PROTECTING HUMAN SUBJECTS

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

Fall 1994

Contents

Introduction and Invitation

This issue of the bulletin offers you a survey of where we've come and where we're headed in protection of human research subjects at the U.S. Department of Energy (DOE). Topics range from Secretary Hazel O'Leary's "Openness Initiative" and the May 1994 report of the human subjects subcommittee of the Health and Environmental Research Advisory Committee (HERAC) to plans for the next database update and resources required to support human subjects protections.

Many of the articles in this issue sum up presentations from the meetings on June 13 and 14, 1994—Protecting Human Subjects in the Federal Government, sponsored by the Interagency Human Subjects Research Committee, and Research Using Human Subjects: Past and Present Viewpoints, sponsored by DOE.

Other articles report on progress and plans by the informal Human Subjects Working Group since then. The Working Group acts in an advisory capacity to the Office of Health and Environmental Research (OHER) at DOE in implementing human subjects protection programs and increasing awareness of Federal regulations, enabling OHER to ensure the protection of DOE human research subjects. Members of the Working Group participate in monthly conference calls and meet in person twice a year. Members are volunteers from Department of Energy program offices, operations offices, and laboratories who have some responsibility for or interest in human subject research.

If you are interested in participating in Working Group meetings and conference calls, contact the Office of Health and Environmental Research at (301) 903-5037 (fax: 301-903-8521). We look forward to having your help in shaping our future directions.

Protecting "Vulnerable" Populations

At the June 14, 1994, DOE meeting on human subjects research, Dr. Joan P. Porter, Senior Policy Analyst, Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), highlighted the challenges Institutional Review Boards (IRBs) face in protecting vulnerable populations.

Defining Vulnerable Populations

Dr. Porter defined vulnerable populations as persons with diminished autonomy—those who are compromised in their ability to give informed consent. She emphasized how broadly this definition applies. Groups often identified as vulnerable include children, fetuses, the mentally handicapped, prisoners, and the economically or educationally disadvantaged. Vulnerability, however, may also characterize students, employees, patients in emergency rooms, institutionalized persons, and people who are not fluent in English, for example. Vulnerability depends on context or circumstances, Dr. Porter stressed. If a person is in a situation in which his or her ability to give informed consent is compromised or eliminated, this person is *vulnerable*.

Shift from Exclusion to Inclusion

How can researchers protect vulnerable populations? For many years, the answer was exclusion. Dr. Porter and other speakers at the June meetings indicated, however, that exclusion without a well-considered protection rationale is no longer acceptable to members of the public. People with incurable diseases do not want protection from the research/"therapy" that may heal them. The AIDS epidemic, Dr. Porter observed, has led people to recognize that those with no other alternatives should, as autonomous individuals, be able to choose to participate in high-risk research. Further, Dr. Porter added, people have become more aware that exclusion of a certain gender, race, or age may result in products or data that cannot be widely and safely used.

Research institutes are also changing perspectives. An Institute of Medicine report (*Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies*, 1994) and a Food and Drug Administration guideline (*Gender Differences in Clinical Evaluation of Drugs; Study and Evaluation Guideline Availability*, 58FR 39406, July 22, 1993) address the issue of excluding women of childbearing age from the possible benefits of research. The NIH Revitalization Act of 1993 (Public Law 103-43) mandates the recruitment and retention of minorities and of both men and women in human subjects studies.

Regulations Protecting Vulnerable Populations

The challenge for IRBs today, Dr. Porter said, is finding a way to include and protect vulnerable populations in research. Regulations protecting vulnerable populations are still being developed. Most Federal departments and agencies do not have formal regulations covering vulnerable populations, but recognize or adopt those of the Department of Health and Human Services (DHHS)—Subparts B (fetuses, pregnant women, and in vitro fertilization), C (prisoners), and D (children) of the DHHS regulations (45 Code of Federal Regulations 46). Members of the DHHS Public Health Services are now reviewing Subpart B to consider whether modifications are necessary.

Most institutions with DHHS Multiple Project Assurances issued by OPRR are required to abide by the regulations in Subparts B, C, and D. Other Federal departments and agencies, including the Department of

Energy, are also considering formal adoption of Subparts B, C, and D. Although only Subpart B is currently under revision, the adoption of the Subparts will be a major step, Dr. Porter concluded, in the effort to protect vulnerable populations in research.

Role of the IRB

IRBs are responsible under the Common Rule for protecting vulnerable populations that participate in research. At a minimum, when IRBs review research that may involve members of any vulnerable population, someone who knows that population should participate in the review. In addition, Dr. Porter noted several other ways IRBs can help protect vulnerable populations in research. They can—

- Encourage understanding of informed consent as an interactive process, not just a document.
- Insist on the subjects' freedom to ask questions and to withdraw from the research project at any point.
- Stress the use of the appropriate language and the need for sensitivity to cultural nuances.
- Adopt the use of "consent monitors" or special advocates for those who are impaired.
- Promote better understanding of vulnerable populations within the research community.
- Be vigilant to prevent coercion and undue inducement (whether payment or other rewards).

Dateline Washington

- On **December 7, 1993**, Department of Energy Secretary Hazel O'Leary launched her "Openness Initiative," triggering public attention to past and present use of human subjects in research.
- On **December 23, 1993**, DOE established a hotline for inquiries from people involved in plutonium experiments and other radiation research. During the first month, the number of incoming calls peaked at 700 calls in 1 hour. As of September 23, 1994, the hotline had logged in over 22,000 calls.
- On **January 3, 1994**, President Clinton created the Interagency Working Group on Human Radiation, whose members are the Attorney General and the heads of key agencies— Department of Energy, Department of Defense, Department of Health and Human Services, Veteran's Affairs, National Aeronautics and Space Administration, Central Intelligence Agency, and Office of Management and Budget.
- On **January 18, 1994**, the President announced the establishment of an Advisory Committee on Human Radiation Experiments to evaluate the ethical and scientific principles of all government-sponsored human subjects research since 1946 that involved intentional exposure to ionizing radiation.
- On **January 19, 1994**, the White House directed key agencies to locate, inventory, and review records of human radiation experiments dating back to 1944. The directive required agencies to redact records—remove all personally identifiable data—to protect individual privacy before making any records public.
- On **February 17, 1994**, the President appointed 15 men and women to serve on the Advisory Committee announced January 18. Individuals selected include ethicists, physicians, scientists, and others. That same day, the White House directed all agencies to ensure that current research complies with the Federal Policy for the Protection of Human Subjects.
- On **April 4, 1994**, the Department of Energy delivered the DOE Human Subjects Database to Senator John Glenn's Governmental Affairs Committee. The same day, the database was made accessible through Internet, giving the public access to information on 175 research projects currently in progress at DOE laboratories or supported with DOE funds at offsite facilities.

- In **May 1994**, a subcommittee of DOE's Health and Environmental Research Advisory Committee reported on the protection of human subjects at eight DOE facilities.
- At the DOE human subjects meeting on **June 14, 1994**, Chris Kline from Senator Glenn's office reported that Congress strongly supported both Secretary O'Leary's "Openness Initiative" and President Clinton's directive on February 17 to ensure compliance with Federal policy on protection of human subjects in research. Congress is likely, Kline suggested, to pass legislation to establish a national advisory committee on ethical, legal, and social issues. Also a possibility, Kline said, is a bill that codifies informed consent regulations and Institutional Review Board procedures. Kline expected Congress to wait for the final report of the President's Advisory Committee on Radiation Experiments before enacting specific legislation.
- On **June 27, 1994**, Secretary O'Leary released to the press a list of 48 human subject radiation experiments from the 1940s and 1950s.

HERAC Subcommittee Report on the Protection of Human Subjects at Eight DOE Facilities

On May 27, 1994, a subcommittee of the Health and Environmental Research Advisory Committee (HERAC) in the Office of Health and Environmental Research (OHER) submitted a report to Dr. Martha Krebs, Director, Office of Energy Research, on protection of human subjects at DOE facilities. The HERAC subcommittee visited the eight DOE sites listed below and concluded that all sites visited "were making a good faith effort" to protect human research subjects.

Brookhaven National Laboratory
Lawrence Berkeley Laboratory
Lawrence Livermore National Laboratory
Los Alamos National Laboratory
Oak Ridge Institute for Science and Education
Oak Ridge National Laboratory
Rocky Flats
Sandia National Laboratories

"Some of the facilities were exemplary in fulfilling regulatory requirements and DOE policies, whereas some of the others . . . were . . . deficient in ways that could be easily remedied and would thus make the DOE's entire program outstanding," reported Dr. Sheldon Wolff, who led the subcommittee and chairs HERAC.

In the HERAC Report, the subcommittee recommended that "DOE should assure that sufficient resources are allocated at each facility and at headquarters to support the IRB's operations and ensure the protection of human subjects." The issue of funding was prominent during discussions in the June human subjects meetings. Dr. Ari Patrinos and Dr. James Decker assured attendees that funding issues would be addressed in the future.

HERAC Subcommittee Recommendations—Additional Highlights

- The subcommittee urged Headquarters to "require each facility director to prepare a written delegation of authority granting the IRB all powers necessary to fulfill its responsibilities."

- Recommendations to IRBs emphasized the necessity of having proper community representation at all meetings. Review of projects involving vulnerable subjects requires, in addition, the presence of someone knowledgeable about or experienced in working with the population in question.
- The subcommittee directed IRBs to make sure consent forms are clearly written, in a language understandable to the subjects. Equally, the subcommittee stressed annual inspection and update of consent forms as part of a thorough review of continuing research.
- IRB minutes must comply with a number of specific regulations, the subcommittee emphasized. The presence of a quorum must be recorded, for example, matters of controversy must be summarized, and members' abstentions from voting due to conflict of interest must be noted. IRB files must also contain all documents required by Federal regulations and DOE policies.
- To monitor compliance with these requirements, the subcommittee recommended that DOE audit each facility regularly.

DOE's Response

On August 4-5, 1994, OHER's informal Human Subjects Working Group met to draft a response to the HERAC subcommittee recommendations. The response includes a list of resources needed by laboratories, operations offices, and Headquarters to carry out responsibilities for protecting human research subjects.

The response recommends creation of an audit compliance system that would ensure visits to DOE laboratories and operations offices at least once every 3 years. The audit team would assess compliance with Federal regulations on human subjects research. Lasting approximately 1-2 days, visits would benefit facilities by providing guidance and training.

As part of the response, the Working Group prepared a checklist of HERAC and Working Group recommendations. The Working Group's draft response was distributed to all DOE facilities for their review and comment. The final checklist, when used as a self-assessment, will provide DOE facilities with guidelines for assuring compliance with subcommittee recommendations.

Resource Requirements

In its August 1994 meeting, OHER's informal Human Subjects Working Group summarized key areas—**staffing, training, communications, and visibility**—where resources are needed to facilitate compliance with regulations and protection of human research subjects. The Working Group's analysis was a response to the May 1994 subcommittee report of the Health and Environmental Research Advisory Committee (HERAC) that indicated a lack of sufficient resources at some DOE laboratories to support IRB operations. The report recommended that DOE Headquarters ensure that sufficient resources are available at all levels—Headquarters, Operations Offices, and Laboratories—to support IRB operations and protection of human subjects activities.

Staffing Needs

Resources are needed for an IRB administrator at the laboratories and a human subjects coordinator at the operations offices with adequate staff, equipment—computers, copy machines, printers—and space for records and equipment. In addition, the Working Group suggested that Headquarters needs a dedicated, full-time

administrator to oversee and monitor human subjects research supported by DOE or conducted at DOE facilities.

Training

The Working Group also emphasized the need for funds to support education, training, and travel for researchers and other laboratory staff, the IRB chair and administrator at each DOE laboratory, and Human Subjects Working Group members. The Working Group added that the human subjects coordinator at each operations office must have the time and funds necessary to coordinate or perform onsite training. Training funds would also cover internal audits at all levels in DOE laboratories and operations offices to monitor compliance and instruct personnel in appropriate procedures. The internal audits are to be performed in addition to regular site visits by Headquarters to DOE facilities to examine current procedures and to update personnel on current requirements and issues.

Communications

Many participants at the June human subjects meetings stressed the need for regular, open communication between Headquarters and facilities. Representatives from operations offices and laboratories stated that direction or information from Headquarters often does not clearly and consistently reach their levels. To address these needs, the Working Group recommended resources be allocated to—

- Install communications software (e.g., e-mail) at all DOE facilities. Support once a month e-mails from Headquarters to inform DOE human subjects administrators, coordinators, and others about pertinent human subjects research issues and developments.
- Establish a hotline/support line from which DOE facilities can get quick responses to questions on human subjects research regulations and processes and on project approval.
- Designate a DOE human subjects point of contact (the human subjects coordinator) at each DOE facility to receive information from Headquarters and disseminate it throughout the facility.

Visibility

The Working Group urged that the human subjects protection program be made more visible, identifiable, and clearly defined within the DOE system and organizational chart. The Working Group identified needs for outreach materials and other efforts to increase awareness of human subjects protections. The Working Group recommended the—

- Annual update and regular maintenance of the online human subjects database displaying all current human subjects research supported by DOE or conducted at DOE facilities.

- Expanded distribution of *Protecting Human Subjects.*

- Production of posters, brochures, and other materials that define human subjects research and protections for human subjects in terms understandable to a wide range of researchers and others throughout DOE.

- Availability of the human subjects program manager to other DOE offices for lectures, seminars, and training sessions regarding human subjects research.

The Working Group argued that dedication of adequate funds to these purposes would help increase awareness of requirements and enhance DOE's ability to comply with regulations, thus ensuring strengthened protection for human research subjects.

NOTE: Resource list drafted by the ad hoc Human Subjects Working Group. Commitments of resources and FTEs will be addressed in the future.

Historical Records Collection: Views From the Field

On December 7, 1993, Department of Energy Secretary Hazel O'Leary launched her "Openness Initiative," which included the public disclosure of past DOE human radiation experiments. In January 1994, DOE laboratories and operations offices were asked to gather and review thousands of historical records. Some of the speakers at the June human subjects meetings described their experiences in responding to this request.

Operations Office Overview

As of May 1994, the Chicago Operations Office had sent out nearly 700 letters requesting information about any use of human subjects under each of the 2,377 grants and contracts awarded since 1988, according to Mr. Charles Pietri, Acting Chief of the Chicago Institutional Management Branch. Ninety-seven percent of those contacted responded. Responses revealed that only 36 awards involved human subjects, and none of these met the records search criteria. Of the nine facilities overseen by Chicago Operations Office, only three—Argonne National Laboratory, Brookhaven National Laboratory, and Fermi National Accelerator Laboratory—had any records of past human subjects research.

Grants, awards, and contracts handled by the Chicago Operations Office from the early 1970s until 1988 total 9,400, with only one-third of the addressees currently known, Pietri stated. The Chicago Office is still trying to identify all the addressees for these awards in order to find out whether human subjects were involved in the studies and, if so, whether the records search criteria apply.

As of June 1, 1994, Pietri reported, Chicago Operations *direct* costs for this effort totaled $75,000. Costs were based on 2,100 staff hours, involving 18 people intensively and roughly another 10 people peripherally. Pietri added that the laboratories had also spent significant amounts of time and resources on historical records collection, estimated at $210,000 for Argonne National Laboratory and $136,000 for Brookhaven National Laboratory.

Pietri concluded by asking whether the historical records collection was a success. Certainly, the Chicago Operations Office found no "smoking gun." Nothing previously unknown—certainly nothing shocking—was revealed.

A Laboratory Perspective

As an administrator who became responsible for the historical records reporting at Brookhaven National Laboratory (BNL), Deborah Maresca, Administrative Manager, said she felt confident at the outset that BNL's research was in compliance with regulations. BNL investigators publish profusely, and no classified research has ever been conducted at the facility. Maresca pointed out that BNL subjects are patients referred by local hospitals and physicians, and BNL provides the referring hospitals and physicians with regular updates on the studies and subjects. Furthermore, the historical records search showed that early on, BNL had ethical safeguards in place. These included—

- A Committee on Radioisotopes established in 1950 that reviewed research with respect to its nature, reason, population, and dosimetry.
- An independent governing body established at BNL since 1957 to formulate rules and regulations that ensure quality of care.
- A Medical Research Committee established in 1955 that reviewed each patient file for completeness and accuracy and revised laboratory forms (e.g., the consent form).
- Comprehensive files that index every patient indicating all radiation treatments and x-rays performed.
- Signed and witnessed subject applications to participate in research.

Despite these safeguards, Maresca had several concerns. She worried about the effect of the records search on departmental funding at BNL. She was also concerned about protecting the privacy of patients involved in the studies being reviewed. Maresca said she considers it impossible to remove enough data from records to guarantee protection of patient privacy.

Practical considerations included obtaining the resources needed to fulfill the request. BNL received no additional funding for materials or staff used to collect the historical records. Maresca reported that she and an assistant ultimately did the work in a few intensive weeks, working long hours overtime for which DOE was not charged. Subsequent requests for information were also fulfilled as an "add-on" responsibility.

The biggest problem, Maresca reported, was lack of definition concerning what information was relevant. Guidance was ever-changing, and turnaround was tight.

She expressed concern, finally, that in the controversy over past radiation experiments, researchers had been unfairly criticized. Maresca emphasized that BNL's investigators are dedicated people who work long hours and are underpaid compared to other medical doctors. A number of BNL's senior researchers continue to work after retirement for no salary. Many use themselves as subjects for their experiments. Maresca expressed fear that the controversy would encourage the public to ignore this type of service and treat "researcher" as a term of abuse.

Privacy Issues: Pros and Cons

The "Openness Initiative" at the Department of Energy (DOE) raises questions about the protection of human research subjects' privacy.

At the June human subjects meetings, Dr. Arlene Lennox reported her experience with privacy versus "openness" dilemmas. As Department Head at Fermilab's Neutron Therapy Facility, Dr. Lennox is in charge of

the medical records of patients treated for cancer at Fermi National Accelerator Laboratory. She found herself directed by Headquarters and laboratory management to copy and release patient records. Dr. Lennox emphasized that *patient* records, which contain background and other personal data, have little to do with the actual research performed. She noted that all the clinical research conducted at Fermilab including protocols used and doses given had been published. If DOE had asked for *research* records, there would have been no problem.

Faced with the directive to release patient records, Dr. Lennox had an urgent need to find legal authority to protect patient privacy. She sought guidance from a number of sources and eventually located the November 6, 1975, *Federal Register* notice which stipulates that medical records are confidential (Section 46.119 of 45 Code of Federal Regulations 46). She found further support in the Illinois Code of Civil Procedure, which states that patient records belong to the patient and the physician. Legally, she could not release the records from the laboratory without "redacting" them—making them ready for public viewing by removing all personally identifiable data.

Marya Rowan from DOE's Office of General Counsel pointed out that the law does not provide protection for the privacy of research subjects in all cases. The Freedom of Information Act (FOIA), which governs the Department's disclosure of materials in its records, provides certain categories of data that may be withheld at the agency's discretion. If a decision to withhold is challenged, the Department has the burden of showing that the subject's interest in nondisclosure transcends the public's interest in disclosure—the public's right and need to know about the activities in which the agency has engaged. Unless protection of individual privacy can be justified, disclosure of personally identifiable information may be ordered by the courts. The fact that the research in question has been performed under contract with the agency and the records reside with a private entity also is no guarantee of nondisclosure, because the agency may direct that possession be delivered to it.

With respect to disclosure of agency records, Secretary O'Leary has established an "Openness Initiative." Its hallmark is the commitment to bring to light as much information as possible concerning experiments involving human subjects supported by DOE and its predecessor agencies. This includes fully informing the public through *maximum disclosure of information relating to agency activities consistent with personal privacy and national security considerations*. In the context of the recent disclosures relating to radiation experiments involving human subjects, the Secretary has determined that the policy of the Department with respect to disclosure of personally identifiable human subjects data will be one of protection, unless subjects or surviving family members consent to disclosure, or unless a court orders disclosure. Other privacy issues continue to be raised and further legal decisions will be rendered as occasions arise.

Auditing and Compliance

The June human subjects meetings highlighted approaches to auditing and compliance at two different agencies, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH).

FDA Process

Paul W. Goebel, Jr., Chief of the Institutional Review Branch in FDA's Center for Drug Evaluation and Research, stated that FDA schedules inspections at least once every 5 years for all Institutional Review Boards (IRBs) that have reviewed FDA-regulated research. FDA also conducts audits in response to complaints. Visits

resulting from a complaint may involve a complete inspection, or simply an inspection of the matter that gave rise to the complaint.

FDA plans over 250 inspections each year, Goebel reported, which are assigned by Headquarters and performed by the 22 district offices located throughout the country. Typically, FDA notifies the site shortly before a visit to assure that appropriate persons will be available at the facility during the inspection.

Inspection results are sent by letter to the person financially responsible for the organization (for example, hospital administrator, proprietor of the IRB, or president of the university) with a copy to the IRB chair. FDA sends the letter to the financially responsible person because that individual commands the resources necessary to make corrections and is also capable of withholding resources if corrections are not made.

Forty percent of FDA audit letters require responses within 15 or 30 days. On rare occasions, serious problems may require a conference of facility and FDA representatives. If satisfactory resolution is not achieved, FDA may disqualify the IRB.

Facilities that are seriously out of compliance with FDA requirements are reinspected in 1 year to assure that adequate corrections have been made. Only 23 percent continue to have serious problems upon reinspection, Goebel reported. Recent data suggest that the state of compliance is improving, but a statistically significant trend has not yet been confirmed.

Goebel identified the most frequent violations found by FDA as—

1. inadequacies in IRBs' written operating procedures,
2. deficiencies in IRB meeting minutes,
3. lack of a quorum at convened meetings, and
4. inadequate continuing review of ongoing research.

The inspection report and post-inspection correspondence between FDA and the IRB become available to the public only after the investigation is closed. While the case is still open, public access is limited to a list of regulatory violations (Form FDA-483) that the FDA investigator leaves at a site following a visit that reveals violations of FDA regulations.

NIH Process

Dr. Thomas Puglisi, Chief of the Human Subjects Compliance Oversight Branch at the Office for Protection from Research Risks (OPRR), described investigations performed by OPRR as "largely complaint-driven." Forty percent or more of recent investigations stemmed from patient complaints. Complaints also come from institutions themselves (reporting noncompliance), funding organizations (after they conduct a site visit), and media exposés. With limited investigative staff (three or four staff members, some of whom are part-time), OPRR currently has 75 investigations underway and has conducted 175 over the past few years.

OPRR performs few site visits; it handles most actions by letter, occasionally issuing a formal report. The institution and the complainant are given an opportunity to respond to the findings. Investigative findings and actions are protected from disclosure under the Freedom of Information Act during the investigation, but are released once a decision has been reached.

Sometimes an investigation shows that no problem exists. More often, OPRR suggests or requests corrective actions such as a change in IRB procedures or composition. It may also restrict a Multiple Project Assurance held by an institution to exclude certain types of research or research from a specific department, so that projects in excluded areas must be approved through a Single Project Assurance. In extreme cases, it may suggest or impose termination of funding. Usually, the facility must submit regular progress reports that indicate implementation of the required actions.

The most frequent violations reported by OPRR are deficiencies in the informed consent document, reported Dr. Puglisi. Deficiencies include failure to give a complete explanation of foreseeable risks and failure to adequately describe available alternative procedures.

Another area where NIH has found significant violation, Dr. Puglisi noted, is failure to perform thorough reviews of continuing research.

Institutional Review Board Issues

Several speakers at the June human subjects meetings encouraged Institutional Review Boards (IRBs) to take active roles in addressing concerns ranging from community awareness to collaborative research.

Increase Awareness of Human Subjects Protections

Paula Knudson, Executive Coordinator of the Office of Research Support at the University of Texas Health Science Center in Houston, advocated a proactive approach to educating the community and conducting IRB reviews. Knudson stated that increased awareness of human subjects protections adds to the likelihood that the IRB will hear of problems. To educate investigators and others regarding human subjects protections, Knudson–

- Involves IRB members in preparing the assurance document.
- Circulates the assurance document.
- Attends faculty meetings, when invited, to discuss human subjects issues.
- Alerts members of the administration, including deans and grants office staff members to human subjects concerns.
- Publishes articles in inhouse publications.
- Determines, in consultation with IRB leaders and other IRB members, whether projects qualify for exemptions or for expedited reviews. Knudson cautioned against leaving these decisions to researchers, who often are not familiar enough with regulations that define human subjects research to decide correctly.
- Teaches classes in all research methodology courses. In the classes, she encourages students to define research interests and then modify research designs both to achieve the scientific objective and to protect the subjects.

IRB Sensitivity to Community Values

Dr. Susie John, Director of Community and Preventive Health Services at the Crownpoint Indian Health Care Facility in New Mexico, emphasized the importance of sensitivity to community values, especially when

researchers are working with communities whose culture differs from their own. Dr. John used her experience with the Navajo people to suggest three ways in which IRBs and researchers could work more effectively with local communities:

- **Sharing Benefits of Research.** The Navajo people have considered stopping all human subject research in their community because some researchers have never returned to the community to share the findings or benefits of a study after using community members as subjects of the research. IRBs should insist that people have access to results and to any benefits of research performed in their community.
- **Communicating with Subjects.** All written and verbal materials, including research findings, should be available in the native language of the research subjects.
- **Respecting Community Beliefs.** IRBs should be sensitive to cultural beliefs and community values of the area in which they operate. For example, tampering with the umbilical cord (extracting cord blood, for instance) and removing other body parts from a person violates sacred Navajo beliefs. Communities can be extremely sensitive to abuses of this sort.

Speakers in the panel on international research reiterated these recommendations as important considerations for research performed in foreign countries.

Employee Surveys

As Medical Director at Los Alamos National Laboratory and head of the IRB, Dr. Jerry Williams raised the question of whether IRBs should review employee surveys. Twenty-five years ago, he recalled, the major concern in human subjects research was physical injury. Now, the emphasis is also on *privacy and confidentiality.* Dr. Williams suggested that workforce surveys may qualify for IRB review because they are systematic investigations designed to produce generalizable knowledge. He noted that even anonymous questionnaires often fail to protect employees' privacy. Surveys almost always collect some personal or demographic data, and only a few items of demographic data are needed to identify most people. Furthermore, people are subject to potential risk if they respond because workforce surveys usually ask for opinions on management.

Cooperative/Collaborative Research

Dr. Robert Jones, former Associate Director of the Inhalation Toxicology Research Institute, recommended that every IRB at DOE facilities review all cooperative/collaborative research projects, including Collaborative Research and Development Agreements (CRADAs). He stated that each IRB is responsible for projects within its own organization, arguing that the local IRB knows its own setting, population, and applicable laws. However, he urged IRBs at DOE facilities not to rely solely on approval by the IRB at the cooperative/collaborative institution. IRBs at DOE facilities should review all projects thoroughly, Dr. Jones stressed, and any questions or differences of judgment should be negotiated with the cooperating/collaborating institution.

The Human Subjects Database: Summer-Fall 1994 Developments

The Office of Health and Environmental Research (OHER) at the Department of Energy (DOE) is presently revising forms and preparing for the 1995 update of the human subjects database on current research projects.

Dr. Susan L. Rose has announced that DOE's Environmental Measurements Laboratory in New York will head up revisions to the database and coordination of the 1995 update.

Following are some of the new features to be available in the 1995 database:

- Project summary forms will be available electronically through e-mail, Internet, or some other accessible system.
- The instruction sheet will include sample responses, definitions, and directions for accessing and using the project summary form electronically.
- Fields are being added to collect information on protocols or subprojects that are linked to projects.
- Some fields will allow respondents to select items from lists, to facilitate the reporting process and to increase consistency in responses.

The revised database, instruction sheet, and project summary form will undergo a field test in early 1995. The update will take place in the fall of 1995, and the database will be made public by the end of the calendar year.

A Note of Appreciation

Harold Harty recently retired as Chair of the Human Subjects Committee at Pacific Northwest Laboratories (PNL), a position he held for 10 years. He saw PNL through the introduction of the Common Rule and played a critical role in helping PNL obtain its Multiple Project Assurance. Dr. Susan Rose expressed appreciation for his responsiveness and thoroughness and for his deep concern for human subjects. Alan Rither, PNL's attorney and long-term member of its IRB, praised Harty for treating others with "patience and respect."

Human Subjects Working Group

The Human Subjects Working Group this year provided ideas, documents, guidance, and advice for the June human subjects meetings, the response to the HERAC subcommittee report, and the human subjects database update, and they are now beginning the task of revising the DOE resource manual. Members are—

- Marya Rowan, Department of Energy, Office of General Counsel
- Charles Pietri, Chicago Operations Office
- Robert Jones, Inhalation Toxicology Research Institute
- Joseph Aaron, Oakland Operations Office
- Linda Erickson, Sandia National Laboratories
- Deborah Maresca, Brookhaven National Laboratory
- Barbara Fitzgerald, Brookhaven Area Office
- Alan Rither, Pacific Northwest Laboratories
- Jerry Williams, Los Alamos National Laboratory
- Chris Byrne, Lawrence Berkeley Laboratory
- Emily Mitchell, National Institutes of Health
- James Tucker, National Institutes of Health
- Dorrette Worrell, National Institutes of Health

The group was led by Dr. Susan L. Rose from the Office of Health and Environmental Research. Special contributions were also made by the following people—

- Merrill Heit, Department of Energy, Environmental Measurements Laboratory
- Camille Marinetti, Department of Energy, Environmental Measurements Laboratory
- Martha Firestine, Walcoff & Associates
- Tana Jorgensen, Walcoff & Associates
- Susan Dallas, Oak Ridge Institute for Science and Education
- Jennifer Dalton, Oak Ridge Institute for Science and Education

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Newsletter Information

This bulletin is designed to facilitate communication among those involved in human subjects research and to inform persons interested in human subjects research activities.

DOE Human Research Subjects Program

- **DOE Human Research Subjects Program Manager**: *Dr. Susan L. Rose*
- **Editor**: *Tana Jorgensen*
- **Graphic Designers**: *David Hoff and Carolyn McHale*
- **Reviewer**: *Dr. Martha Firestine*

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Dr. Susan L. Rose
Office of Biological and Environmental Research, SC-72
U.S. Department of Energy
19901 Germantown Road
Germantown, MD 20874-1290

PHONE: (301) 903-5468
FAX: (301) 903-8521
E-mail: kim.laing@science.doe.gov or joanne.corcoran@science.doe.gov