PROTECTING HUMAN SUBJECTS

U.S. DEPARTMENT OF ENERGY,
OFFICE OF BIOLOGICAL AND ENVIRONMENTAL RESEARCH — ISSUE NO. 15

Risk, consent, & IRB models

SACHRP members debate recommendations for important changes in the Common Rule and in OHRP guidance

What is the best way to protect decisionally impaired research subjects? When does mental impairment translate into a subject's inability to give informed consent? How should minimal risk be defined? When is it reasonable to waive or alter consent requirements? Would alternative Institutional Review Board (IRB) models enhance scientific progress and research protections?

These issues dominated discussion at the recent meeting of the U.S. Department of Health and Human Services (HHS) Secretary's Advisory Committee on Human Research Protections (SACHRP).

Participating in the meeting were the eleven SACHRP members and ex-officio (non-voting) members from other HHS agencies and other federal departments and agencies, including DOE. *(See article describing*

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Inside

DOE's redesigned HS Web site

http://humansubjects.energy.gov

Charles Pietri

The DOE Human Subjects Research Program Web site has been redesigned with a new look, improved navigation, expanded content, and more features to enhance the user's online experience.

Over the past decade, the program has used its Web site to communicate mainly within the DOE community. However, during the past few years, it became evident that the site, because of its limited content and focus, was not completely achieving its objective of providing significant human subjects protection information to its constituency.

by Charles Pietri, CEO HITECH Consultants

Last year, the Office of Biological and Environmental Research, under the direction of **Dr. Michael Viola**, Director, Life and

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Ethics education

Mock trials and other vehicles are unique compliance training tools

Sherry Brewer

The courtroom fell silent as Dr. Marcus Welby took the witness stand.

The venerated physician had treated the plaintiff for nine years, but now he had some explaining to do. How would he justify his decision not to withdraw his patient (now the plaintiff) from the clinical trial he was conducting?

This courtroom drama, which occurred during a mock trial conference, is one of several vehicles we have used for teaching research compliance. The idea is to bring "first-person" experiences to human subjects education. Typically, few topics inspire less excitement than mandatory "compliance training."

by Sherry Brewer, Director Office of Research Integrity University of Tennessee School of Medicine

That challenge—how to create interest in research ethics and compliance training—led us to develop a variety of participatory teaching environments using audience involvement to enhance learning.

Participatory learning

Our first foray into participatory learning for human subjects training was the mock trial described above, C.J. Craig vs. Marcus Welby. In this fictional scenario, C.J. Craig (yes, the television character from "West Wing" found a

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The one notable change in the order concerns the National Nuclear Security Administration, a semi-autonomous agency within DOE responsible for enhancing national security through the military application of nuclear science

Revised DOE order waiting final approval

Revised DOE directives for the protection of human subjects — a short history

DOE Directives are the official communications of policies, requirements, and procedures for the Department. A draft revised Policy (DOE P443. X) and Order (DOE O 443.1A for the protection of human subjects in research have been prepared, reviewed, commented on, and final revisions made.

These documents are currently awaiting approval, expected shortly, by the Deputy Secretary of Energy, **Clay Sell**. This will be the third revision of these directives since their inception.

Research using human subjects provides important medical and scientific benefits to individuals and to society.

The order notes separate (and in many cases parallel) responsibilities for the DOE and NNSA human subjects research program managers. NNSA sites should not notice any significant differences in day-to-day practice, however, as NNSA has indicated its intent to work within the existing DOE structure with regard to human subjects protection and to let many day-to-day responsibilities continue to be managed by the DOE program manager.

The need for this research does not, however, outweigh the need to protect individual rights and interests. In December 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research recommended and proposed a uniform set of regulations, based on those of the Department of Health and Human Services, to be adopted by all Federal agencies and departments conducting human subjects research.

Establishing the Common Rule

A proposed model Federal Policy for the protection of human subjects was published in the Federal Register on November 10, 1988 establishing this uniform set of regulations as a "Common Rule." DOE policy regarding this issue was established in the Federal Policy for the Protection of Human Subjects, adopted by DOE on June 18, 1991 as 10 CFR 745.

On August 23, 1990 DOE Order 1300.3, Protection of Human Subjects, was published. This Order implemented 10 CFR Part 745, as initially written, and at any such time that it is amended to conform with the "Common Rule". It is notable that the policy statement for human subjects protection was incorporated into this Order and not issued as a separate policy directive at that time.

On May 15, 2000, the Order was revised and published as DOE Order 443.1, Protection of Human Subjects. At the same time, DOE policy was incorporated into a separate policy document, DOE Policy 443.1, Protection of Human Subjects. Applicable federal and Departmental regulations, the DOE policy statement, and the DOE order must be met before any research involving human subjects can be initiated.

Extensive internal review

The next and current revision of the DOE policy document and the order occurred during the 2006-2007 timeframe. After extensive internal review by members of the DOE Human Subjects Working Group (HSWG), a revised draft document was further refined and submitted to the online DOE RevCom system (Review and Comment System) for comprehensive review by all DOE organizations.

Most of the comments, including non-binding suggestions, were incorporated. No significant changes

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Previous Director of the Office of Former Worker Screening Programs

White named new HS protection officer

Elizabeth White has been appointed Human Subjects Protection Officer for the DOE, in the Office of Science (SC), Office of Biological and Environmental Research (OBER).

Elizabeth White

Peter Kirchner

She will work closely with **Dr. Peter Kirchner** (see background information in *Protecting Human Subjects*, issue 13, p. 5), who has been responsible for the human subjects program along with his other responsibilities over the past few years.

Kirchner has undertaken multiple initiatives, including revision of the DOE Order on the Protection of Human Subjects (443.1A) and a major overhaul of the department's Web page on human subjects protection.

White moved to the Office of Science from DOE's Office of Health, Safety and Security (HSS), where she was Director of the Office of Former Worker Screening Programs.

During her twelve years in HSS and its predecessor organization, the Office of Environment, Safety and Health, White managed both domestic medical screening services and international radiation health effects research involving human subjects.

In those positions, she worked closely with the Office of Science and applicable IRBs to ensure initial and ongoing compliance with human subjects protection requirements.

White managed domestic medical screening and international radiation health effects research involving human subjects.

White also worked with **Dr. Susan Rose,** longtime DOE Human Subjects Protection Officer and leader in the field, to jointly establish the DOE-wide Central Beryllium Institutional Review Board, which addresses beryllium-related human subjects protection issues associated with research and medical screening.

White has a master's in Business Administration from Northwestern University and a master's in Public Health from Johns Hopkins University.Δ

DOE's HS research funding up again in 2006

Funding for individual projects ranged from 800 dollars to $14 million, with an average of $469,000

by Donald Watkins, Oak Ridge Institute for Science & Education

The DOE Human Subjects Research Database (HSRD) is updated yearly and contains information on all research projects involving human subjects that are not exempted by the

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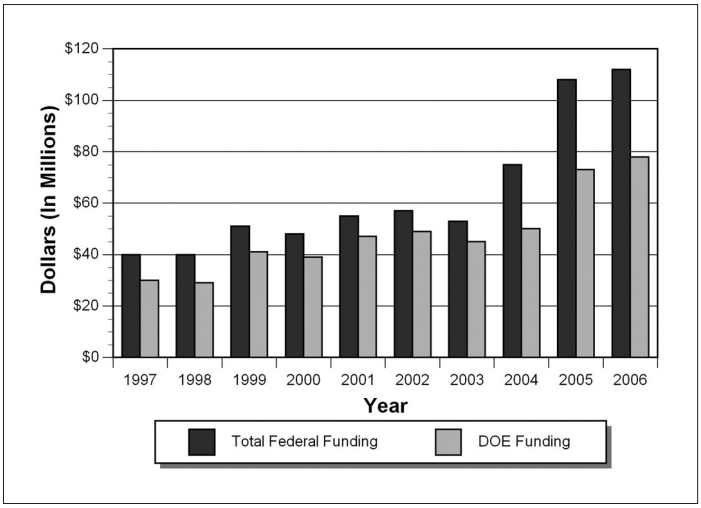

This graph presents the number of projects by year broken out in funding increments. The figure shows variation over the years with an upward trend since 2000 in the number of projects in the upper funding brackets, with the greatest increases in projects funded at $500,000 or more.

When is it justifiable to say that a research protocol has minimal risk, thereby making it eligible for expedited IRB review procedures?

SACHRP: Risk, consent, and IRB models

(Continued from page 1)

SACHRP's responsibilities and its decisionmaking process on page 6.)

The two-day session in Arlington, VA., focused on two subcommittee reports, research during emergencies, two panels, and outgoing OHRP director Bernard Schwetz's discussion on alternative IRB models.

SIIDR Subcommittee
The first report came from the Subcommittee on the inclusion of Individuals with Impaired Decisionmaking in Research (SIIIDR). A part of its mandate has been to formulate guidance on how investigators should assess people's "understanding" of consent.

In addition, the committee has been considering the advantages of developing a nationwide standard defining a Legally Authorized Representative (LAR) for potential research subjects who have diminished capacity to consent. Before proceeding with recommendations based upon the subcommittee's work, SACHRP decided to seek legal counsel about how best to encourage adoption of LAR standards, either by states or by the federal government.

Subpart A Subcommittee
The second report came from the Subpart A Subcommittee, which was responsible for reviewing and assessing all provisions of Subpart A of 45 CFR 46, as well as all OHRP guidance documents, and then making recommendations for consideration by SACHRP.

The subcommittee divided its recommendations into two, albeit related, parts.

The first recommendation was concerned with when it is justifiable to say that a research protocol has minimal risk, thereby making it eligible for expedited IRB review procedures.

The second was concerned with when it is acceptable to waive or alter informed consent requirements for protocols having minimal risk. SACHRP approved the subcommittee's recommendations on these issues with minor revisions.

In making its recommendation, the subcommittee noted that while obtaining informed consent is traditionally regarded as a cornerstone for the ethical conduct of research, "and a fundamental protection for participants' rights," there are other complex considerations. For example, "it is recognized that there is valuable research that would be difficult, or impossible, to conduct if consent were required and that subjects can still be adequately protected in the absence of full consent."

Because of this, HHS regulations allow for waivers or alterations, allowing "the interests of subjects to be balanced with societal interests in research, and both will be well served if this regulatory provision is understood and applied appropriately."

SACHRP's review of this issue was prompted by concerns that IRBs sometimes are uncertain about whether they should waive consent. It was also prompted by the fact that reviews are sometimes inconsistent, especially when multiple sites and multiple IRBs are involved in one study. These issues can lead to underutilization of the waiver when it may be warranted. Conversely, lack of understanding may lead to inappropriate application of the waiver. Thus, some research may have been unnecessarily precluded while other research may have been inappropriately allowed.

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Related Web sites

SACHRP
http://www.hhs.gov/ohrp/sachrp/

Rethinking IRBs: Central vs. Local
http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=401619

Conference on Alternative IRB Models
http://www.aamc.org/research/irbreview/2006/start.htm

U.S. Department of Health & Human Services, Office of Research Integrity
http://ori.dhhs.gov/

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SACHRP: Risk, consent, and IRB models

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If adopted by the HHS Secretary, the guidelines SACHRP is recommending will, for the first time, provide review boards and investigators with very specific guidance in an area of research protection that many believe has lacked clarity.

Research during emergencies

SACHRP also heard from **HHS Assistant Secretary John Agwunobi**, who addressed the group on the second day of the meeting. (Admiral Agwunobi has since resigned from the HHS post.) He urged the committee to consider ways to improve the efficiency of developing and approving new protocols for research during disasters, disaster relief, and other emergencies. (See related articles on pages 16, 18, and 20.)

"The time it now takes to identify and authorize a protocol precludes real-time research in the aftermath of emergencies such as hurricanes," Admiral Agwunobi explained. "Almost all research looks back, rather than directly at the acute, transient events of an emergency."

He said he would encourage "discussions about how this might proceed" so that processes could be established that would both encourage progress in the gathering of scientific data and at the same time protect research subjects who might be involved in emergency events.

Informed consent panel

The meeting also included a panel discussion among **Gigi McMillan**, Executive Director, *We Can, Pediatric Brain Tumor Network*; **Howard Dickler**, Association of American Medical Colleges Director for Clinical Research; **Jonathan Moreno**, University of Pennsylvania Professor of Medical Ethics; and **Alan Fleischman**, Albert Einstein College of Medicine Professor of Pediatrics. They explored ways to improve informed consent processes.

Fleischman's presentation included the viewing of an interactive video developed to be used as an "E-consent" tool that he said had the potential to improve subjects' understanding of the protocol and their involvement in it.

The E-consent tool was developed by the National Children's Study at the National Institute of Child Health and Human Development, which is part of the National Institutes of Health (NIH). Fleischman serves as ethics advisor and Chair of the Federal Advisory Committee to the Children's Study. The interactive video format could provide standardization among study sites and address issues of cultural sensitivity and diversity.

Panel on including minorities

A second panel discussion considered ways to enhance diversity in clinical trials. Panelists **Vivian Pinn**, Director, NIH Office of Research on Women's Health; **Dorothy Height**, longtime civil rights activist and recipient of the Congressional Gold Medal; **Giselle Corbie-Smith**, University of North Carolina, Chapel Hill; **Barbara Pence**, Texas Tech University Professor of Pathology; and **Leonard Sacks**, George Washington University Assistant Professor of Medicine. They focused on issues such as whether human research subjects represent the population whom the research is intended to serve.

They said minorities are often underrepresented in clinical trials and recommended that federal funding and oversight agencies should do more to involve them. However, they also cautioned that the issue is too complex to be solved merely by adding more minorities as subjects in all studies.

IRB models

In closing the meeting, **Bernard Schwetz**, director of HHS's Office of Human Research Protections, encouraged the committee and the research protections community generally to act on recommendations that alternative IRB models be considered.

Pointing to results of a national conference in late 2006 where many of the participants strongly recommended innovative IRB models, including central IRBs, Schwetz said new review processes are necessitated by the changing nature of research. Multi-site protocols, for example, create often-insurmountable difficulties for traditional single-site IRBs, he said.

Little progress has been made in this direction, Schwetz and other committee members said, because IRBs, like most institutions, are resistant to change. Many in the research protection community also fear that central IRBs and other models would result in a loss of local control and compromise ethical oversight.

Schwetz said similar recommendations for alternative models have been proposed in the past, but were largely ignored. Because problems associated with reviewing multi-site and other new forms of research have become chronic, it is important, Schwetz said, that the committee find ways to develop interest in finding alternative approaches.Δ

What is SACHRP? Why does it have so much influence?

The HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) influences human research protection not only within HHS and at all HHS (NIH) funded research sites but also in the much larger community of all 18 Federal Agencies that have adopted the Common Rule.

The 11-member SACHRP committee is appointed by the HHS Secretary and draws on highly qualified senior researchers, ethicists, and administrators from universities and private organizations throughout the country.

After approval by the HHS Secretary, SACHRP recommendations are converted by OHRP into new guidelines and interpretations of the Common Rule and, when needed, into revisions of the Common Rule. One to two representatives from multiple federal agencies, including DOE, are invited to serve as ex-officio members of SACHRP, and contribute their views and experiences during sub-committee and committee meetings.

Recommendations by SACHRP develop by way of several routes. Within the framework of its charter, the group is free to consider a wide range of issues related to human subjects protection.

Affects almost all human subjects research
Given that the Common Rule has been adopted by 18 federal agencies, including DOE, any changes to it made by HHS as a result of SACHRP recommendations affects almost all human subjects research receiving any federal funding.

SACHRP meets two to three times a year to deliberate and make recommendations to the HHS Secretary.

Recommendations by SACHRP develop by way of several routes, according to **Samuel Tilden**, who chairs the committee. Within the framework of its charter, the group is free to consider a wide range of issues related to human subjects protection.

Some suggestions develop during subcommittee discussions when one or more members believe an issue is sufficiently compelling that the entire SACHRP Committee should debate the need for new regulatory changes. Topics for discussion and review can be raised during the meeting by any member of SACHRP or by an ex-officio member from another Federal agency or even by non-members during the public comment period of every meeting.

Recommendations
Some recommendations come from formal reviews done by other advisory groups and panels, such as the National Academy of Sciences or other organizations.

"Other suggestions," Tilden said, "result from our conversations with people such as **Bernie Schwetz** (the recently retired director of the Office of Human Research Protections)."

Schwetz traveled around the country talking to groups of all kinds about human subjects protection. "When he heard from many different people in many different parts of the country that something is a problem, his awareness about this provided information that helped us prioritize our work," Tilden said.

Establishing new subcommittees
When the full committee meets, it hears ideas that have filtered into discussions about issues on which SACHRP might focus. If enough members are interested, they can decide to establish a new subcommittee to investigate. If that happens, the subcommittee reports back to the full committee, suggesting recommendations for regulatory change. The committee then decides whether to proceed with a recommendation to the Secretary.

Those recommendations are usually accepted. During the four years since SACHRP was formed, it has made recommendations related to research on children, on prisoners, and on individuals with impaired decision-making capacity.Δ

DOE's human subjects research funding increased

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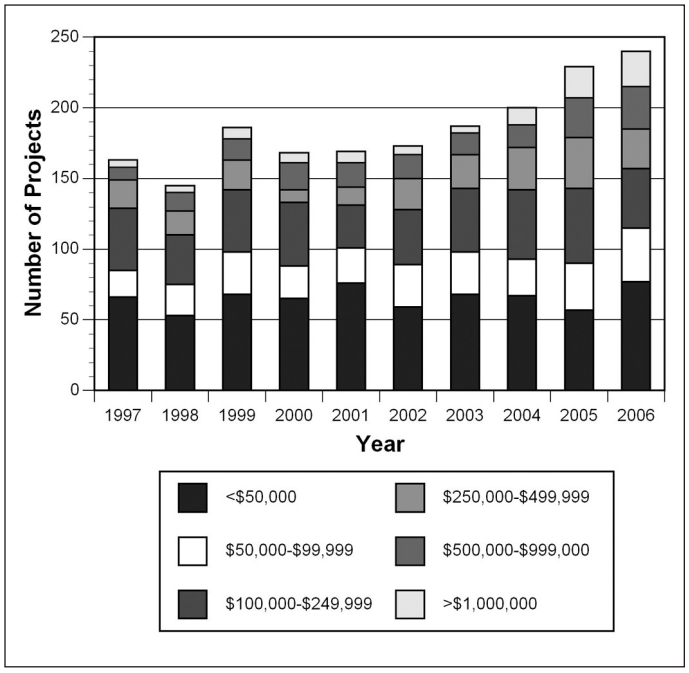
local Institutional Review Board (IRB) and: 1) are funded by DOE; 2) are conducted in DOE facilities and performed by DOE or contractor personnel; or 3) use DOE workers as human subjects.

Reports from the database about research in 2006 indicate that DOE funding increased $5 million since 2005 to a total of $78 million, and that total funding (including DOE and other federal funding) increased by $4 million since 2005 to $112 million.



This graph shows historical funding levels for human subjects research sponsored by the DOE compared to total federal funding. DOE funding has increased steadily each year, except in 2000 to 2003, consistent with total federal funding. DOE funding made up 67 to 70 percent of total federal funding from 2004 to 2007,

In FY 2006, funding for individual projects ranged from 800 dollars to $14 million. The average project received $469,000 compared with the median project, which received $100,000 in FY 2006. Funding for all international projects was 16 percent of total project funding.

In FY 2006, the total number of human subjects involved in DOE-related projects was over 970,000, a decrease of 5 percent from FY 2005, which was preceded by a decrease of 18 percent from 2004 to 2005.

Of that number, 78 percent of all subjects were involved in studies conducted by DOE facilities and the remaining 22 percent were participating in studies funded by DOE but conducted by non-DOE facilities, compared to 33 percent and 24 percent conducted by DOE facilities, respectively, in 2005 and 2004.

The abrupt shift in the total number of human subjects at DOE facilities from 33 percent in FY 2005 to 78 percent in FY 2006 is attributed to the transfer of two large records-related studies to a DOE site from outside organizations. As a result, 59 percent of all human subjects were involved in studies being conducted by the Oak Ridge National Laboratory. In FY 2006, as in 2005 and 2004, 48 percent of projects were records-related and epidemiologic-type studies.

The number of active projects increased slightly in FY 2006 to 290 (from 285 in FY 2005), with 59 percent conducted by researchers at DOE facilities and 41 percent at non-DOE facilities, compared with 72 percent and 28 percent, respectively, in 2005.

Of the 290 projects, over 50 percent were funded by DOE. Forty-seven research organizations provided data this year. Twelve of these were DOE laboratories and 35 were non-DOE facilities. These numbers are fairly consistent with the breakdown for 2005 and 2004.

Four national labs, one research institute

In FY 2006, four national labs and one research institute accounted for 61 percent of the active projects—this included Brookhaven National Laboratory, Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, Los Alamos National Laboratory, and The MIND Institute. Lawrence Berkeley had the greatest number with 45 active projects, followed closely by Lawrence Livermore with 43 projects.

Nineteen projects were reported as being international. The Russian Health Studies Program and the joint U.S.-Japan research program on atomic bomb survivors at the Radiation Effects Research Foundation, funded by the DOE Office of Health and Safety (HS-10), reported 96 percent of all foreign subjects.Δ

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New HS Web site—more content, improved navigation

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Medical Sciences Division, and ***Dr. Peter Kirchner,*** Senior Science Advisor, launched an initiative to redo the Web site with input from the entire Human Subjects Working Group (HSWG) and the assistance of ORISE.

As a first step in the project, an extensive review of the needs of the DOE human subjects protection community was made, followed by an examination of material from other Web sites as to specific information that would be of value to the Web site users. The goal was to provide current, pertinent, and comprehensive information within the proposed Web site, either directly or through links to other Web sites.

The Web site has been redesigned to enhance and promote communications among IRB members and administrators, researchers, institutional officials, management, and potential human subjects within the DOE research community. It is equally important that this Web site serve as a means of connecting with other individuals and organizations in the global human subjects protection community.

This new site will share information and provide resources that continually help to improve our processes and practices in the most productive and ethical ways. With this approach, DOE not only has a continuous educational program to complement its human subjects research program but also a means to demonstrate to other agencies, organizations, and the public the variety of research studies and the breadth and depth of DOE's protection program.

The following are a few of the features incorporated in the new Web site:

- Reorganized format that encourages easy retrieval of information
- A comprehensive Site Map for ready access to information on the site
- Details of the Human Subjects Working Group, its background, activities, and accomplishments
- Descriptions of the DOE laboratories and other facilities performing human subjects studies or their involvement in related activities such as worker studies

- Expanded and updated information on the DOE worker health-related studies and programs
- Updated human subjects regulations, orders, and policies
- Inclusion of many Web site links to direct DOE interests as well as related information from other Web sites – "one stop shopping" methodology
- Incorporation of existing DOE educational material such as current and archived issues of the DOE *Protecting Human Subjects Newsletter* and the new *DOE Human Subjects Protection Resource Book*.

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New DOE Human Subjects Protection Program Web site

Revised DOE order waiting final approval

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in practices or policies were identified except to update information, where appropriate. As in the previous version, a Contractor Requirements Document (CRD) is included to point out specific requirements to be met by contractors in managing their human subjects research studies.

National Nuclear Security Administration
The one notable change in the order is recognition and accommodation of the authorities and responsibilities of the National Nuclear Security Administration (NNSA).

NNSA was established by Congress in 2000 and is a semi-autonomous agency within DOE responsible for enhancing national security through the military application of nuclear science. Several of the DOE laboratories and sites fall under NNSA's jurisdiction.

The order notes separate (and in many cases parallel) responsibilities for the DOE and NNSA human subjects research program managers. NNSA has named a program manager, **John Ordaz**, who will work closely with the DOE program manager. NNSA sites should not notice any significant differences in day to day practice, however, as NNSA has indicated its intent to work within the existing DOE structure with regard to human subjects protection and to let many day-to-day responsibilities continue to be managed by the DOE program manager.

All sites, including NNSA sites, will continue to be represented at the Human Subjects Working Group meetings and calls. The NNSA program manager will join these meetings and calls and work with the DOE program manager in addressing issues that arise with regard to any NNSA sites.▲

HS Web site revised

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The DOE Protecting Human Subjects Web site was developed under contract between Oak Ridge Associated Universities (ORAU) and DOE.

Joanna Wilkins, ORAU Web Developer/Communications Specialist, and associates, were instrumental in designing the Web site, laying out the proper format, and compiling/sorting the submitted material. Her many useful suggestions and creative approaches helped make the site enhancement a more useful and accessible tool for research and reference.

Denise Viator, Project Manager, Oak Ridge Institute for Science and Education, provided valuable coordination support on this project.

The redesigned Web site can be found at **http://humansubjects.energy.gov**. To suggest contributions, contact Charles Pietri (cpietri@aol.com) and Denise Viator (denise.viator@orise.orau.gov).▲

(Editor's note: Charles Pietri provided the technical information and support that made possible all of the enhancements to the redesigned site. Much of the contgent was provided by HSWG members and contributors from other government agencies.)

News notes

Online research ethics seminar

North Carolina State University has developed a free, online "Open Seminar in Research Ethics" to provide the research community with an ongoing forum for discussion of continuing issues. The university's international virtual meeting space is at **http://dhill-8218-1.lib.ncsu.edu/dolphin/**

The online forum is part of a research ethics program that includes an initiative funded by the National Science Foundation, "A Model Curriculum for Land Grant Universities in Research Ethics" (LANGURE), which is a national network of eight land grant and historically black universities developing a model curriculum in research ethics.

Listing of research ethics activities

The Alden March Bioethics Institute maintains a comprehensive listing of conferences, educational programs, and other activities related to research ethics and related issues.
For information, see:
http://www.bioethics.net/events.php?page=1

For a listing of bioethics news generally, see the institute's site at:
http://www.bioethics.net/

Typically, few topics inspire less excitement than mandatory "compliance training." That challenge led us to develop a variety of participatory treaching environments using audience involvement to enhance learning.

Using mock trials for compliance training

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way into the facts) had been a patient of Dr. Welby's for nine years for her psoriasis when he suggested that she would be a good candidate for a study. The doctor had signed on with sponsor Big Pharma to investigate an experimental drug for psoriasis.

Unfortunately for C.J., obtaining valid data about the new drug being tested in this trial required that she discontinue (or "wash-out") other drugs, including the methotrexate which had been successfully controlling her condition for several years.

Confidence in her physician

After the wash-out period, the study design dictated that she would be randomized to receive a blinded dose of either the study drug or a placebo. C.J.'s confidence in her trusted physician, Dr. Welby, led her to agree to participate in the trial despite the risks of being without the methotrexate.

Things did not go well. C.J.'s condition deterioriated during the wash-out period and dramatically worsened into psoriatic arthritis once she was into the active portion of the study.

Her visible and painful deterioration was evident on frequent study-related visits, but neither the coordinator nor Dr. Welby suggested coming off the study until months into the study when C.J. finally announced that she wanted to withdraw. By then, she was suffering from blistered skin with oozing sores and she had difficulty walking.

To adapt this teaching method to your needs, begin by identifying some of the issues that frequently require training or which you commonly find as problems on post-approval monitoring, such as inconsistent data collection, surrogate consent, and research with vulnerable populations.

Build these facts into a fictional situation with three to five characters who will testify during the trial. Next, develop "documents" such as an informed consent form, IRB minutes, abbreviated protocol, etc.

Outside the box

The courtroom is not the only setting available for engaging learning. Most real-life situations involving tension or the potential for conflict can be used to drive home your message.

For example, the delicate balance of trust between IRB members and the investigators who submit protocols is easily upset when one participant does not understand the tasks and responsibilities of the other.

One way of bridging this lack of understanding is to create a mock IRB meeting and invite investigators, coordinators, and other research staff to serve as the IRB. Using an existing protocol as a guide, develop a fictional study with supporting documents, including protocol, consent form, and IRB application.

Begin by identifying some of the issues that frequently require training or which you commonly find as problems, such as inconsistent data collection, surrogate consent, and research with vulnerable populations.

Mistakes, errors, problems

Build in mistakes, errors, and problems that your IRB typically encounters. Send everything to the participants in advance of the meeting. If your IRB uses a primary reviewer system, ask one or two individuals to act in that capacity. At a minimum, your audience will quickly appreciate the amount of time IRB members spend preparing for a meeting.

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The thought of a news team showing up at our IRB's doorstep creates tension that can be harnessed for a good cause. You can put that dramatic potential to use in your own teaching by developing a story based upon issues you never hope to see in a news story.

If your IRB chairperson is willing to serve as chair for this mock meeting, he or she will have a great opportunity during the meeting to offer explanations and background information. Guide the discussion toward the required elements of an IRB decision and then call for a vote, using the same procedure that would normally be used. There's nothing like having to go "on record" by voting your support or disapproval to get someone individually involved in an outcome.

The thought of a news team showing up at our IRB's doorstep creates tension that can be harnessed for a good cause. You can put that dramatic potential to use in your own teaching by developing an investigative news story based upon issues that you never hope to see in a news story.▲

Related books

The ethics of bioethics: Mapping the moral landscape. Lisa Eckenwiler, Felicia Cohn. Baltimore: The Johns Hopkins University Press, 2007. 352 pp. ISBN 978-0-8018-8609-6.

The student's guide to research ethics. Paul Oliver. Maidenhead, UK/New York: Open University Press, 2007. 156 pp. ISBN 0-335-21087-2.

Research ethics for social sciences: Between ethical conduct and regulatory compliance. Mark Israel and Iain Hay. London/Thousand Oaks, CA: Sage, 2006. 193 pp. ISBN 1-4129-0390-4.

Law and ethics in biomedical research: regulation, conflict of interest, and liability. Trudo Lemmens and Duff R. Waring, eds. Toronto/Buffalo, NY: University of Toronto Press, 2006. 267 pp. ISBN0-8020-8643-8.

The great starvation experiment: The heroic men who starved so that millions could live. Todd Tucker. New York: Free Press, 2006. 270 pp. ISBN 0-7432-7030-4.

Evaluating the science and ethics of research on humans: A guide for IRB members. Dennis Mazur. Baltimore: Johns Hopkins, 2007. 252 pp. ISBN 978-0-8018-8502-0.

News Notes

Online seminar in research ethics

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Research in developing countries

The Science and Development Network has created an online center focusing on issues related to research in developing countries. The center includes discussion of the need for care when determining how research ethics committees in developing countries can be adequately trained and resourced, "while remaining independent of governments, institutions and research sponsors."

For information, see **http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierItem&Dossier=5&CFID=4503794&CFTOKEN=35342078**

"I found a mismatch between where OHRP was focusing its attention and where the greatest risk to subjects was. OHRP was traditionally and naturally connected to the IRB community, but the greatest risk to subjects is at the hands of investigators."

Bernard Schwetz: International research creates special challenges for protecting human subjects

The former director of the HHS Office for Human Research Protections discusses current and future issues related to international research and the difficulties of protecting human subjects in a world of diverse cultures. Dr. Schwetz retired from the directorship on September 30, 2007, after serving in the post for four years.

Bernard Schwetz

(Editor's note: This article, which was first published in the *FDANEWS* publication *Drug Industry Daily*, is used by permission. For information, see http://www.fdanews.com.)

Almost one-quarter of patients in NIH-funded clinical trials are not in the U.S., and the numbers are rising, according to **Bernard Schwetz**, recently retired director of the U.S. Health and Human Services (HHS) Office for Human Research Protections (OHRP), said in an interview with the FDANEWS.

In an exclusive interview on the eve of his retirement, Schwetz listed the increase in international trials as one of the major human research protection challenges his successor will face. "There's no reason to believe that won't continue, and we have less knowledge and less confidence [in our] knowledge about those [foreign-based trials] than about the domestic scene. That makes me nervous."

"We don't know how many investigators, IRBs, and subjects there are. We depend on subjects to tell us what's wrong in the enterprise."

Mismatch

The next OHRP director (See article about Schwetz's successor on page 13 of this issue) should also keep trying to focus on clinical investigators, Schwetz said. When he assumed the directorship, he said, "I found a mismatch between where OHRP was focusing its attention and where the greatest risk to subjects was. OHRP was traditionally and naturally connected to the IRB [institutional review board] community, but the greatest risk to subjects is at the hands of investigators."

Unfortunately, OHRP "had little contact with investigators," and Schwetz said his efforts to establish direct contact by inviting them to conferences "hit a blank wall," since they are busy writing grant proposals, seeing patients, and otherwise engaging in research. "I began to search for a means to contact investigators more efficiently than my requests to meet with them directly."

Outreach effort

Therefore, Schwetz said, he began a concerted outreach effort targeting "institutional signatory officials" who are responsible for training investigators and protecting patients under their care.

"I am very pleased with the inroads I've made meeting with institutional officials and talking with them about how OHRP can be of more help to them," Schwetz said. "We have been focusing on a broader range [of people involved in research] than just IRBs. We have gotten the attention of sponsors and subjects through an outreach program to subjects."

In general, OHRP needs better knowledge of the entire human research enterprise, Schwetz said. "We don't know how many investigators, IRBs, and subjects there are. We depend on subjects to tell us what's wrong in the enterprise, but we don't have enough data."

(Continued on next page)

Schwetz said his successor should address the proliferation of central and commercial IRBs. "We have begun to wonder what the atmosphere is like at an institution that doesn't have its own IRB."

Bernard Schwetz

(Continued from previous page)

Media reports about the number of people seriously injured in clinical trials seem to point to a fairly small number of cases, certainly in comparison with the high numbers of patients that the Institute of Medicine has said are injured by standard medical care, Schwetz said. He added that while it would therefore seem that participating in clinical research is actually safer than receiving standard healthcare, "we need numbers!"

Another major area Schwetz said his successor should address is the proliferation of central and commercial IRBs. "We have begun to wonder what the atmosphere is like at an institution that doesn't have its own IRB. If an institution has its own IRB, it creates a reservoir of information within the institution for investigators. [Internal] IRB officials know their own institution and its rules. Central or independent IRBs are not accessible in the same way."

A balance of tools

Schwetz said that under his directorship, "OHRP is perceived as having a better balance between compliance and noncompliance activities than it was when we were perceived as shutting down research institutions. We are not just a compliance office—there is a balance of tools in our toolbox."

However, one industry observer fears that OHRP may not have enough tools to do its job properly. As of last year, OHRP had only "24 out of 32 positions filled," and there was a hiring freeze, **Jonathan Moreno**, a professor at the University of Pennsylvania's Center for Bioethics, said. He added that the office is underfunded.

Schwetz responded, "We were in a hiring freeze for the past couple of years." He disputed Moreno's figures, however. "At our lowest point," OHRP had 33 to 34 out of 38 full-time equivalent positions, and the office has now filled all 38, he said.

As to budgeting, "very few federal agencies would say they have enough," Schwetz said. "Most have budget restraints that make it hard to fill posts. We are low but not disproportionately lower than other parts of HHS."Δ

Pritchard named acting OHRP director

Succeeds Bernard Schwetz in HHS post

Ivor Pritchard has been named Acting Director of the Office of Human Research Protections (OHRP) for the U.S. Department of Health and Human Services.

Kevin Prohaska, a Captain in the Public Health Service, has been named Acting Executive Director of SACHRP.

Pritchard's appointment was effective September 17, 2007. A Senior Fellow in the OHRP, Pritchard previously was a Senior Research Analyst for the Institute for Education Sciences at the U.S. Department of Education. He has a Ph.D. in philosophy from Boston University. His research interests are in research ethics and federal policy, moral and civic education research and practice, and education policy.Δ

Related Web sites

International Bioethics Exchange Program
http://bioethics.georgetown.edu/ibepltr.htm

Is the IRB Model Relevant in Africa?
http://www.bioethicsforum.org/ethics-review-of-medical-research-in-Africa.asp

Research Ethics Committees in Africa
http://www.hopkinsmedicine.org/bioethics/news/africa.html

Aboriginal Community Values (from the *Journal of Empirical Research on Human Research Ethics*)
http://www.csueastbay.edu/JERHRE/notes/AboriginalComm_Values.pdf

Fair Standards in International Resarch
http://www.bmj.com/cgi/content/full/321/7264/824

Resources for International Research Ethics
http://www.hf.uib.no/i/Filosofisk/ethica/research.html

Issue No. 15

"I spend time with hundreds of families who have children with brain tumors. Nearly all are enrolled in clinical trials. As I spoke, the voices of the children and their families range through my head."

Listening to the voices of children, families

"I cannot do this alone. I cannot create a community on my own."


Gigi McMillan

by Gigi McMillan, Executive Director of We Can, The Pediatric Brain Tumor Network

This was my third Public Responsibility in Medicine & Research (PRIM&R) meeting, and I was very excited. I knew that the three speakers would tell a powerful collection of stories about their personal experiences with research, both as advocates and as subjects. Before I introduced them, I took a few moments to share some stories of my own.

The voices of children

I spend time with hundreds of families who have children with a brain tumors. Nearly all are enrolled in clinical trials. As I spoke, the voices of the children and their families rang through my head:

Acknowledge us. I am a parent/patient/sibling/family member. I have emotions to deal with, unique situations, cultural traditions, and desperate needs. But I also have skills to bring to the table, the desire to learn, and a burning passion to imagine a healthy future.

Give me information. I want to understand. I want to participate. Respect my capabilities. Guide me. I often don't know what I need. I rely upon you, with greater experience and wider perspective, to suggest a path toward rational, positive behavior.

Give me tools. Give me the article, the checklist, the phone number, the meeting date, the confidence to do what I have to do to successfully navigate the treatment and consequences of this disease.

I cannot do this alone. I cannot create a community on my own. Give me a framework that I can use to help my family to reach for a happy ending.

As I spoke, I realized there were some voices in my head that were louder than others—those of the Latino families who recently participated in We Can's first Spanish-only family camp. It had been a magical weekend, where these families met others like themselves and, in the comfort of their native language, shared their hearts and their stories with each other.

In the dead silence of the ballroom, I made a wish: Please, please, someone, ask me what I said.

The fathers who spoke were devastatingly moving when they stood up in a group session and talked about their families. In this safe place, men could weep together, women could be angry, and the visiting doctors got a glimpse of parents struggling to find meaning in the ways a horrible disease affected their children and their families.

A chance to speak

The point of the camp was to give these families, these children who are research subjects, a chance to speak and be heard. At PRIM&R it seemed appropriate to mention this.

Gigi McMillan, who is executive director of the organization "We Can, The Pediatric Brain Tumor Network," moderated the panel discussion, "In Their Own Voices — Research Subjects Speak," at last year's PRIM&R meeting in San Diego. She wrote this article about part of that experience.

"The families at our (Spanish) Camp told us that it was a big surprise for them to learn that non-latin people and doctors wanted to help them."

From the podium I said, "Let me share one final perspective with you: Las familias en nuestro Campamento nos dijeron que fue una gran sorpresa que habian personas y doctores que no son latinos que quieren dar les ayuda, y lo mas importante, es que personas que no son latinos, pueden entender sus situaciones de vida, y saben como ofrecer apoyo."
(*See translation at end of article.)

And in the dead silence of the ballroom, I made a wish: Please, please, someone, ask me what I said.

I took a breath, concluded my remarks, and introduced my three amazing panelists. The next 45 minutes were riveting. Afterward, during the 17 minutes of questions and answers, I waited for someone in the audience to ask me to translate those brief Spanish sentences. As far as I was concerned, this was the point of the panel discussion topic: The audience, as subject, needed to speak out, needed to ask for information.

More importantly, someone in the audience should recognize that the voice of Latino subjects was not going to be heard until a translation was offered.

Nobody asked.

*("The families at our (Spanish) Camp told us that it was big surprise for them to learn that non-latin people and doctors wanted to help them. And more importantly, that non-latin people (and doctors) could truly understand the circumstances of their lives and knew how to offer help.")Δ

New books

Science, ethics of research on humans

Evaluating the Science and Ethics of Research on Humans: A guide for IRB Members. By Dennis J. Mazur, 2007. 252 pp. Baltimore, Johns Hopkins University Press. $50 cloth, $29.95 paper.

This book discusses the issues and ways of thinking about the ethics, regulations, and procedures involved in reviewing human research protocols.

He discusses the way research participants should be recruited and some of the pitfalls of that endeavor. He attends to the requirements and the controversies of informed consent. He also has some interesting things to say about IRB workloads and the various difficulties IRB members encounter when they conscientiously try to both understand the protocols and guard the well-being, including the privacy, of participants. The analysis of a study's risk-benefit ratio is especially good.

Experiments on African Americans

The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present, by Harriet A. Washington. 501 pp. Doubleday, 2007. $27.95.

Washington asserts that African Americans have been exploited and badly served by a racist medical establishment.

The politics of difference in research

Inclusion: The Politics of Difference in Medical Research, by Steven Epstein. Chicago Studies in Practices of Meaning. 413 pp. Chicago, University of Chicago Press, 2007. $29.

Epstein discusses the efforts to reduce disparities in medical research, especially by including under-represented groups. This account examines the creation of new ways to think about research and human differences, which sought to set aside hierarchical notions of human beings.

Disaster research

When emergencies strike, protecting human subjects does not have to conflict with gathering data

The following section of *Protecting Human Subjects* explores aspects of a nationwide effort to improve the timely gathering of information during disasters, while simultaneously protecting the well-being of people involved in the studies. The difficulty of doing this during emergencies is apparent—communities may be ravaged; people dead, maimed, frightened; and public health and safety systems compromised.

This is why former HHS Assistant Secretary **John Agwunobi** in July told many of the federal government's top advisers on protecting human subjects that the research community should find ways to more efficiently develop and approve protocols for gathering data during disasters and other emergencies.

"The time it now takes to identify and authorize a protocol precludes real-time research in the aftermath of emergencies such as hurricanes," Admiral Agwunobi explained during a meeting of the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP). "Almost all research looks back rather than directly at the acute, transient events of an emergency." Ways should be found, he said, to both encourage progress in the gathering of scientific data and at the same time protect research subjects who might be involved in emergency events.

In the following articles, we look at some of what has been learned from disaster research, including work conducted after the World Trade Center attack. Many universities are establishing disaster research centers, including graduate programs to train more investigators, and two of the following articles (on pages 16 and 18) offer their perspectives. Each of these articles emphasizes that when emergencies strike, protecting human subjects does not have to conflict with gathering data.Δ

Findings from the WTC evacuation study

Do disaster survivors require additional protections as human subjects?

"Disaster research can provide valuable information that can lead to improvements in the prevention, mitigation, response, and recovery of other significant events," say the authors of a new report discussing how to protect human subjects during research studying disasters.

Robyn Gershon, of Columbia University, led a team of investigators studying the factors associated with survivability after the September 11 attack on New York City's World Trade Center (WTC).

"This holds true for all types of disasters," they said, "including naturally occurring (e.g., weather or geological events or epidemics), inadvertent technologic accidents (e.g., industrial or transportation accidents), or intentional events (e.g., terrorism or civil strife).

The article, "A Roadmap for the Protection of Disaster Research Participants: Findings from the WTC Evacuation Study," is in the October, 2007, issue of the *Journal of Prehospital and Disaster Medicine*. It is co-authored by **Kristine A. Qureshi, R. R. Gershon, Elizabeth Smailes, Victoria H. Raveis, Bridgette Murphy, Frederick Matzner, and Alan R. Fleischman**.

Challenges to conducting well-designed, ethical disaster research include funding timeliness; rapidity of IRB approval of applications; time required for the preparation of research protocols, instruments, and other materials; access to survivors and/or families

(Continued on next page)

Related Web sites

World Trade Center Evacuation Study
http://www.mailman.hs.columbia.edu/CPHP/wtc/

WTC Survivors' Network
http://www.survivorsnet.org/programs/remembering.html

Ethical issues in disaster studies—WTC Study
http://www.mailman.hs.columbia.edu/CPHP/wtc/documents/Ethics%20of%20Disaster%20Research%20Final.pdf

While the resulting measures taken to ensure the safety of participants may appear to be tedious, even onerous, implementing the recommendations was relatively simple, did not add greatly to the cost, and added only slightly to the timeline.

World Trade Center

(Continued from previous page)

of victims; and sampling biases. Most important, they write, "is the challenge of conducting disaster research while maintaining a high level of protection for participants against psychological injury associated with study participation."

Heightened sensitivity among researchers, IRBs, advocacy groups, and government officials have sparked discussion about whether disaster survivors require additional protections above and beyond existing protections. "Since survivors frequently have already experienced adverse psychological effects related to the disaster, there is a concern that re-living these experiences through research participation may exacerbate pre-existing mental health problems and vulnerabilities," they say.

When conducted correctly, however, participation in these studies may be beneficial for some survivors. Trauma researchers, for example, have found that discussion of the traumatic experience in a safe and supportive manner can be healing.

Concern about further victimization

Because there was concern about further harm, researchers were especially cautious about protecting all study participants—survivors, their family members, first responders, and the general public.

The New York Academy of Medicine and the National Institute of Mental Health convened a panel of ethicists, mental health professionals, disaster researchers, public health officials, IRB members, disaster survivors, and family members of deceased victims.

They issued recommendations addressing a variety of considerations, including decisional capacity, psychological state, referral of subjects in need of mental health consultation, training of investigators and staff to recognize emotional problems, assessment of the risk and benefit of participation, community involvement, consent procedures, confidentiality, and more.

While the resulting measures taken to ensure the safety of participants may appear to be tedious, even onerous, the authors said that, instead, implementing the recommendations was relatively simple, did not add greatly to the cost, and added only slightly to the timeline originally set for the study.

In conclusion, they said, adherence to ethical recommendations demonstrated that vulnerable groups can be adequately protected during participation in post disaster research.Δ

Web sites

High School Bioethics Curriculum Project (Georgetown University)
http://highschoolbioethics.georgetown.edu/

FDA Information Sheets for IRBs
http://www.fda.gov/oc/ohrt/irbs/appendixc.html

The National Academies Institutional Review Board
http://www7.nationalacademies.org/irb/

Human Subjects Research Training, sponsored by The Collaborative IRB Training Intiative (CITI) and The University of Miami
http://www6.miami.edu/citireg/

Office for Human Research Protections (OHRP), Department of Health and Human Services
http://www.hhs.gov/ohrp/

Office for Human Subject Protections (OHRP)—IRB Guidebook
http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

National Standards to Protect the Privacy of Personal Health Information
http://www.hhs.gov/ocr/hipaa/

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 Office of Human Radiation Experiments
http://www.eh.doe.gov/ohre/

"It should be made clear when seeking consent from potential subjects that while confidentiality is a goal, the nature of the research, the subjects, and the situation often means confidentiality cannot always be guaranteed.

Hurricane Katrina investigation

Lessons from the field: Human needs often complicate ethical duties in disaster research

by Lauren E. Barsky and William R. Donner, University of Delaware, Disaster Research Center

When 18th century French philosopher Denis Diderot said, "There is no moral precept that does not have something inconvenient about it," he could have been referring to ethical standards in disaster research, especially when it comes to protecting human subjects.

William Donner

Lauren Barsky

The underlying system of ethics taught in all scientists' first research methods seminar includes a straightforward system of protections: never lie to subjects; never under any circumstances expose them to dangers beyond what is approved by the Institutional Review Board (IRB); and, of course, be sure to maintain the confidentiality, anonymity, and privacy of our participants. In addition, all research subjects should freely and openly consent to participate and they must know that they have the right to withdraw at any time.

The murky world of fieldwork

Unfortunately, in our experience it is often difficult to extend the litany of "do's" and "don'ts" of ethics training into the more murky and problematic world of fieldwork.

The system of codified ethics we learned in the classroom often seems confoundingly impractical and is often inconsistently applied in practice.

In disaster studies—largely governed by social science methodologies—fieldwork is challenged by a variety of potentially harmful ethical dilemmas.

In the aftermath of Hurricane Katrina, we were among a group of researchers funded by the Natural Hazards Research and the Applications Information Center at the University of Colorado, Boulder, as well as the Disaster Research Center (DRC) at the University of Delaware.

Abstract principles offered little help

We were assigned to collect data on warning response, evacuation, and other important disaster response issues. Although we were not unaware of ethical issues inherent to this kind of study, many on the team found that the abstract principles encountered years earlier in research methods courses offered little help when faced with immediate ethical challenges.

It is often difficult to extend the litany of "do's" and "don'ts" of ethics training into the more murky and problematic world of fieldwork.

For instance, although incentives for research subjects are allowed under certain conditions, there is still considerable disagreement about whether incentives are ethically appropriate.

The rule of thumb is that it is generally not advised for fieldworkers to offer potential respondents any incentive, including money and food, unless doing so is specifically stated in the approved methodology. To ensure consistent application, the methodology is carefully negotiated prior to fieldwork so as to not produce "undue influence." These guidelines traditionally extend to after the

interview as well, precluding payment as a reward that could affect decisions made by other potential research subjects.

Working in ravaged areas
It is especially unsettling for disaster researchers to work in ravaged areas among people who are suffering, traumatized, fearful, and often grieving.

During the quick-response research following Hurricane Katrina, we confronted precisely these problems. The residents who survived often had lost everything—homes, families, friends.

Ethical guidelines forbidding incentives were of little assistance when confronted with people who could not work and were unable to find adequate food or shelter.

For example, when people asked for money or other assistance, we were conflicted. It was hard to resist. Years of theoretical training in applying objective standards did not help when faced with real human suffering.

Maintaining these standards in the midst of confusion and uncertainty often creates inevitable ambiguities.

The myth of "disaster shock"
Field researchers also face serious challenges in protecting the psychological well-being of subjects. Although the disaster literature generally shows that "disaster shock" and widespread traumatization are a myth, potential subjects are nevertheless facing serious challenges. It is possible that speaking with them about their behavior or experience during a disaster can open deep psychological wounds and cause additional harm.

To avoid harm, investigators must be willing before fieldwork begins to evaluate whether an interview could cause harm and whether there are ways to lessen that harm. Although an interview may theoretically cause no harm, in practice things do not always go as planned. If problems occur, research subjects should have access to counseling.

Disasters that occur in remote regions, as well as in some foreign countries, produce especially troublesome dilemmas because resources can be scarce and counseling is not accessible. Thus there are not always ready solutions, which means it is important to prepare for as many eventualities as possible. One way to do this when working in remote or foreign regions is to include team members who have an understanding of the culture, language norms, and interaction customs.

Confidentiality can often be difficult to honor in certain areas of disaster research, as well as in related studies of close-knit institutional communities.

It should be made clear when seeking consent from potential subjects that while confidentiality is a goal, the nature of the research, the subjects, and the situation often means confidentiality cannot always be guaranteed.

It is important to be clear about what is possible and what is not possible. Without this forthrightness, it would be disingenuous to claim to be getting informed consent from research subjects. It is always better to be honest, even if this means more refusals or attrition than anticipated.

Withdrawing from studies
Similarly, it must be made clear to research subjects that they can withdraw from the study or interview at any time, especially during periods immediately following a disaster. People are often consumed with cleaning up, earning money, and caring for their families, which may preclude time to participate in research. If they are not told they can withdraw, they may feel compelled to complete the project even if they have more pressing responsibilities. Researchers must always remember that time is a precious commodity for disaster victims.

Maintaining these standards of confidentiality, truth-telling, informed consent in the midst of confusion and uncertainty often creates inevitable ambiguities. As a general guideline, however, one should always err on the side of ethical standards. Methodological problems can be overcome by way of revisions or collecting additional data; breaches in ethics, unfortunately, cannot so easily be overcome.Δ

Related books

Inclusion: The Politics of Difference in Medical Research. By Steven Epstein. Chicago: The University of Chicago Press. 424 pp., cloth $29, 978-0-226-21309-5.

Dark Medicine: Rationalizing Unethical Medical Research. By William Lafleur, Gernot Bohme, and Shimazono Susumu, eds. Bloomington: Indiana University Press. 280 pp., cloth $35, 978-0-253-34872-2.

"Some will criticize our decision to proceed with the interviews without in all cases obtaining their signature . . . (but) this seemed to be the best way to honor the mandate to first do no harm."

Protecting human subjects from themselves . . . after the disaster

Henry Fischer

by Henry W. Fischer,
Professor of Sociology & Director,
Center for Disaster Research & Education,
Millersville University of Pennsylvania

The Center for Disaster Research & Education sends field teams into impacted areas after disasters occur. They focus on a variety of issues, including behavioral and organizational response challenges encountered by the disaster responders.

Our field teams arrive within days, sometimes weeks (occasionally months) of impact. As a result, we often find ourselves in the unusual circumstance of needing to protect our sources from themselves.

The 2004 South Asia Tsunami

Working with the first of two recent field experiences, the Center obtained funding from the National Science Foundation (NSF) to send three field teams to South Asia to interview responders on the challenges encountered in mass fatalities management after the massive tsunami hit Thailand on December 26, 2004.

We arranged for a team from Oklahoma State University (led by **David Neal** and **Brenda Phillips**) to go to India, a team from North Dakota State University (led by **Arthur Arroya** and **Jennifer Wilson**) to go to Sri Lanka, and a team from Millersville University of Pennsylvania, which I led, traveled to Thailand.

Burying 5,400 people

We went to study the sociological effects of having at least 5,400 people to bury. We wanted to know how people rebuild their social lives , rather than merely rebuilding structures and homes.

"We went to study the sociological effects of having at least 5,400 people to bury. We wanted to know how people rebuild their lives socially, rather than merely rebuilding structures and homes"

Joe Scanlon, of Carleton University, interviewed those from European nations who participated in the international response to the tsunami. IRB approval was obtained for the project (required by the NSF as well as the individual participating universities). The protocol included the usual procedures of following the pre-approved interview guide, use of informed consent, and confidentiality.

Local guide helped with entrée

We also advertised in-country for a graduate student to function as the language interpreter and culture guide. The goal of "causing no harm" was more attainable, in our view, if we had a team member who spoke the language and could guide us so that we would not inadvertently offend due to our ignorance of culture and local customs.

Relying upon the advice of our culture guide, we modified the informed consent protocol because the people we interviewed (mostly affiliated with the local, provincial, or federal governments, and some from non-government organizations) did not want to sign anything. Ironically, these same people said they had no problem being publicly identified as an interviewee and were even willing to be quoted by name.

Cultural norms

We learned that cultural norms about signing a document created an issue analogous to entering

"We were faced with a dilemma: If we insisted upon a signature for informed consent, there would be no interview; yet they were eager to be interviewed . . . ."

into a contract, which made our respondents very uncomfortable.

Because we were unaware of this concern before entering the field, we were faced with a dilemma: If we insisted upon a signature for informed consent, there would be no interview. Yet they were eager to be interviewed because they wanted to help others learn from their experiences. They also waived any concern about having their comments shared publicly, with attribution, and said they felt honored to be asked.

They urged us to not worry about protecting their identities.

We resolved the dilemma by reading the informed consent form to them and asking for verbal understanding and agreement. We also left them alone with the interpreter so that they would not feel pressured by our presence. After consent was, in our view, freely given, we then returned and the interview got under way.

In addition, despite their willingness to be identified, we told the respondents that we would maintain confidentiality. Thus we found ourselves not having to work at gaining entrée but rather at protecting our very helpful interviewees from themselves.

Hurricane Katrina

The center obtained additional NSF funding to continue its work on mass fatalities management after Katrina devastated the Gulf Coast. We also obtained funding from the Natural Hazards Center, University of Colorado-Boulder, to conduct a study on the response problems.

We interviewed first responders six weeks after impact to obtain their fresh, raw observations on what went right, what went wrong, and why. They had plenty of recommendations, and their emotions were still so raw that they, like their South Asian counterparts, urged us to not worry about protecting their identities.

Again, like the tsunami study, many of our respondents preferred not to sign the consent form. So we modified the process for those who were uncomfortable by reading the form to them, giving them a copy, and obtaining verbal agreement after providing them time to think about it.

As in South Asia, we followed the protocol by protecting their confidentiality. While we acknowledge interviewing responders from various organizations, we do not identify the specific organizations, the position within the organization, or the individual.

While everyone will support our protecting confidentiality regardless of the almost universal articulation of its lack of necessity by our subjects, some will criticize our decision to proceed with the interviews without in all cases obtaining their signature.

Honoring the mandate to do no harm

In our view, we followed protocol, adjusting it only to meet the needs of the respondents who wanted to talk but did not want to put their name on a document. This seemed to be the best way to honor the mandate to first do no harm.Δ

Related Web sites

Center for Disaster Research & Education
http://www.millersville.edu/~CDRE

Disaster Research Center—University of Delaware
http://www.udel.edu/DRC/

Emergency Management Program
http://www.millersville.edu/~cdre/

UnScheduled Events
http://muweb.millersville.edu/~isarcdue/

Terrorism & Disaster Center—University of Oklahoma
http://tdc.ouhsc.edu/drt.htm

Disaster Research Center—University of Delaware
http://www.udel.edu/DRC/

Disaster research training for children and families — University of Washington School of Public Health and Community Medicine
http://www.nwcphp.org/training/courses-exercises/courses/drt

News notes

Ethical guidelines proposed for influenza pandemic

Recommended ethical guidelines for pandemic influenza have been prepared for the Centers for Disease Control and Prevention (CDC) by **Kathy Kinlaw** of Emory University and **Robert Levine** of Yale University.

Their recommendations are based on the work of the CDC's Ethics Subcommittee, which includes several bioethicists and public health experts. The CDC is evaluating the recommendations and is expected to adopt most if not all of them before the end of 2007.

An influenza pandemic, which is an epidemic that has spread through an entire region or through much of the world, has not occurred since early in the twentieth century. However, public health officials have become increasingly concerned about the threat of another pandemic such as bird flu, because of a more mobile population, as well as other factors.

Contact: Drue Barrett, PanFluEthics@cdc.gov. For a copy of the recommendations, see **http://www.cdc.gov/od/science/phec/panFlu_Ethic_Guidelines.pdf**

Research integrity newsletter now available free on the internet

Michigan State University's Graduate School has made its Research Integrity Newsletter available, free, on the internet at **http://www.msu.edu/user/gradschl/integrity.htm**

The most recent issue of the newsletter focuses on objectivity and conflict of interest in research. It includes articles on "objectivity, integrity & academic freedom," Perspectives in anthropology," "Inside a research controversy," and others. Previous issues explore plagiarism and the federal common rule concerning research misconduct, as well as issues related to research mentoring and the inclusion of students in protocols.

University of Illinois Center for Advanced Study's White Paper on IRB mission creep

A White Paper prepared by the University of Illinois Center for Advanced Study discusses "mission creep" in IRBs. It is available as a pdf document at **http://www.law.uiuc.edu/conferences/whitepaper/papers/SSRN-id902995.pdf**

The authors say

> Our system of research self regulation, designed to provide internal checks and balances for those who participate in research involving human subjects, is under considerable stress.
>
> Much of this crisis has been caused by what we call mission creep, in which the workload of IRBs has expanded beyond their ability to handle effectively. Mission creep is caused by rewarding wrong behaviors, such as focusing more on procedures and documentation than difficult ethical questions; unclear definitions, which lead to unclear responsibilities; efforts to comply with unwieldy federal requirements even when research is not federally funded; exaggerated precautions to protect against program shutdowns; and efforts to protect against lawsuits.
>
> Honest IRB specialists admit that they operate under constant concern about the one case in a thousand that might slip through review — with the consequence that the other 999 receive exaggerated reviews and risk rejection in an effort to err on the side of caution.
>
> As a consequence, mission creep is causing IRBs to lose the respect and "buy-in" of the very people they are meant to regulate; they are misdirecting their energies, threatening both academic and first amendment freedoms; and most importantly, mission creep is taking needed resources from the most risky research, which truly does need IRB oversight.

Meetings

International conference on Ethics of Stem Cell Research and Moral Responsibility in ART
Nov. 30–Dec. 1, 2007
Ghent, Belgium, Ghent University Bioethics Institute
For information, see **http://www.bioethics.ugent.be/BIGconference**

PRIM&R's 2007 Annual HRPP Conference: Human Research Protection Programs in an Evolving Research Landscape
December 1–4, 2007
Sheraton Boston Hotel, Boston, Massachusetts, U.S.A.
For information, see **http://www.primr.org/Conferences.aspx?id=540**

2008 Annual Human Research Protection Programs (HRPP) Conference
November 16–19, 2008
The Swan and Dolphin Hotels, Orlando, Florida, U.S.A.

First International Congress for the Ethical, Legal and Social Implications (ELSI) of Human Genomics Researchers
The Center for Genetic Research Ethics and Law at Case Wesgtern Reserve University will host the Congress.
May 1–3, 2008
Cleveland, Ohio, U.S.A.
For information, contact Roselle Ponsaran at roselle.ponsaran@case.edu

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CIP certification/recertification review course
January and August 2008
Certified IRB Professions (CIP) courses will be offered by the education division of IRB Synergy.
San Antonio, Texas, U.S.A.
For information, contact Irvin Moss at irb-synergy@hotmail.com

Poynter offers online seminar on the ethics of research with human subjects

An online seminar on the ethics of research with human subjects has been developed by the Poynter Center for the Study of Ethics and American Instiuttions at Indiana University.

The seminar is scheduled to meet online February 25 through May 4, 2008. It will consist of a one-week introductory orientation followed by four units of two weeks each and one week of evaluation. Registrants are expected to work on the seminar twice a week for several hours.

The fee is $300. The online registration form must be completed by February 8.

For information, see ***http://www.indiana.edu/~poynter/sas/sasos.php***.

Please address questions to the SAS Project Director, **Kenneth D. Pimple**, at the Poynter Center for the Study of Ethics and American Institutions, Indiana University, 618 East Third Street, Bloomington IN 47405-3602; (812) 856-4986; FAX 855-3315.Δ

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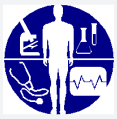

Protecting Human Subjects

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.

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