# PROTECTING HUMAN SUBJECTS

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

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## Focusing on community-based research

Many Institutional Review Boards (IRBs) know little about "community-based research." This issue of Protecting Human Subjects hopes to remedy that. Community-based research is resarch performed in or with communities that have health concerns related to their location or to specific pollution sources in the vicinity or are culturally diverse communities with life styles or disease prevalences that separate them from unaffected groups. This kind of research can be problematic because of hardened attitudes, paternalism, community inclusion or exclusion, benefits promised or ignored, competition for limited research funding, and scientific merit or lack of it.

Community research was the focus at a wonderful conference held at Brown University this past summer. Spreading the message from that meeting, as well as noting other community-based research resources, is the focus of this newsletter. Those with IRB knowledge and those from community research organizations must learn to speak with similar language and understanding of the other's role. Highlighting the topic in this newsletter will at least add to the perspective of our readers and further the much-needed dialogue.

***—Susan Rose, Director,***
***DOE Human Subjects Protection Program***

# Improving ethics in research

*Conference included community representatives, funders, and researchers*

*By Dianne Quigley*
*Syracuse University*

**Dianne Quigley**

Culturally diverse populations and collaborative community health studies were the subject of a research ethics conference this summer at Brown University.

The meeting brought together community representatives, academic scientists, government researchers, and funders in the field of environmental and public health.

Through case-study presentations and panel discussions, participants generated new recommendations, tools, and resources to improve research ethics and expand networking. Information about how research may harm communities and better ways to conduct research was also provided.

### *Recommendations*

Among the recommendations made was that new models be created to ensure the protection of community rights in research and that meaningful independent community

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# Research ethics conference (Continued from page 1)

review processes be developed. Such models might do a better job of ensuring equitable community control and of creating a good balance of power among diverse stakeholders.

Other speakers recommended that to improve IRB processes, the most essential components—IRB training, community participation, and strengthening ethical principles for community-based research—must be made more effective.

***Research protections***
Some conference speakers focused on innovations that address research harms, including the harm of providing no benefits to communities, exploitation of community members, and failure to inform about risks and benefits.

Other presentations discussed increased community control as a strategy to further community collaboration in research. A tribal group presentation focused on how its community research councils established criteria to allow or disallow research. Also discussed was the Southeast Community Research Center in Atlanta, Georgia, which provides infrastructure support and participatory strategies to communities involved in health studies with academic researchers.

***Promoting community (group) rights in research***
A Syracuse University group debated the position that ethical principles protecting individual rights in research also should be applied to community rights. One side of the debate argued that employing community-based participatory research (CBPR) models that share decision-making and resources between communities and researchers creates more of a likelihood that communities will be treated fairly and respectfully. This, in turn, will increase the likelihood that communities will accept the results.

One ethicist argued, however, that there are difficulties in trying to protect group rights. The ethicist said there are no established principles on group rights in research and that attempts to establish such rights will face a complex set of new problems. When, for example, does a group become worthy of separate ethical consideration? How should informed consent guidelines be modified to take into account particular group characteristics? How does the researcher deal with competing representatives in one community; the problem of community stigmatization from research results; the questions of ownership of data and results? How are individual rights protected when the community owns the data?

One presentation featured field stories from community-based organizations engaging in collaborative research with academic and government scientists. Speakers discussed struggles among communities and researchers in their efforts to share control.

They also noted the efforts to stop researchers from misusing community projects by overriding community consultation and control. They said culturally diverse communities can become mere guinea pigs for multiple research teams that provide no benefits to the community and frequently do not even report findings back to the community. Part of the discussion focused on the ethical challenges of

***About the conference***
Sponsored by the "Collaborative Initiative for Research Ethics in Environmental Health," the national conference "Dialogues for Improving Research Ethics in Environmental and Public Health" was held at Brown University in June .

Administered by Syracuse University, the Initiative involves an interdisciplinary team of public health, social science, biomedical and behavioral researchers, including several ethicists from five collaborating universities.

The conference was attended by 107 participants, half of which represented some 40 community health organizations across the country. About 40% were academic researchers, and 10% were government researchers and state/tribal health officials. It was a diverse group: 42% caucasian, 26% African-American, 16% Native American, 14% Hispanic, 6% Asian, 3% other.

Evaluation comments, conference proceedings, and recommendations will be compiled into a conference report available by the end of 2003 on the project's Web site, www.researchethics.org.

The conference was funded by the National Institute of Health, National Institute of Allergies and Infectious Disease Grant Program for Research Ethics – T15 A149650-01.

For information, contact Dianne Quigley, (315) 443-3861, diquigle@syr.edu.

Jessica Henry and Doug Taylor, staff from the Southeast Community Research Center in Atlanta, Georgia, attending the Brown University conference.

Discussion sessions at the Brown University conference were attended by more than 100 registered participants.

stigmatization from environmental contamination results, access to data, and reporting of data to study participants.

***Reshaping science***

Other conference speakers discussed "native" science methods as a model for more integrated, holistic research approaches. They highlighted limitations of scientific "objectivity" and suggested a multitier definition of health incorporating cultural as well as accepted practices. A culturally based risk assessment study, for example, may produce findings that go beyond such things as measuring levels of PCB in fish to also noting such values as loss of language and cultural practices.

***The status of funding***

Lack of funding for CBPR was said by some speakers to be a significant challenge facing efforts to employ more ethical research methods. Speakers from the National Institute of Environmental Health Sciences and the Environmental Protection Agency discussed their agencies' commitment to CBPR and the challenges involved in funding decisions.

A community speaker argued that communities should have control over research funding to ensure ethical treatment of subjects and communities. A speaker from the Indian Health Service (IHS) said the IHS IRBs already employ guidelines requiring community (tribal) approval, cultural sensitivity, and community partnerships in each stage of research.

Other speakers expressed concern about whether "community members" are treated equitably on IRBs and suggested alternative IRB models to ensure community independence from academic control. One of the speakers highlighted the important role community members can play on IRBs, noting that, among other things, they can work to ensure that ethical standards reflect community values. The speaker recommended that community members, and perhaps even all IRB members, should receive training in CBPR, which would be expertise they could bring to the board.

Informed consent procedures were discussed by some speakers who said problems include determining who should provide consent, particularly in very culturally diverse communities, and how one can determine benefits and risks. Other problems arise in how to balance power among partners, how to get community input and integrate community knowledge, and how to promote institutional change. Speakers noted the need for agreement about community control, skills-building for community members, inclusion of qualitative data of the community's experience of contamination, identification of concrete benefits to the community, and translation of research results to the community.

Both academic and community presenters focused on the challenges to partnerships that result from unequal power differentials, especially those related to white privilege issues and domination of research interactions by powerful academic institutional values.

They said trust can be increased by seriously listening to each other and trying to understand each other's values. Most said it is important that resources and time be provided before research begins so that communities can ask questions that derive from their own experience rather than from scientific frameworks. Δ

# Failed community representation

## *Does the process inhibit full IRB participation by community representatives?*

During my decades-long experience with IRBs, first as the bioethicist with oversight of the intramural IRBs at the National Institutes of Health (NIH) in the late 1980s and later as the bioethical representative to several IRBs at NIH and elsewhere, I was repeatedly impressed by the failure of community representatives to fulfill their mandated functions.

Ernest Wallwork

The several reasons for this failure are noteworthy because they help account for a particularly weak spot in the ethical review of research involving human subjects.

***The selection process***

One reason community representatives underperform stems from the selection process. Too often, community IRB representatives are chosen for the wrong reasons. Instead of being singled out for their intimate knowledge of the community or ability to speak on its behalf, the primary criterion for selecting a community representative is simply that he or she has happened to come to the attention of an administrator. One community representative was appointed after meeting a medical director at a New Year's Eve party!

***Docility as an important trait***

From the administrator's perspective, the most important trait for a community representative appears to be docility. Those who do speak up frequently are trained in circumspection by admonishments from the chair for "taking up the valuable time of other members of the IRB on trivial matters."

Reappointment should offer an opportunity to reward community representatives who take active roles rather than those who do not make waves.

The prospect of reappointment also serves to keep some community representatives in line during their tenure because appointment to an IRB of a premier medical institution is a valuable status perk that goes far beyond the minimal financial incentive. For one clergyman representative with whom I talked, a conciliatory posture not only accorded well with his moral theology, it assured him of retaining the stature his IRB role conferred on him with his congregation.

***Group dynamics***

The subtle group dynamics of many IRBs also inhibit community representatives from taking an active role, even when they may be personally disposed to do so. The most obvious inhibitor is the community representative's sense that he or she is an outsider to the medical community.

*By Ernest Wallwork*
*Professor of Ethics*
*Syracuse University*

Without the credentials of the health care professionals who dominate many IRBs, the community representative may lack confidence in the wisdom of his or her questions and concerns. Hearing a sophisticated scientific or statistical discussion of a protocol, a less well educated layperson must not be silent out of a fear of sounding stupid or ill-informed.

***Nonverbal dynamics***

Another, particularly pernicious source of inhibition that affects community representatives stems from the nonverbal dynamics of the IRB group process. For example, a community representative may have difficulty finishing a thought when the IRB's medical representatives become restless or impatiently shuffle their papers. Nonverbal communications put pressure on the community representative to shorten a point or to drop points he or she was contemplating. They also divert the medical representatives from attending fully to the community representative's points.

The inability to hear is a symbolic symptom of the difficulty the medical IRB representatives have

***—Continued on page 14***

*"The reasons for failure help account for a particularly weak spot in the ethical review of research involving human subjects."*

# Facilitating participatory research

## *Community Partnerships for Health*

A wide variety of Web sites provide helpful information about community-based research and related issues. The two noted on this page are good indicators of what is available on the Internet. Addresses for more sites are on page 11.

### *Community-Campus Partnerships*

Community-Campus Partnerships for Health (CCPH) is a nonprofit organization that promotes health through partnerships between communities and higher educational institutions.

With a network of over 1000 communities and campuses, CCPH facilitates collaborations through community-based research, service-learning, community service, and other strategies. Its programs include the following.

• CCPH Consultancy Network—People from higher education, health professions, and community-based organizations who have experience, expertise and records of success in important areas related to community-campus partnerships. CCPH consultants conduct training workshops, consult, and coach partnerships to fully realize their potential.

• Annual Conference—for community and campus leaders who are building community-campus partnerships, are involved in health professions education, or desire to improve the overall health of communities.

• Service-learning institutes—for campus- and community-based health professions faculty who wish to integrate service-learning into their courses.

• Member listserv—interactive discussion forum with nearly 800 subscribers from across the United States and, increasingly, the world.

• Information clearinghouse—print and Web-based publications on service-learning, health professions education, principles of partnership, community-campus partnership models that work, and much more.

• Online Membership Directory—password-protected directory to help locate and network with other members.

• Consultancy Network fosters partnerships between communities and educational institutions through high-quality and effective training and consultation.

Founded at the University of California–San Francisco Center for the Health Professions in 1996, CCPH is funded by a variety of public and private organizations, government agencies, philanthropies, and individual citizens. For information, visit http://futurehealth.ucsf.edu/ccph/commbas.html. Δ

### *Institute for Community Research*

In collaboration with community partners, the Institute for Community Research conducts research to promote justice and equity in a diverse, multiethnic, multicultural world.

The organization engages in and supports community-based research partnerships to reverse inequities, promote positive changes in public health and education, and foster cultural conservation and development.

Founded in 1987, the Hartford, Connecticut, nonprofit institute has several goals, including to

• establish partnerships that make research accessible to broad audiences;

• train youth, adolescents and adults to conduct and use research for community change;

• develop new models of public health prevention and test new ideas for effectiveness;

• promote cultural expression and community cultural resources;

• use research to advocate for positive change; and

• share results, models and information through conferences, workshops, publications and other public forums.

The institute's web site is http://www.incommunityresearch.org/. Δ

# "Women's Health in Women's Hands"

*Researchers at this Ontario, Canada, clinic must be prepared for a new way of thinking about responsibility to subjects*

Conducting research at the Women's Health in Women's Hands clinic sometimes requires researchers to think very differently about their responsibility to human subjects.

The Ontario, Canada, health care center primarily cares for Black women and women of color from Africa, the Caribbean, Latin America and South Asia, with a special emphasis on these who are living in poverty.

**Notisha Massaquoi, Women's Health in Women's Hands clinic program manager**

This group offers a rich resource for researchers interested in learning more about the women's experience with health care, their ideas about medical treatment, and their perceptions of health care providers. As a result, there has been a steady stream of requests from a variety of researchers seeking permission from the center to do surveys, examine the women's histories, and otherwise gather information.

*Researchers should not merely come to the clinic, get the information they want, and then leave. They should also give something back to the community.*

***Benefits***

The center's program manager, Notisha Massaquoi, said that participating in research benefits both the clinic and the women who are its clients. But she adds that it is important for researchers to understand that they should not merely come to the clinic, get the information they want, and then leave.

"They should also give something back to the community. It is not acceptable that research be a one-way thing. When you pull something from the community, you should also put something back in."

***Co-investigators***

The first of several criteria the center established for considering research proposals is that the center be involved as a co-investigator from the beginning.

"This means" Massaquoi said, "if they already have a proposal that has been funded, we won't agree to let them do research at the center. We want to be involved in developing the proposal and in the funding process."

A large number of the center's clients are new to Canada, and very often English is not their first language. Massaquoi said this makes them vulnerable to situations in which they may misunderstand what is expected of them.

"For example," she explained, "if a woman receives care here, she may assume that because she likes the clinic, then the research study is something she should agree to participate in, no matter what it is. But that's not a good enough reason."

Neither is it sufficient, she added, to offer $20 or $30 for participation. Instead, there should be a significant effort to provide tangible benefits in return for the benefits the researchers are receiving.

Among the restrictions the center places on research projects is a firm policy of not allowing its own physicians or other health care providers to ask research questions, conduct surveys, or hand out questionnaires.

"We don't want our clients to feel they have an obligation to cooperate. We don't want them to feel that they won't get health care if they choose not to participate," Massaquoi explained.

An example of the center's effort to make research more equitable is a current study for which the contract requires researchers to give to the clinic all computers, video equipment, books, and other materials used during the research.

"The contracts we require are very specific. They outline the benefits expected by the researchers and then say what the center will receive and what the community will receive," Massaquoi said.

She said some researchers are reluctant to agree to the center's expectations, and some funding agencies are similarly less than enthusiastic. "But we have also found that many researchers understand both why we have these guidelines and why they are important," she said.

Among the most important of the center's emphases on research is a move toward participatory action research.

The idea is to "engage research subjects in a manner that empowers them in some way at the end of the study. Ideally, this means putting the subjects in the position of being researchers. We would like them to reflect on and research their own experiences in health care."

She said the purpose of participatory research is to enable research subjects not just to find ways to protect themselves, but also to be actively involved in the research.

***Case study employs center principles***

"For example, we participated in a recent study looking at the health care experience of 16 to 21-year-old women of color. Among other things, we wanted to know something about the nature of racism they have encountered in the health care system. We wanted to know how they responded and in what ways this affected the way they sought health care after their experiences."

Methods of participatory research were employed in the study because this age group is especially difficult to access, she said.

"We recruited 10 young women, and then we got help from Ph.D. students at the university to help them learn research skills.

"Then each of the 10 interviewed 10 of their peers, paying each of them $10 each. We ended up getting information from 100 young women. But in addition to that, we helped to create a support group for the women and we were able to get much richer information because the women who were doing the interviews understood both the language and the experience of the women they were interviewing.

"I think we also demonstrated to them that they need not be immobilized by bad experiences in health care, that they can develop the power both to understand the system and to get it to respond to their needs."

The group being studied, she said, often is reluctant to get involved in the health system for a variety of reasons. The project helped educate them both about the system and about the health care center as a valuable resource.

"So, while it might often be hard to get researchers to understand why it is so important to work on an equal basis with community groups, our experience has been that it's worth the effort," Massaquoi said. "Everyone can benefit, if you try hard enough to make sure that happens." Δ

## Database moved to Oak Ridge

Management of DOE's Human Subjects Research Database (HSRD) has been reassigned to the Oak Ridge Institute for Science and Education (ORISE).

The database had been managed by DOE's Environmental Measurements Laboratory (EML) since it was begun in 1994. The change was effective October 1, 2003, after EML was transferred to the U.S. Department of Homeland Security (DHS).

The database, updated annually, contains information on 240 active research projects. It is a searchable interface with detailed descriptions of all research projects involving human subjects conducted with DOE funding, at DOE institutions, or by DOE personnel as required.

The HSRD will be the second major human subjects protection activity to be assigned to the Oak Ridge site. The database complements the existing Central Beryllium IRB, which addresses DOE-wide beryllium-related human subjects research and ethics issues.

# Protecting vulnerable populations

*Tuskegee's National Center for Bioethics in Research and Health Care is helping to pioneer participatory methods*

Tuskegee, Alabama, once the site of an infamous research project, is now a thriving center of bioethics that is developing new methods employing participatory research.

Tuskegee became known in bioethics primarily as the place where the U.S. Public Health Service conducted a syphilis study on black men. The study was criticized for failing to protect the well being of its human subjects in the most basic sense of medical care.

Stephen Sodeke

***Involving subjects***

Now, Tuskegee University's National Center for Bioethics in Research and Health Care is employing a combination of methods to ensure that human research subjects are protected. These methods are designed to fully involve subjects in developing the kind of research that will be done and in being involved as researchers themselves.

The Bioethics Center itself is employing a multidisciplinary approach in exploring core issues underlying research and medical treatment for African Americans and other underserved populations. Interim Director Stephen Sodeke said the Tuskegee center is an attempt to find a way forward from the tragedies of the past.

***Empowering the community***

Among the most important of its projects, he said, is to find ways to empower the community. "Historically, vulnerable populations and, in particular, African American communities have been marginalized politically and economically, have developed a sense of powerlessness, and have lost trust in the health care infrastructure.

"These communities are usually among the poorest in the nation, have fewer resources, and often face seemingly insurmountable obstacles when they attempt to redress these problems. Such bioethical issues deserve special attention.

"So, among the Center's stated goals is 'to develop significant levels of trust in the national health care infrastructure–transcending boundaries of economic status, social status, race, ethnicity, and gender.'"

One way to do this, Sodeke said, is to go out into the community and help determine both what people need and how they can get it.

He said one of the tools that can help is Community-Based Participatory Research (CBPR), in which studies are conducted by trained researchers and lay participants or communities. The expert and lay participants are equal partners in an endeavor that seeks to ensure that the views, concerns, and interests of all participants are given equal weight.

This equality extends to determining the focus of the research questions, the approach to be taken to identify answers and solutions, and the use and significance of the products of the research.

*Participatory research enables research subjects not just to find ways to protect themselves, but also to be actively involved in the research.*

Sodeke said Tuskegee's Communities of Color and Bioethics Project, under the leadership of Kimberly McCoy-Daniels and Douglas Taylor, will provide assistance to communities in voicing their views on the ethics of health practices and medical research and "to clearly articulate and disseminate information that can usefully influence public policy.

"We want the community to understand that it can contribute as an equal partner in research," he said. "The community itself can identify its own needs and can have an equal hand in determining what research is done and how it is done."

Most importantly, he said, "we have a responsibility to assist the community to understand why research

is done and how it can help individual members of the community."

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.

***Challenges***

The university for a long time, he said, has, like all universities, had an IRB that includes community members. "One of the biggest challenges has been to recruit and then to retain those community members.

"It shouldn't be surprising that this is not easy. Most community members are concerned primarily about making a living and getting by from day to day. They are not as concerned about how and whether research is done."

Sodeke said the Center's emphasis on participatory research is partly an effort to address this problem. "I think that if the community comes to think of itself as knowledgeable and capable, we will see changes in many directions."

To do this, the Center is trying to address communication challenges and organizational barriers to community representation. This attempt 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.

A workshop to be held at Tuskegee this Fall is designed to find ways to help people in communities understand the purpose of research, the nature of IRBs, the terminology of research, and the reasons research is important.

***Four goals***

"We have to develop methods that will accomplish four goals," Sodeke said. "One is to make serving on IRBs as community representatives important enough and attractive enough that people will take the time and effort to participate.

"The second is to educate entire communities about research, IRBs, the terminology, its goals, and how it can benefit them.

"The third is to involve community members at the earliest stages of research by training them to identify in health care the things a community needs to flourish. This will involve an examination of their value system, their culture, and how they want to develop as a community.

*The community must develop the tools it needs to translate its needs into research questions.*

"Finally, the community must develop the tools it needs to translate its needs into research questions.

"By working toward these goals," he said, "the community will see itself as an equal partner in the research, as equally able to contribute the knowledge base for research studies."

It is important to involve specific populations of people in the research process, Sodeke explained, because more information is needed about how they are affected by various facets of the health care system.

"For example, I recently was prescribed a drug and was told I should take it once a day. But the side effects were terrible. I decided to take it every two or three days and it worked well without the side effects.

"Where did my physician get the information about the dosage I should take? He got it from the average American, who is white. It is often the case that if we get data about specific populations, such as Black Americans and other people of color, we find that something different may be required in prescribing dosages than for the average American."

The only way to get the best information, he said, is to involve more of the various populations of people that make up a community in the research process.

"This means we must involve them as research subjects in clinical trials as well as in community groups and as community representatives on IRBs. Until we do that, we won't be getting all the information we need." Δ

*"If the community comes to think of itself as knowledgeable and capable, we will see changes in many directions."*

# Mentoring graduate students

*University of Washington Ph.D. candidate Nancy Shore is guiding fellow student researchers through the challenges of protecting human subjects*

The University of Washington is institutionalizing a program pioneered by Nancy Shore, a Ph.D. candidate in the school of social work.

For two years, Shore has served on the University's Institutional Review Board (IRB) as the representative from the school. But she also took on another responsibility—guiding fellow graduate students through the often intimidating requirements of ensuring that human subjects are protected in their research.

Nancy Shore

"The School of Social Work's Associate Dean for Research asked me to help other students who were conducting research that involved human subjects."

*When students begin doing research, they can become overwhelmed by the maze of requirements that must be met.*

This help included consulting one-on-one with students. Shore also did presentations for graduate research classes about ethics and the human subjects regulations.

The idea of a consultant, or mentor, for students surfaced from a research project Shore conducted with her supervisor, Peggy West, the School of Social Work's Manager of Research Development.

Shore and West interviewed faculty, staff, and graduate student researchers to learn about what types of resources or supports the school could offer to facilitate the human subjects review process. The study also assessed what were the recurring challenges identified by the IRB. Prior to the study, Shore commented how "we had been hearing some student researchers voice confusion regarding the human subjects review process. So we decided to do something about it."

***Overwhelmed***

The problem was that when students begin doing research, she said, they become overwhelmed by the maze of requirements that must be met.

"This is especially difficult because most of the time they have been concentrating on methodology—what the goal is and how they're going to proceed—and they've not been thinking as much about the implications of working with human subjects."

When students look at the various Web sites explaining the process and at the other sources describing the regulations, it seems especially daunting, she said, because they are working with a specific deadline.

***One thing at a time***

"From the feedback I've received, it seems students find it very helpful to have me to sit down with them and go through the steps they will have to take. I do it slowly, one thing at a time, and it seems to work well."

One of the facets about which students ask the most questions, Shore said, is the consent form. At first students may not realize that the University requires a standardized format. But rather than having students just copy from the template, Shore takes the time to explain the importance of informed consent. "We often discuss issues about language choices and the importance of clearly describing the study procedures. While the focus may be on the informed consent document, I also talk about the informed consent process, including issues of coercion."

When a student comes to her for help, Shore begins by asking for an overview of the project. Then she asks questions to elicit information about how it

*"One of the facets about which students ask the most questions is the consent form."*

involves human subjects and the potential risks and benefits.

"My focus is not on the science of their study; their faculty supervisor offers mentorship in that area. My job is getting them to think critically about what the risks are. For example, some of the projects entail focus groups. So we talk about what confidentiality might mean in a group setting."

Experience on the university's IRB was the most important factor in the success of the mentoring program, Shore said.

"I learned a lot, right from the beginning. The other committee members were very supportive. When I had a question, they were good about explaining the process. I felt that my student status was not a problem, that they respected my input."

Shore's dissertation research is focusing on issues related to IRBs and the review of community–based participatory and conventional social science research. Based upon her preliminary findings, one of the challenges for the research community today, she said, is in involving community representatives on IRBs. "One of the issues raised is the need to recruit and support community members who are knowledgeable about the local community and who come from diverse backgrounds." Another challenge for IRB committees, said Shore, is having adequate representation of social science researchers who use a range of methodologies.

Her research often dovetails with the work she is doing with other students. "A lot of social work projects are on vulnerable populations. So it's important for both regular researchers and student researchers to understand how to minimize risks when studying these groups."

***Future plans***

The School of Social Work is very committed to providing ongoing support to students and making sure that research is conducted ethically. It plans to offer a research assistantship to a doctoral student who will continue to support graduate students in the human subject review process.

Shore and her supervisor drafted a school policy regarding the human subjects review process. The policy includes guidelines on how to determine whether a project requires human subjects review and outlines the responsibilities of the faculty supervisor. For a copy of this policy, contact Peggy West at plwest@u.washington.edu. The school's website on human subjects is at http://depts.washington.edu/sswweb/hsweb/index.html. Δ

# Participatory Research Web Sites

**Community–Campus Partnerships for Health**
*http://futurehealth.ucsf.edu/ccph/commbas.html*

**Partnership for the Public's Health**
*http://www.partnershipph.org/col1/about/overview.html*

**The Collaborative Initiative for Research Ethics in Environmental Health**
*http://www.researchethics.org/*

**Community-Based Collaboratives Research Consortium**
*http://www.cbcrc.org/*

**National Higher Education Community Research Project**
*http://www.bonner.org/campus/communityresearch.htm*

**Interagency Working Group for Community-based Participatory Research**
*http://www.niehs.nih.gov/translat/IWG/iwghome.htm*

**Communities and Colleges Working to Invigorate Grassroots Democracy in Appalachia**
*http://www.justconnections.org/*

**Roundtable on Comprehensive Community Initiatives**
*http://www.aspenmeasures.org/*

**The National Community-Based Research Network**
*http://www.cbrnet.org/*

**Community Linked Interdisciplinary Research**
*http://www.clir.buffalo.edu/*

**The Institute for Community Research**
*http://www.incommunityresearch.org/*

**Essay: The Promises and Dilemmas of Participation**
*http://www.cardi.cornell.edu/canal/Schafft_Greenwood.pdf*

**Southeast Community Research Center**
*http://www.cbpr.org/cbpr.htm*

# The Buffalo Project

*A Buffalo, New York, community group and researchers at SUNY are co-investigating the incidence of lupus near toxic dump sites*

When a group of 22 women suffering from the effects of lupus met with one of the members of the Buffalo, New York, city council, they set in motion an ambitious project that would develop into a model community participatory research study.

A professor at the State University of New York in Buffalo, Peggy Brooks-Bertram is working with fellow professor Carlos Crespo on what has come to be called The Buffalo Project. They designed the study to investigate the incidence of lupus and the women's concerns that the disease might be related to toxic dump sites in the community.

But the Buffalo Project is also designed to involve the women not just as human subjects but also as developers of the research and as co-investigators.

*The study is designed to involve the women both as developers of the research and as coinvestigators.*

Brooks-Bertram and Crespo became involved because the council member, after hearing the women's concerns, contacted the university's Environmental Science Center in the Department of Social and Preventive Medicine.

"After we agreed to become involved," she said, "we got funding to investigate biomarkers, do a survey, set up a registry, and begin community education regarding the hazardous waste areas and the incidence of lupus.

"We wanted to know whether there was anything unusual about the cluster of lupus and whether it had anything to do with toxic sites."

***Door-to-door survey***

The project is beginning the community outreach component, which involves a door-to-door community survey to determine whether the incidence of lupus is greater than the cluster previously identified. More than 30 additional cases of lupus have been found in the survey.

***Protecting themselves***

Brooks-Bertram said that part of the task of the project has been to work with the community, both to assure people that they are protected by the IRB and to develop in them the ability to protect themselves.

"To do this we have been forming an organization of stakeholders. The goal is to make this a fully participatory research study."

Brooks-Bertram said the organization is fully equal with the university's researchers.

*The researchers don't do anything unless it is in concert with the stakeholder organization.*

"They can write grants in their own name, as well as write them collaboratively with the university research group," she explained. "This means they can raise their own questions about human subjects protection. They can raise questions about what happens to the data and how they would like it handled."

The researchers don't do anything unless it is in concert with the stakeholder organization. "They selected the physician who works with them. They didn't like the first one they had, so he was dismissed."

***IRB training required***

She said the women went through IRB training, as did everyone else in the project, and had to pass the training test. The training and testing was done through the SUNY-Buffalo IRB.

Participatory research is far more difficult than is a study fully controlled by the researchers and an IRB,

➢

*"And often there are surprising resources they have that we've discovered along the way"*

she said. "It's not easy working with community groups. They don't have the resources the university has, and they are more concerned about making a living than about doing a scientific study.

"It's also difficult because the stakeholders have different levels of capacity to understand the process. Some have been to school, some haven't. They don't have experience in developing organizational infrastructures."

***Surprising resources***

"So we work with them a lot. We try to be conscious of what they need, we try to be sensitive, and we try to show them how they can do this. And often there are surprising resources they have that we've discovered along the way."

One of those was a separate organization, the Sisters of Lupus, which had previously formed in the community.

"Once we found the Sisters of Lupus, all sorts of new things opened up for us. It was an established group of women who had for a long time been getting together as a support group to talk about problems and ways to resolve them. This gave us access to more people and more information."

The researchers and the women from the stakeholders organization have together sought information about other women who have lupus in the community. They go to fairs and other community gatherings.

"We walk up to people and ask whether they know anyone who has lupus. And we're finding that by working together, we have more resources, we can cover more ground.

"The advantage to participatory research," she said, "is that we can get more done, and we can do it in a way that gives research subjects the power to control both how the study is conducted and what is done with the data. It also ensures that they feel involved in developing the boundaries and the methods." Δ

# Web sites

**The history of genetics**
*www.History.nih.htm>www.History.nih.gov/exhibits/genetics*

**The consortium to examine clinical research ethics**
*http://csmeh.mc.duke.edu/cecrelndex.htm*

**Bioethics resources on the Web, from the National Institutes of Health**
*http://www.nih.gov/sigs/bioethics/index.html*

**Center for Bioethics and Department of Medical Ethics at the University of Pennsylvania**
The center focuses on bioethics research and its deployment in the ethical, efficient, and compassionate practice of the life sciences and medicine.
*http://www.bioethics.upenn.edu/*

**National Reference Center for Bioethics Literature**
A specialized collection of books, journals, newspaper articles, legal materials, regulations, codes, government publications, and other relevant documents concerned with issues in biomedical and professional ethics.
*http://www.georgetown.edu/research/nrcbl/nrc/*

**Bioethics Information Retrieval Project**
Online bibliographic database with a scope that spans the literature of the health sciences, law, religion, philosophy, and social sciences. Access information is provided.
*http://www.georgetown.edu/research/nrcbl/ir/bioline.htm*

**National Information Resource on Ethics & Human Genetics**
Bibliographic databases searchable via the internet, full text of online annotated bibliographies, and print publications related to ethics and human genetics.
*http://www.georgetown.edu/research/nrcbl/nirehg/*

# DOE is committed to excellence & leadership in human subjects protection

### *AAHRPP accreditation for laboratories*

U.S. Department of Energy (DOE) labs conducting a substantial number of human subjects research studies are expected to seek accreditation in 2004 by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

This will "assure that the DOE Human Subjects Research Protection Program remains on equal footing with the best academic medical centers and the National Institutes of Health," according to a notice issued by Ari Patrinos, DOE's Associate Director of Science for Biological and Environmental Research, on behalf of the DOE Human Subjects Protection Program.

The AAHRPP (http://www.aahrpp.org) is the accrediting board begun by the Association of American Medical Colleges and a coalition of interested organizations. AAHRPP will work with the Human Subjects Protection Program and the DOE sites to tailor the accreditation process to DOE needs. Alternatively, labs can choose to have an on-site review conducted by the Human Subjects Protection Program and an outside review team.

An AAHRPP/DOE workshop is planned in Washington, D.C., December 8, 2003, for all DOE human subject contacts. It will address the process, delineate expectations, and answer questions.Δ

### *Mandatory human subjects education*

DOE has notified researchers working at DOE sites, using DOE funds, or using DOE personnel that it expects all IRB members and researchers to take and pass the Collaborative IRB Training Initiative (CITI) tutorial. The notice said that alternatively they could substitute an equivalent vigorous human subjects education program.

The notice was sent by Ari Patrinos, DOE's Associate Director of Science for Biological and Environmental Research. Patrinos said DOE "is committed to maintaining national excellence and leadership in the protection of human research subjects.

"This requires ongoing effort, education, vigilance, and innovation." Toward this end, Susan Rose, director of DOE's Protecting Human Subjects Program, has provided the tutorial to all DOE sites. Recent problems with the tutorial are being addressed by a small working group. Δ

### *Lawrence Livermore lends its IRB*

Lawrence Livermore National Laboratory (LLNL) is lending its IRB expertise to the University of California (UC) during the startup of a new UC campus in Merced (UC Merced).

UC Merced is utilizing the institutional committees of LLNL until they have enough faculty and infrastructure to develop their own institutional committees. The LLNL IRB will serve as the UC Merced IRB to review protocols during the startup period. As UC Merced develops its own IRB, its members will augment the LLNL IRB. This is a tribute to the IRB and the PHSP at LLNL. Δ

## Failed representation? *(From page 4)*

entertaining the idea that serious ethical objections can be raised by a layperson about the work of a senior medical researcher.

Recognition of these and other factors inhibiting full IRB participation by community representatives is important as a first step in designing strategies to overcome them.

Such strategies should include training programs for all IRB members that prepare them not only for their obvious responsibilities, but also for some of the nonobvious dynamics they are apt to encounter.

Administrators and scientific IRB members need to be made more aware of the ethical rationale for community representatives, including the value of hearing different voices when evaluating protocols with potentially unanticipated impacts on lay participants. Instead of being merely tolerated, community representatives should be welcomed and their numbers expanded to improve the ethical acceptability of research.

Federal policies probably should be amended to provide better guidance and support to administrators and IRB chairs in selecting, instructing and facilitating the important work of community IRB members. 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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## LBL's Byrne gets performance award

An Outstanding Performance Award has been presented to Chris Byrne, the IRB coordinator at Lawrence Berkeley National Laboratory. Chris received the award in recognition of her contribution to the University of California (UC) working group tasked with implementing Health Insurance Portability and Accountability Act (HIPPA) in research.

She was recognized for the special effort she made to present the perspective of researchers and committees at sites like the federal labs and UC campuses without medical schools. With the goal of one universal policy and training program, UC needed to develop policies and training materials that would facilitate compliance at all sites, even those lacking the administrative and research infrastructure provided by a medical school.

# Meetings

**OFFICE FOR HUMAN RESEARCH PROTECTIONS WORKSHOPS**
OHRP sponsors 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 serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other public health service agencies.
For information, including dates, see http://ohrp.osophs.dhhs.gov/wrkshp.htm

**PRIM&R/ARENA ANNUAL IRB CONFERENCE – 2003**
December 4–7, 2003
*Washington, D.C.*
Among other events, the DOE Human Subject Working Group will participate in a workshop on the nuts and bolts of accreditation.
For information, see http://www.primr.org/conferences.html\

**PRIM&R/ARENA ANNUAL IRB CONFERENCE – 2004**
October 30–November 2, 2004
*San Diego, California*
For information, see http://www.primr.org/conferences.html

Past newsletters are available at
http://www.science.doe.gov/ober/humsubj/newslett.html

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