing force. Among Native Americans, one tribe buries the placenta by a Pinion tree so the child will always return home.

So, when we quickly assume that the placenta and umbilical cord can be taken without consent, we may be violating people's basic beliefs.

In this and other areas, if we are going to meet the mandates of the Belmont Report in regard to respect and consent, we need to do the same kind of research that we use for clinical understanding. We need data about what constitutes respect, what constitutes consent. We must understand that respect and consent is an individualized process. The way we respect one person may be very different from what is needed for another.

For people from the Philippines, the placenta is an amulet worn around the neck of the child.

STEVEN JOFFE:
It's a measure of progress that it is hard to imagine research conducted in this society today that doesn't take seriously the Belmont principles: people must be treated as autonomous agents, and those with diminished autonomy are entitled to protection.

But we know problems still exist with informed consent in research. There is disagreement about how much we can rely on informed consent and whether it is sufficient.

Part of the difficulty is the tendency to equate respect for persons with respect for autonomy. I think respect for persons is a much wider concept than respect for autonomy. Equating the two reflects a very thin concept of personhood that doesn't sufficiently account for persons as embodied, social, historical, and more.

A strong case can be made for recognizing a principle of respect for persons with respect for their autonomous choices being simply one of its aspects, though perhaps its main aspect. But even then we would have to stress that persons are social, historical, et cetera.

Further, because autonomy is diminished in some people, including children, it is not helpful to establish protection for them in principles of respect for persons. Isn't it plausible instead that the obligation to protect those with diminished capacity is rooted in a commitment to beneficence, that is, to seek to provide a good for them? The principle of beneficence is connected to paternalism, which is explicitly what is required of IRBs in limiting the risk to which children may be exposed.

For all research subjects, it might be helpful to develop an expanded vision of respect for persons. This should always begin with freedom from coercion and honest disclosure. But we should add to these such things as representation in research design and oversight by subject advocates or community representatives. We might also include gratitude and the return of results, as well as respect for community and culture.

JAMES CHILDRESS:
I agree that protecting nonautonomous people is best understood under beneficence, or even justice, rather than under the principle respect for persons.

Respect in most hard cases is often a matter of balancing competing claims: allowing choices versus protecting people. By thinking about protecting nonautonomous persons under beneficence, we can began to see how dilemmas emerge.

Respect for autonomy cannot be applied mechanically. Persons are complex, with variations in capacity. They are often unclear and ambivalent. We have to think about their choices and their sociocultural context in order to understand them. Furthermore, they change over time.

Another candidate for a guiding vision, along with respect for persons, is respect for human dignity. It has a significant place in our moral discourse. A researcher told me that after his thirty years in medical studies, the biggest change he had noticed was a shift in prepositions, from "on" to "with"—from research *on* human subjects to research *with* human subjects. That shift captures the vision of the partnership, the collaboration, the covenant.Δ

Rabbi Edward Boraz

IRB community member serves partly from interest in civic good, partly from historical concern for tragic consequences

Rabbi Edward Boraz signed on as an IRB community member with a deep understanding of the complex issues that would be brought to the table, including the competing interests of community versus individual well being.

Educated as an attorney and with a Ph.D. in Talmudic studies, Boraz is also a pastor, which is part of what he believes gives him the understanding needed to provide a special voice in IRB deliberations.

Edward Boraz

Competing interests

"I understand that the purpose of research is the advancement of science for the public good, but as a pastor I look at proposed protocols from the human side, primarily in how to protect the individual," he said. "These competing interests sometimes conflict, and while both are important, I try to be the voice of the person who is considering whether or not to consent to participate in the protocol."

Boraz is the rabbi at Dartmouth University and a member of the National Institute of Occupational Safety and Health IRB and the DOE Central Beryllium IRB.

He agreed to participate on the boards partly because he believes it is important for people to make a contribution to the nation, as a kind of civil service.

Humanistic emphasis

"I think it's good for the country when people who are concerned about ethical behavior in scientific research do something to further that cause.

"The element that I hope to contribute to the IRB discussion is the continued emphasis on the humanistic aspect of the research protocol," he said.

Another concern Boraz brings to the IRBs is historical. "Given the history of horrible human experiments with tragic consequences, and my own personal sensitivities to the Nazi era, I want to be as watchful as possible about avoiding harm to research subjects," he said.

Boraz said his central concern as a community member is to ensure that consent is as fully informed as possible. "Some parts of the science in the protocols goes right over my head," he admitted. "So the best expenditure of my time is to examine closely whether the protocol ensures real, honest consent."

Law school taught him not only to analyze issues and language, he said, "it also taught me how to put myself in the place of others, and to try to understand why people might feel confused, uncertain, or fearful."

Balancing representation

The IRBs on which he serves work well, he said, and if there is any area that needs improving it is perhaps in providing more balanced representation.

"I'm listened to and made to feel that I contribute to the deliberations. More than that, I'm encouraged to ask questions and express my opinion." But Boraz said that it could be helpful to have more community representation on IRBs. "The boards work pretty well as they are, but it might also be good to supplement that with members who are independent physicians, not at all connected to either the institution or the proposed research," he said.

It is the combination of voices, he said, that will be more likely to ask the important questions about whether the protocol will protect research subjects and ensure that the focus is on safety as well as on results.Δ

"I think it's good for the country when people who are concerned about ethical behavior in scientific research do something to further that cause."

Jeremy Wood developed ***IRBtool.com*** and other educational systems designed to assist researchers. He also designs researcher-oriented Web sites, primarily at the University of Pennsylvania. He taught at UCLA and worked with legislative and regulatory policy for the Federation of American Societies for Experimental Biology. For more information, see **http://www.HumanSubjectsTools.com**. Below is a synopsis of Wood's discussion about how to train researchers to protect human subjects.

Educating the researcher

Imparting dry information is not the best way to get people to stop smoking or practice safe sex. So why should it work to get researchers to protect human subjects?

If the goal is to protect human subjects, the focus should be on giving researchers the information, insight, motivation, and tools they need to accomplish the goal.


Jeremy Wood

Remember that the goal is neither to improve the researcher's character nor to educate merely for the sake of education. Instead, it is to encourage behavior that protects research subjects and, when necessary, to change researchers' behavior.

Living with contradictions

Experience and research show that imparting dry information is not the best way to get people to stop smoking, fasten their seat belts, or practice safe sex. Information, education, and communication (IEC) campaigns are strikingly ineffective. And further, people can live quite happily with brains that are full of apparent contradictions.

By analogy, imparting information about the common rule and instances where human subjects were abused in the past is not the best way to get people to protect human subjects.

Instead, the campaigns that are most effective at affecting individual behavior change are typically:

- are personalized,
- are emotionally compelling,
- make extensive use of role models,
- demonstrate sensitivity to social and cultural norms and expectations, and
- recognize the unique impediments and facilitating factors in the environment.

Don't focus on teaching the rules; there are too many to learn. They quickly become overwhelming, and most do not apply to a given researcher. Remember that the best law schools do not teach the details of the law as much as they train students in legal principles, thinking like a lawyer, and legal research.

We should also learn not to focus on teaching the facts of history. The facts of history are a long way from protecting human subjects today. It's too easy for investigators to convince themselves that they would never do the terrible things that were done by the Nazi or Tuskegee folks.

Make it fun, challenging

A good way to motivate researchers is to engage them with the material. The ability of the "must-pass" quiz to motivate real learning and behavior change is quite limited. So make the course fun, interesting, and challenging.

When necessary, it is important to motivate researchers to change their behavior. Scare tactics are generally ineffective, but you do want to provide them with emotional (gut) reasons to listen.

Self-interest

Make researchers feel how human subjects can be hurt. Show them that protecting human subjects protects researchers (even if you think that appealing to self-interest is unethical or undignified). Make it real, but do not overpromise dire consequences.

Finally, show them how others are able to both protect human subjects AND get their research done. Make compliance less burdensome by translating the regulations relevant to each researcher into an easily understandable language and format.Δ

Protecting Human Subjects

This newsletter is designed to facilitate communication among those involved in emerging bioethical issues and regulatory changes important to both DOE and the human subjects community.

DOE Human Subjects Protection Program Manager
Susan L. Rose, Ph.D.

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Accreditation workshop at HSWG meeting

Susan Rose, at top, addressed the HSWG meeting. Leading the accreditation workshop were Marjorie Speers, left, and Jeffrey Cooper, above.

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