

PROTECTING HUMAN SUBJECTS

U.S. DEPARTMENT OF ENERGY, OFFICE OF BIOLOGICAL AND ENVIRONMENTAL RESEARCH



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"Neighbor and partner"

Conference continues challenge to ensure community IRB members are fully involved in protecting human subjects

In a challenge issued two years ago, Susan Rose asked the human subjects protection community to embark on a serious discussion of largely ignored issues important to guarding the well-being of research subjects.

The first response was from Melinda Hurst, a community member of the Los Angeles County/University of Southern California Institutional Review Board (IRB). She wrote to suggest greater involvement of community members, more institutional support, and development of a national program to find ways to increase community member effectiveness. (Opinion articles related to this discussion are welcome.)

At the conference

In April 2002, DOE's Human Subjects Research Program, which Rose directs, convened a conference to consider an important part of this discussion—the crucial role of the community IRB member. The conference, "The Community IRB Member: Neighbor & Partner," was a direct result of the conversation that began when Hurst responded to Rose's challenge.

At the conference, national and international speakers and panelists from universities, government, and the private sector spoke about the importance of community members on IRBs and ways to expand their participation. Hurst, conference co-chair, offered one of the opening addresses (see page 3).

Much of the discussion expanded on Rose's initial challenge, in which she said recognition of the unaffiliated, or community IRB member, "is essential to the human subject protection process."



Melinda Hurst

She also suggested that it may be "time to partner with groups like the American Association of Retired Persons or other groups to identify new sources of community members, to educate them on the latest in science and bioethics, and to refresh our rosters across the nation."



Susan Rose

Rose said that each IRB "should try to have one member who comes from the same cohort as the majority of subjects

used at the site or by that institution. For example, at DOE we are encouraging appointment of a worker or union member on each IRB where workplace studies predominate."

Bucking herd mentality

At the April conference, Rose continued her encouragement of community members' involvement, saying they should buck the herd mentality of going along with whatever is the usual way of doing things.Δ

Conference coverage

This issue of the *Protecting Human Subjects* newsletter reports on the U.S. Department of Energy's April 2002 conference on "The Community IRB Member: Neighbor and Partner."

The conference was held in Gaithersburg, Maryland. It was sponsored by DOE's Human Subjects Research Program, Office of Biological and Environmental Research in the Office of Science.

Historic look at community members

Yale's Susan Lederer:

Sixties' questioning of authority sparked change

Following opening remarks on the first day of the conference, Susan E. Lederer of Yale University delivered a short history of IRBs and the involvement of community members.

She said the political activism of the civil rights and women's movements, along with the fierceness of the anti-war protests, sparked profound challenges to authority generally during the 1960s.

"There developed on the part of many Americans a profound skepticism and suspicion about doctors, lawyers, clergy, politicians and Presidents and the firm belief that those who represented THE ESTABLISHMENT could not be trusted."

Rise in litigation

By the early 1970s, she noted, Americans witnessed a massive rise in malpractice litigation against physicians. Expectations about what constituted good medical practice had changed. One of the causes was a series of public and profoundly disturbing research abuses involving human subjects. Especially troublesome was the revelation of the government-sponsored Tuskegee Syphilis Study, the 40-year study of untreated syphilis in some 600 African American men in rural Alabama.

Lederer said the litany of problems included reports of the Willowbrook State School in which retarded children were deliberately infected with hepatitis, and the testing of contraceptives on indigent Mexican American women. Congressional and public disaffection with human experimentation prompted passage in 1974 of the National Research Act. It mandated that institutions receiving federal funds must have an IRB to review protocols involving human subjects.

The Act also created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, an interdisciplinary group of physicians, philosophers, lawyers, and theologians. One of the final actions of this Commission was the Belmont Report, which identified three cardinal principles for ethical human experimentation: respect for persons, beneficence, and justice.

Even before all these developments, there was by 1969 a growing recognition within the Public Health Service that important decisions could not remain solely in the hands of the research community. Much of this recognition



Susan Lederer

came in response to research abuses. By 1974, soon after Tuskegee ended, new IRB regulations were issued calling for a committee of not fewer than five who would judge a protocol involving human subjects in terms of community attitudes.

The committee could not be composed solely of people who worked for the organization where research was being conducted. Nor could they be from the same professional group. It was the first of several steps toward ensuring that the decision-making would not be left entirely to the research community.

From the start there were questions about what having lay people on such a committee would mean and how it might work, including who they actually represent. These were more than the theoretical concerns of professional philosophers and policy makers. Community members themselves experienced some of the tensions of their unresolved role as community or lay members.

Being the lay person or community member on such a committee was often a lonely experience, Lederer observed. Some commentators, recognizing this, have argued since the 1970s that the proportion of nonscientist and noninstitutional members be increased.

AIDS activism

Patient advocacy was transformed in the 1980s by the AIDS epidemic, Lederer said. "To a large extent, AIDS activists brought an unprecedented level of energy, confrontation, and urgency to health policy and medical research. They were successful, for example, in expediting drug approval from the Federal Drug Administration, in getting pharmaceutical companies to lower the price of antiviral drugs, and to increase research funding."

The apparent success of AIDS activism has not been lost on advocates for patients with other diseases, she said, including those representing women with breast cancer. As a result, "some lay groups are having more say in setting the research agenda and in the political negotiation over funding of research."

Nevertheless, she concluded, too often the reality is as a survey of Australian research ethics committees reported: "lay members were usually seen as relatively inactive and their views relatively unimportant." The question, then, is whether a history of IRBs told ten years from now will have found that this attitude has changed.Δ

Expectations had changed, caused by a series of profoundly disturbing abuses . . .

of contraceptives on indigent Mexican American women.

Congressional and public disaffection with human experimentation prompted passage

Being the community member on such a committee was often a lonely experience . . .

"Can we agree," conference co-chair Melinda Hurst asked in her opening address to the conference, "that the community member serves a unique role by virtue of not being affiliated and not being invested in the institution?"

In a wide-ranging discussion of the value and difficulties presented by inclusion of community members on IRBs, Hurst talked about her experience as one of those members. A longtime community representative on the Los Angeles County/University of Southern California IRBs, Hurst also served for 18 years on the California State Committee for the Protection of Human Subjects and the Cedars-Sinai Medical Center IRB for six years.

To frame her talk, she said it is important for IRBs to wrestle with questions related to what value is brought to the process other than nonaffiliation and where support can be found for establishing the significance of the non-affiliated member's presence on the board.

Hurst said she does not think she was especially valuable during the early years of her work with IRBs because she and everyone else were still learning how to do the job. Nearly 30 years later, it is more important than ever, she said, that unaffiliated members get the funding and other kinds of support to make them effective representatives.

It is also crucial that institutions take seriously the regulations requiring diversity of experience and expertise. "Women are somewhat well-represented on IRBs if you include community representatives, scientists, and others," she said. "But real diversity, which includes many voices, is most likely possible by adding lay members."

It's not resistance

She said it is not resistance to the concept of diversity so much as a lack of creativity in the search for community members that has held back progress in diversity on IRBs. It can be hard to find people who have the ingredients necessary for being effective lay members. "The time involved, the burden of study to be adequately prepared, the problem of missing work all conspire to make it difficult to serve."

She suggested several steps that might help. "First, the ratio of outside members needs to be increased. The National Bioethics Advisory Commission's final report urged that the number of nonaffiliated and nonscientist members should aim for 25%.

Melinda Hurst: 27 years as IRB community member

20% from outside

"If we understand that the mandate is for one nonaffiliate and one nonscientist in the basic committee of five, and if we avoid the clever device of making this the same person, we should end up with a minimum of 20% from outside the institution.

"Second, some of you are aware of the campaign to correct the somewhat insulting contradiction in the regulations in which a nonaffiliate is required to be a member of the basic committee but is not required for a quorum."

Hurst said current community members can press for support and for change, but both will occur only if there is institutional commitment. "Nevertheless, we are not as invisible as in the recent past, largely because of the conviction of Susan Rose and DOE, whose newsletter *Protecting Human Subjects* initiated the challenge to begin discussing the role and possibilities of unaffiliated members. "Today's meeting is an outgrowth of that challenge and is a remarkable recognition of the potential of the community member."

Organize locally, nationally

To fulfill that potential, Hurst urged that community representatives organize locally and nationally and that institutions develop strategies to support them. "This should begin with resource materials. For example, I would like to see regular workshops that include mock IRB sessions so that we could observe and participate in the resolution of difficult research questions."

Hurst closed her talk by saying that accomplishing these goals requires time and money. "We must also understand that belief in our mandate calls for assertiveness, which can best be accomplished by joining together to lobby for more training, identify issues around which we can develop expertise, expand our collective voice, and broaden diversity."Δ

"Community IRB Member"

The title of the DOE April meeting and this newsletter reference to the "outside, nonaffiliated" IRB member as community IRB member was chosen with care and purpose. The term "community," far more descriptive than nonaffiliate, is currently used by some federal advisory groups or enlightened IRBs. The term can mean a subject population community, an institution's geographical community, a member of an activist community, or all of these. In fact, on the IRB, it represents the community of subjects: those obviously not present to speak for or protect themselves. This is unarguable; it honors these IRB members and their responsibility, and it is the term we will continue to employ!

—Susan Rose, DOE Human Subjects Protection Program Manager

A representative of an AIDS coalition said the difficulties encountered in gaining access to the research system in the early 1980s is being seen again today.

Gary Rose said that in the first few years, as the world was beginning to learn the extent of the crisis, AIDS activists were ignored when they asked to participate in decision making about the research agenda.

"We now have tens of millions of people infected, and no one is listening again," he said.

Living with AIDS for nearly six years

Rose said he tested positive in 1985 and has been living with AIDS for nearly six years. He learned about the disease and the difficulties of getting anyone to listen from a friend who has since died of AIDS.

Most of what people learned during the 1980s was a result of bits of information passed along by word of mouth. "People took classes in virology and began learning about how research is conducted, who makes the decisions, and who is left out of the process."

People were very angry, he said. "Friends and neighbors were dropping dead every day, and it seemed that too few people were paying attention." By the late 1980s, the culture had dramatically changed. Committees of all kinds, including IRBs, began including AIDS activists. "We crashed every party and finally gained the power to influence research and development, even to get reduced prices for HIV drugs," he said.

Speaking with Rose, Brenda Lein of Project Inform, said the effectiveness of AIDS activists has provided a model for what is possible when community-based groups make

AIDS activists recount years of being ignored

A model for community member IRB action

AIDS activist Gary Rose, left, and Brenda Lein of Project Inform discussed the effectiveness of AIDS activism in demonstrating how to change research and development policies and "gain a seat at the table."



a determined effort to ask questions, get information, and seek to influence decision making. Her talk offered a model for an effective community member coalition for IRBs.

"It had always been assumed," she said, "that decisions about medical research should be left to the experts. But as more people got involved in information and advocacy, they learned that everyone had a responsibility to get involved in the process, share the benefits, and evaluate the risks."△

Community IRB member online discussion group welcomes members

A community IRB member online discussion group has been developed as a result of ideas presented during the "Community IRB Member: Neighbor and Partner" conference held in Gaithersburg, Maryland, April 8-9, 2002.

Development of the discussion group was approved by a committee that was formed to follow-up on ideas suggested during the conference. Susan Rose, U.S. DOE Human Subjects Protection Program Manager, said the idea for an online group got wide support from conference participants and from others queried about it.

The discussion group is designed to provide timely information, news, and opportunity for dialogue between community members. The Community IRB

Member listserv is administered by the Oak Ridge Institute for Science and Education (ORISE) and is a moderated subscription list. That is, messages sent to a specific list address are automatically forwarded to the ORISE moderator, who reviews content and posts messages to the entire subscribed distribution list. To post messages to the list, subscribers send an email or reply to the list address.

Nonaffiliated community IRB members or those interested in issues related to community members serving on IRBs are invited to participate.

Please visit the website at <http://www.ornl.gov/communityirb/> to subscribe or learn about more follow-up conference activities.△

When cultural differences clash

Creating ethical oversight and resolving value differences in international research



Godwin Ndossi

In doing human subjects research in Africa, much of the ethical restraint must be self imposed.

This is because ethics review committees (ERCs) are almost nonexistent and infrastructures are seldom funded, according to Godwin Ndossi, director of the Tanzania Food and Nutrition Center's department of food science and nutrition.

"In those few places an ERC does exist," he said, "member diversity is lacking."

Progress is being made largely because foreign institutions are imposing an increased emphasis on ethical conduct in research, but adequate oversight and funding "is still a long way out in the future."

Regional cultural differences

Ndossi said many African countries have no formal review process at all, partly because the dramatic cultural differences from region to region make it difficult to establish countrywide consistency in any meaningful sense.

Foreign institutions are imposing an increased emphasis on ethical conduct in research.

This becomes even more troublesome when U.S. and other foreign-based researchers enter a country like Tanzania and expect to find values and regulations like those they are accustomed to in their own countries.

When other countries attempt to impose their values on long-

established cultures, the result may tend to be a combination of resentment and resistance.

Foreign-based researchers who come to Tanzania, Ndossi said, are required by their home institution or country to meet certain ethical guidelines. When those conflict with traditional ways of other countries, conflicts may arise. A common problem is the conflict between individual autonomy versus community decision making.

Efforts are being made to implement a regional network of ERCs, he said, but without national

regulations and funding to support the network, these efforts will tend to be mostly unsuccessful. National consistency would be helpful for foreign researchers, but it may be impractical in some places.

More promising, he said, is a trend toward individual organizations establishing their own review and oversight process.

The Tanzania Food and Nutrition Center, for example, established its own ERC. It includes a few members from the Center and six outside members.

Three essential criteria

When research protocols are considered, the committee considers three essential criteria. They are

- a risk/benefit analysis, which includes examining the study's design and the qualifications of the principal investigator;
- respect for persons, which includes informed consent and subject protection, especially vulnerable persons; and
- ensuring justice, which comprises subject selection, including inclusion, exclusion, and recruitment.

These elements speak to creating oversight based in Tanzanian culture, rather than simply mimicking or following the oversight values of other countries.

Ndossi said that foreign researchers may be uncomfortable with differences in protective regulations, but protections must ultimately be grounded in the culture rather than in others' ideas about what is best.Δ

Web sites a few of those cited at conference

National Society of Genetic Counselors, Inc.
<http://www.nsgc.org/>

Tuskegee University National Center for Bioethics in Research & Health Care
<http://www.tubioethics.org/>

Community Coalition for Substance Abuse and Prevention
<http://www.ccsapt.org/>

Foundation for Blood Research
<http://www.fbr.org/>

Center for Molecular Medicine & Genetics, Wayne State University School of Medicine
<http://www.genetics.wayne.edu/>

The moral voice of community can be reflected in IRB composition

Community vs enclave

The notion of “community,” Sister Carol Taylor says, can be contrasted with “enclaves of lifestyles.” Understanding the difference is important.

An ethicist and director of Georgetown University’s Center for Clinical Bioethics, Taylor is also an assistant professor of nursing at Georgetown and a member of the hospital’s ethics committee.

To say Americans are individualistic, she says, is not to imply that they prefer being alone to belonging to groups. “By the logic of individualism, though, the only belonging that is meaningful is that which is freely chosen by individuals. Americans emphasize ‘getting involved’ over ‘being involved.’”

This characteristic emphasis on voluntary association, Taylor explained, tends to lead American to live in what Robert Bellah’s book *Habits of the Heart* calls “lifestyle enclaves” rather than communities “in the strong sense.”

The difference between these two notions is important to understand in the context of community-member involvement on IRBs.

“Community in the strong sense is a group of people who are different yet interdependent, who are bound together by mutual responsibilities arising out of a common history, a history which they have not chosen to be a part of but which they are nonetheless responsible for carrying on.”

Lifestyle enclaves

“By contrast, a lifestyle enclave is a group of people who choose to be together because they are similar in some dimension of life that is important to them—for example, the amount of money they have, or the professional status, or leisure activities they enjoy.”

Most associations in our society retain at least some of the elements of real community, Taylor explained. “But the tendencies that predominate are those that lead them toward becoming lifestyle enclaves.”

Quoting from Bellah’s later book, *Individualism & Commitment in American Life: Readings on the Themes of Habits of the Heart*, Taylor said “To the extent that our society is composed mainly of lifestyle enclaves rather than communities, it will be difficult for us to understand how and why we should act justly and decently toward those who are so different from ourselves that we would not voluntarily choose to be associated with them.” It is



Sister Carol Taylor

therefore difficult to give “substantive content to the idea of public good.”

Most important to issues related to protecting human subjects is understanding that it is through community that we find reinforcement for our moral inclinations and provide reinforcement to our fellow human beings.

“We are each other’s keepers,” she said. Referring to a thesis of Amitai Etzioni’s 1993 book *The Spirit of Community: Rights, Responsibilities, and the Communitarian Agenda*, she said our communities speak to us in moral voices, making claims on their members. Communities, Etzioni argues, are the most important source of moral voices other than the inner self.

Among the difficulties we face in thinking about moral claims is that there is “a tendency to accept the *de facto* empowered group as adequate for ethical decisions.”

“We don’t know” This acceptance constricts our ability to see certain important things about making moral decisions, and the problem is that “we don’t know that we don’t have this knowledge.” The result is that we assume we know the issues and that we are acting as we should because, based on the values of the dominant group, we seem to be acting properly.

We don’t know

It is not for lack of compassion that our depth of vision is limited, but rather from lack of awareness, Taylor suggested.

If we want to change this, we must recognize the limitations of our awareness and then seek to build a culture in which decision makers live by the credo: “In this organization, decisions start with defining and gathering the community of concern.”

Because no single community of concern exists for all issues, it is important to seek out people who have a strong perspective on the issues at stake and who “share an overarching concern for the common good.”

With lifestyle enclaves, it is difficult for us to understand how and why we should act justly and decently toward those who are different from ourselves.

Thus, when community members have a significant role in an IRB, they are what J. W. Glaser in a recent essay called “double advocates.” That is, as Glaser puts it, “They bring to the process the living and detailed presence of a unique, essential perspective and simultaneously intend a larger common good—the accomplishment of which may entail some sacrifice in terms of their special perspective.”^Δ

Organizing the unorganized

Bus riders union: A successful model for organizing a coalition representing voices of a special group

Lian Hurst Mann, plenary speaker for day two of the conference, presented a model for organizing the disparate folks who make up the nation's IRB community members.

These members nationwide have similar needs: to be educated, to be heard, to be empowered, to be effective, and to find other souls like themselves.

Founded by Strategy Center

The model she presented from her own work with the Labor/Community Strategy Center in Los Angeles is called the Bus Riders Union (see <http://www.busridersunion.org>). The Strategy Center founded the union following efforts by the Los Angeles Metropolitan Transit Authority (LAMTA) to cut bus service in order to fund a new rail project. At the same time, the LAMTA was ignoring the needs of those dependent on the bus for their livelihoods.

The Bus Riders Union stepped into this situation and eventually won a federal civil rights consent decree with the LAMTA. The effort required finding a common thread to reach folks who were not self-identified as a group and organize them to protect themselves. The union grew and grew and eventually won its case against the LAMTA.

Meetings were held with translations done in all the languages represented.

It is now active, vibrant, and a beautiful model for disparate IRB community members.

Most IRBs have only one community member and that person often has much in common with other IRB community members who they do not know. What follows are

the steps she outlined for the bus riders, which is offered here as a model for IRB community members.

Mann said the idea was to "build bridges between disparate people in pursuit of common goals."

Ensure representation at meetings

One of the things Mann said was learned early in the organizing effort was to be very sure that all stakeholders were represented before meetings were held.

"Without that representation," she said, "whatever conclusions were drawn at the meeting would eventually be dismantled" because those who had had no voice would eventually surface to object.



Lian Hurst Mann

"We also learned to be sure the meetings were held with translations done in all the languages represented," she said. "And we were always sure to have food at the meetings. People will come if there is food."

Everyone is an advocate

Mann said organizers of the union began with the philosophy that everyone's world has merit and should be considered. "Everyone is both an advocate for themselves and at the same time is

a member of a community," she said.

The project was begun by conducting an intensive series of study groups. Following that process was a period of self-education for everyone. "That was a crucial part of the effort," Mann said, "because everyone has different ideas about how things should be done and about what is important and what is not important."

One element that was most successful during the early stages, she said, "was the willingness of people to identify similarities and differences. When there are similarities, it's easier to talk about differences."

"It's also necessary to look at yourselves when you're trying to understand others," Mann noted. "Sometimes this leads to a certain discomfort. But discomfort can be good if it helps you see how some of your perceptions are skewed."

When IRBs seek to build bridges with the communities they hope to represent, she said, "it might be helpful to think about the process in ways similar to those employed by the organizers of the Bus Riders Union."

Teaching how to organize

One of the most important parts of the unionizing effort, she said, was to begin by teaching people how to organize and how to become advocates for a position. "You must begin by expressing strong support for the value of a different voice.

"Without that, people will tend not to believe you, whatever your intentions. If people don't trust you, if they don't think you indeed have a serious interest in ensuring that diverse voices are heard, your effort will ultimately fail." Δ

Discomfort can be good if it helps you see how some of your perceptions are skewed.

Puetz, Michel discuss community member support groups

Understanding regulations, getting respect, community member survey



Vicki Michel,
University of
California at Los
Angeles, Community
IRB member

Linda Puetz and Vicki Michel recounted the experiences of community IRB member support groups, saying that the intention is to provide an opportunity to discuss common problems they encounter and find ways to solve them.

Michel, an attorney in Los Angeles and community member of the University of California's IRB, told the conference that the support group will try to develop practical information about how to obtain and understand regulations, how best to contribute to the IRB's discussion, and about how to get the respect of other IRB members.

Puetz, an adult education specialist at the Midwest Bioethics Center in Kansas City, Missouri, said she conducted a survey to learn about community members in the Kansas City area but so far had received only a small sampling of replies. The survey does indicate that only about half of the community members are compensated for the time spent working on IRB business.△



Linda Puetz,
Midwest Bioethics
Center, Adult
Education Specialist

Human subjects notes & Web sites

■ Web sites

The Community IRB Member: Neighbor & Partner

This site was developed in response to ideas developed at the conference to enhance communications between community IRB members and to provide resources for them.

<http://www.orau.gov/communityirb/>

Quality Improvement Program—Office for Human Research Protections, U.S. Department of Health and Human Resources

<http://ohrp.osophs.dhhs.gov/humansubjects/qip/qip.htm>

National Human Research Protections Advisory Committee:

<http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm>

■ Scientific journal article

This article may interest readers:

"Workers as Research Subjects: A Vulnerable Population," Susan L. Rose and Charles E. Pietri, *Journal of Occupational and Environmental Medicine*, 44.9: 801-05, Sept. 2002.

The article argues that workers should be considered as a vulnerable human subjects research population because they require special protections. It also addresses concerns about establishing a formal ethical framework to address this vulnerability.



Kim Laing,
DOE Life
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Division



Ethel Jacob, DOE
Environmental
Measurements
Laboratory



Amparo
Henderson,
Oak Ridge
Institute for
Science and
Education

Three critical contributors to the meeting

Three less visible but vitally important people made this conference possible and enjoyable. They handled logistics, web services, audio-visual, lodging, guest and speaker arrangements, food, troubleshooting, and creature comfort. Thanks to

Amparo Henderson, Ethel Jacob,
and Kim Laing.
Good job!

Community members want training

Survey of conference participants: experience, perceptions of IRBs vary widely

A survey of participants at the community representatives conference indicated that more training is needed in understanding protocols and the nature of vulnerable populations. More opportunities to attend professional meetings and development of better mentoring programs were also cited as ways to increase effectiveness.

The survey asked questions about qualities that make the best representatives, about what is needed to better represent the community, and about issues.

Of the 41 participants who responded, 31 were IRB community representatives and 10 were IRB staff or regular members.

*A starting point
to learning
whether
experience should
be more uniform*

Most telling among the results was an apparent difference in the experience or perhaps the perceptions of the respondents. This was clearest in the section asking about issues.

For example, while 23 said scientific members sometimes undervalue community members because they don't have a scientific background, 17 said they had not seen this.

Similarly, 28 said the role of the community member is clearly defined, but 12 said it is not. And when asked whether community members know the boundaries of their role, 25 indicated they do not understand the boundaries and 25 said they do.

Different personalities

These differences are probably the result of the different characteristics and personalities of the various IRBs represented at the conference. They will also represent anomalous understandings of how to respond with true/false answers to questions that represent more complex issues.

Still, the results can be valuable in demonstrating that there is a widely disparate experience. This can serve as the starting point to learning whether the experience should be more uniform or whether each IRB, representing its own institution and its own region and population, should have a unique identity and therefore should have qualities that are not uniform throughout the nation.

When asked about the role of community members, the respondents overwhelmingly (36 to 5) said they should

represent and advocate for potential subjects. Similarly, they clearly said (39 to 2) community members should provide balance by bringing a perspective that is different from that of other IRB members.

On the other hand, there was not as much of a consensus (24 said yes, 16 said no) for the question of whether community members should act as an educator to the rest of the board.

An almost-even split (20 true, 19 false) occurred when respondents were asked whether their IRB clarifies expectations for the board and the community member.

A split

A split also occurred in reference to the statement that community member is a misnomer because they don't represent the community (19 true, 20 false).

Asked about things they need that they're not getting, respondents said, among other things:

- discussion about the meaning of terms, such as Phase II, III, etc.,
- training in ethics, IRB regulations,
- professional meetings,
- guidance in reading proposals,
- more clearly written protocols,
- guidance about what constitutes a vulnerable population,
- mentoring, and
- more communication among other community representatives.

Asked about qualities that make the best representatives, respondents listed dedication, civic sensibility, humor, not too cynical or too idealistic, independent, compassionate, thoroughness, sound judgment, personal integrity, curiosity, common sense, and objectivity.Δ

*Differences
probably result
from varied
personalities of
IRBs represented*

*Overwhelming
support for
acting as
advocate for
research subjects*

Building a resource . . .

Tuskegee's National Center for Bioethics in Research and Health Care



Stephen Sodeke

When Tuskegee University established its National Center for Bioethics in Research and Health Care, it took on a task that had never been tried.

Its purpose was to be the first university to employ a multidisciplinary approach in exploring core issues underlying research and medical

treatment for African Americans and other underserved populations.

In a discussion of the Center's purpose and activities, Associate Director Stephen Sodeke said the founding principle is to examine issues in science, technology, and health as they impact people of color.

Impact of history

Sodeke spoke to the impact of history on issues affecting people of color, citing the eugenics movement and the Tuskegee syphilis study. He said the Tuskegee center is an attempt to find a way forward from the tragedies of the past.

Funding for the center came partly from federal sources announced by President Clinton in 1997 when he apologized on behalf of the U.S. Government to all people who were harmed by the U.S. Public Health Service syphilis project. The goals are

- to advance a more sensitive and effective health care ecosystem, undergirded by sound and ethical medical research practice;
- to eliminate racial disparity in medical treatment;

- to encourage holistic approaches that integrate biomedical interventions with health care, education, and social service programs,
- to educate and train substantial numbers of African American bioethicists;
- to develop significantly higher levels of trust in the national health care infrastructure—transcending boundaries of economic status, social status, race, ethnicity, and gender; and

- to serve as a clearinghouse and resource in cultural diversity for strategic planning, service, and programmatic activity.

A significant part of the Center's activity, Sodeke said, is to develop a "context-appropriate" IRB to fully involve the community.

To do this, the Center tries to address communication challenges and organizational barriers to community representation. This encompasses efforts to ensure an understanding of the research process and the language of research. It also encompasses training to improve the capacity of community members to participate effectively on IRBs.

In addition, the Center's community-based participatory research actively tries to identify and discuss obstacles to participation. It assists in defining research agendas. It also incorporates a program to identify and engage community representation.

The purpose, Sodeke emphasized, is always to regain, rebuild, and maintain the trust of the community.Δ

To explore core issues underlying research and medical treatment for African Americans and other underserved populations

Locating new members

Three participants in a panel discussion about locating and educating new community members, were, from left, Abbey Meyers, president, National Organization for Rare Disorders; Stefanie Davis, IRB administrator and federal compliance officer, Kaiser Permanente, California; and Dale Mintz, National Director of Womens Health, Hadassah, The Women's Zionist Organization of America. See article, page 11.



Among the varied discussions at the conference, the ideas presented about finding and training nonaffiliated members to serve on IRBs drew enormous interest.

One of those was offered by Stefanie Davis of Southern California's Kaiser Permanente IRB (see photo, page 10). As the nation's largest nonprofit health plan, the organization has eight IRBs, each of which reviews research conducted within its own region.

Davis outlined the process of finding community members and then the various ways they are trained and involved with the IRB.

They receive on-the-job training as invited guests at IRB meetings

Two community members

She said the southern California IRB has two community members. One is an assistant professor at a theological seminary who is an experienced newspaper

writer and speaks French, German, and Spanish. The second is a retired personnel director for Los Angeles County, who has a graduate degree in philosophy and served in the U.S. Army.

Like all IRB members, they receive on-the-job training as invited guests at IRB meetings and are encouraged to attend local lectures and conferences relevant to the work. Davis said they also attend "IRB 101," a course developed by Kaiser Permanente that

... asked to obtain certification in the University of Rochester's program

provides a comprehensive review of responsibilities.

The organization's Department of Research and Evaluation encourages community members to use its archive of articles, journals, books, and videotapes, in addition to the materials included in the monthly IRB meeting package.

Formal discussions

She said committee meetings are preceded by a formal discussion of topics pertinent to human subjects protection, an effort to ensure continuing involvement with issues.

In addition, community members are asked to obtain certification in the University of Rochester's program, "Protecting Study Volunteers in Research." Earlier this year, members also began participating in the nationwide

Training an IRB's nonaffiliated members

Collaborative IRB Training Initiative (CITI), a web-based tutorial and testing site.

Conference participants also heard reports from a PRIM&R workshop on the role of nonaffiliated members, including ideas intended to solve several common problems with training and involving nonaffiliated members in the review process.

David Bernhardt and Judith Frazier, reported that the discussion included concerns that some IRBs don't listen to community members, that scientific members undervalue the contribution of community members, that community members don't know the boundaries of their role, and that they don't really represent the community.

Solutions

Solutions to these issues included the following:

- Clearly define the roles and clarify expectations. Write a job description.
- Have community members do presentations at IRB meetings.
- Solicit regular feedback from all IRB members.

New faces, fresh voices: spelling out an IRB's responsibilities to the community

It was suggested at the PRIM&R workshop that the role of nonaffiliated members might include the following:

- Represent and advocate for potential subjects.
- Provide balance by bringing a different perspective.
- Educate other board members about the community.
- Seek clarity and understanding in the informed consent process.
- Ensure sensitivity to subject needs, values, strengths, and weaknesses.
- Remind the IRB and the principal investigators of human factors, including anxiety and emotions.

Finally, it was suggested that in considering potential community members, IRBs should look for certain elements. They include an analytical mind, the ability to articulate ideas, assertiveness, a sense of altruism, and the time to devote to the job.Δ

The view from the director:

Government alone cannot adequately protect human subjects



Greg Koski

One of the troubling realities of the effort to protect human research subjects is that too often a single individual is the only community representative on a board composed of several researchers.

Greg Koski, Director of the Office of Human Research Protections, Department of Health and Human Services,

said the ideal toward which we should move is an expectation that every IRB member brings to the board an intention to protect human subjects as their paramount concern.

In an opening-day address at the conference, Koski said the present design for protection is largely the same as the system that has been in place for 30 years.

Everything has changed

"And yet everything has changed, including funding. The vast amount of human research is no longer funded by the government. It's funded by private sources."

Koski said IRBs have for too long been viewed as administrative entities designed to comply with regulations. "Today we are instead encouraging IRBs to become proactive. They should be actively intent on preventing harm to research subjects," he said.

Government agencies should not be the primary source of protection, he emphasized. Community groups, volunteer groups, and IRBs should be working toward a public/private/governmental partnership aimed at not

merely meeting requirements, but "trying to bring excellence to the effort of protecting human subjects."

Improvements in cooperation

This means serious changes should be made in the process so that the entire research community is concerned with fairness, openness, and justice.

"If a community member feels strongly about an issue and it is a minority view, the rest of the committee must take this seriously and be willing to review the protocol again."

Some changes have already begun, Koski said, including dramatic improvements in cooperation among the various federal agencies involved in protecting human subjects.

Fairness, integrity

But he emphasized that improvements in the governmental system of regulation compliance is not enough, and can never be enough, to ensure that people are treated with fairness and integrity.

Koski said the goal of fairness and integrity can be met only if the research community takes completely seriously its responsibility to human subjects. "Researchers must work together with the public to develop an understanding of concerns and issues important to all the stakeholders."△

IRBs have for too long been viewed as administrative entities designed to comply with regulation.

Genetic counseling

Beth Sheidley, a certified genetic counselor, representing the National Society of Genetic Counselors, told conference participants that the need for people who can speak knowledgeably about genetic issues has shifted dramatically since her organization started in 1979, and especially since the first 10 graduate students completed the first training program in 1971 at Sarah Lawrence College.

She said there are now 1931 members, 94% of whom are women and 93% of whom are white. The primary job for most counselors, she said, is to speak with parents about reproductive issues, including the risks and benefits of testing. The counselors also work with psychiatric, pediatric, and oncology issues. There are 28 graduate programs in genetic counseling in the United States, three in Canada, one in the United Kingdom, and two in Australia. Sheidley is a counselor for the Department of Psychiatry, New England Medical Center.

For information, see <http://www.nsgc.org/>



Beth Sheidley

Focus of training . . .

Programs needed to ensure that the process is continuous



Jeff Cohen

When IRB members are being trained, it is important to focus on three specific tasks, according to Jeff Cohen, Associate Director for Education, Office for Human Research Protections.

The first is science education—“basic science training, including statistics, experimental design, scientific terms, and so forth.”

Second is assertiveness training. “They have to be convincing, to speak up,” Cohen said. “They have to understand that their role is crucially important and other members have to understand this as well.”

The third task is to ensure that all voices are heard and valued. To accomplish this, it will be necessary to provide more training for IRB chairs so that they know how to make this happen.

“One way to do this,” he said, “is by employing Roberts’ rules of order at meetings. They really do work; it’s a good way to make sure that everyone is heard.”

Focus on three areas: science education, assertiveness training, and ensuring that all voices are heard and valued

IRBs should make sure that their members have a good grounding in ethical principles, including those stated in the Belmont report. “It must be made clear that regulations are the floor, not the ceiling of what is needed,” he added. “Merely following regulations is not sufficient.”

Training should also cover the policies of the institution that the IRB represents, he said.

“It should also provide awareness of applicable state laws. All 50 states have laws regarding human subjects research and often they are very different. So it’s necessary to know which laws apply to your institution.”

Finally, Cohen said, IRBs should institute programs that ensure that training of members is ongoing, Cohen emphasized. “This must be a continuous process. It’s not the sort of thing that can be adequately covered in a weekend workshop.”



Panel members considering the special problems unique to IRBs dealing with vulnerable populations, from left, Cassandra Novak, Children’s Hospital of Orange County; Terry Powell, Alaska Native Medical Center Area IRB; and Sylvia Kieding, Center for the Protection of Workers’ Rights.

Novak discussed issues that arise when working with children, including the recognition that children respond to medications differently from adults. Powell noted the importance of ensuring consent forms are both understandable and sufficient when used in communities of people whose culture, such as Native American, is different from that of the researchers. Kieding discussed the history and issues related to protecting human subjects in workplace research projects.



Jean Taylor-Woodbury, of Independent Review Consulting, explained the special problems associated with IRBs trying to protect human subjects when research is conducted in prisons.

Special problems and advocacy when serving on IRBs dealing with vulnerable populations

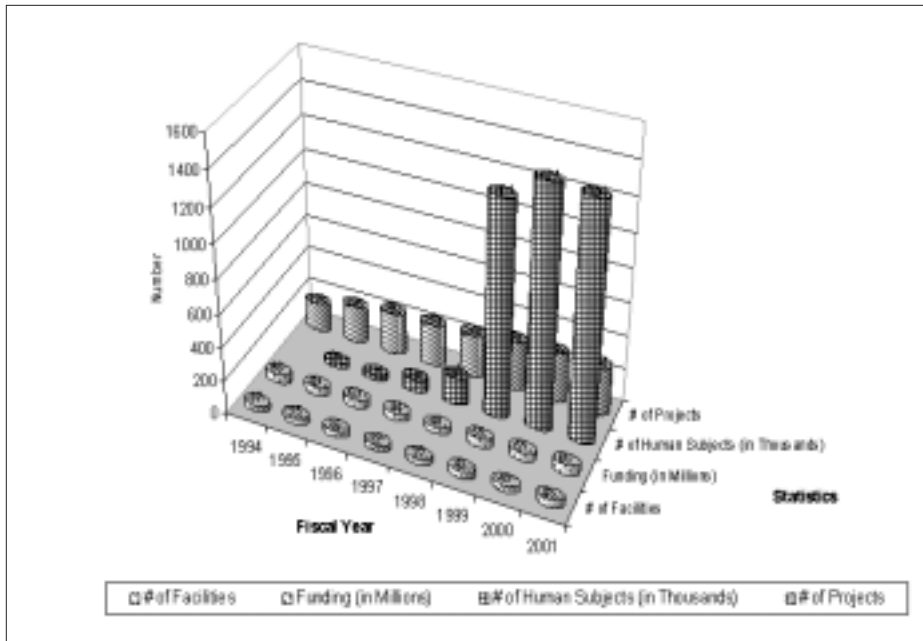


Figure 1. Trends in the number of reporting facilities are shown in the graph at left. Funding is depicted in millions for tasks or portions of projects involving human subjects. The total number of human subjects is shown in thousands. Much of the increase in subjects resulted from the addition of epidemiological studies.

Human subjects database

By Richard Larsen,
Ethel Jacob, and Camille Marinetti,
DOE Environmental Measurements Laboratory

The FY 2001 update of the DOE Human Subjects Research Database (HSRD) is now on the World Wide Web at <http://www.eml.doe.gov/hsrd/>. The database had 40,259 visitors in 2001, an increase of about 67% from 2000.

Initiated in 1994 and updated annually, the database contains information on research projects that involve human subjects and that were funded by DOE, conducted at DOE facilities, or performed by DOE personnel.

294 projects and 46 research facilities

The database consists of 294 projects, of which 71% were conducted at DOE facilities and 29% at non-DOE facilities (such as hospitals and universities). There are 46 reporting research facilities, including 14 DOE laboratories and 32 non-DOE facilities.

DOE funding directly associated with tasks involving human subjects was about \$47 million. Other federal and private funding at DOE facilities was about \$13 million. A total of 1,398,245 human subjects were reported, about 99% of whom result from records collected in registries, questionnaires, surveys, and epidemiological studies.

Although the projects highlighted in the FY 2001 database are primarily medical, biological, and epidemiological, some of this year's projects reflect advanced engineering concepts developed in DOE's national laboratories and connected to the war on terrorism. These include development of new

technologies to detect intentional deception, concealed weapons, border intruders, and a person's identity using a video camera.

Big increases, but drops expected

Figure 1 presents trends in the number of reporting facilities—funding directly associated with tasks or portions of projects involving the human subjects (in millions), the total number of human subjects (in thousands), and the number of projects reported.

Most evident in these trends is the explosive increase in 1998's reported number of human subjects. This resulted from the addition of epidemiological studies from the Former Worker Projects and from the National Institute of Occupational Safety and Health. Because these projects are beginning to terminate, the number of subjects will begin to return to pre-1999 levels.

There was also a gradual increase in the number of facilities and the funding for human subjects research reported this year.Δ

*40,259 visitors,
up 67% from the
previous year,
visit database
web site,
which includes
294 projects.*

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
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This newsletter is available at no cost to anyone interested or involved in human subjects research at DOE. Please send name and complete address (printed or typed) to the address below. Please indicate whether information is to

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Meetings

■ AMERICAN SOCIETY FOR BIOETHICS AND HUMANITIES 5TH ANNUAL MEETING

October 24-27, 2002

Wyndham Baltimore Inner Harbor Hotel • Baltimore, Maryland

Sponsored by the American Society for Bioethics and Humanities and the American Academy of Hospice and Palliative Medicine.

For information, telephone (847) 375-4745, email info@asbh.org, or see <http://www.asbh.org/meeting/>

■ NATIONAL HUMAN SUBJECT PROTECTIONS EDUCATION

October–November 2002

Albany, New York

The Office for Human Research Protections (OHRP) continues to sponsor a series of workshop on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB.

For information, email gcarter@osophs.dhhs.gov, or see <http://ohrp.osophs.dhhs.gov/wrkshp.htm>

■ PRIM&R/ARENA ANNUAL MEETINGS—PROTECTING HUMAN SUBJECTS: WHAT'S BEST? WHAT WORKS? WHAT'S WORTH DOING?

November 16–19, 2002

Town and Country Resort and Convention Center • San Diego, California

Cosponsored by the Boston University School of Medicine and the University of California, San Diego.

The 17th annual meeting of the Applied Research Ethics National Association (ARENA) will be held November 17, the first day of this combined session. The annual PRIM&R IRB Conference will be held November 18–19.

For information about the conference, including the agenda, speakers, online registration, and hotel, see: <http://www.primr.org>. You can also contact PRIM&R/ARENA at (617) 423-4112 or info@primr.org.

Past newsletters are available at

<http://www.science.doe.gov/ober/humsubj/newslett.html>

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