PROTECTING HUMAN SUBJECTS

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

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Contacting us

The *Protecting Human Subjects* newsletter can be found on the internet at **www.science.doe.gov/ober/humsubj/newslett.html**

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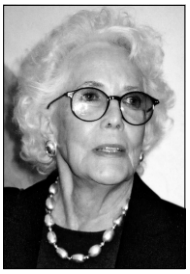
The value of difference

Nonaffiliates on IRBs provide alternative views

(Melinda Hurst, nonaffiliate member of the Los Angeles County/University of Southern California Institutional Review Board presented "The Value of Difference" at the Fifth World Congress of Bioethics held in London. Excerpts are offered here in response to the challenge posed in the last issue of this newsletter asking for discussion about issues faced by those of us involved in protecting human subjects.)

By Melinda Hurst

Institutional Review Boards (IRBs) are required to have a member not otherwise affiliated with the institution.



Melinda Hurst

This member represents the interests of the research participant and, as much as possible, serves as a reflection of the community.

All members of the committee share review responsibility, but federal authorities believe a person can be particularly valuable if there is neither involvement nor vested interest in the research.

For 27 years I have served as a community member on the Ethics Committee and the IRB of Cedars-Sinai Medical Center. I have also served on California's Human Subjects Protection Committee.

I have been a member of the Research Committee of the Los Angeles County/University of Southern California Medical Center, and the Institutional Animal Care and Use Committee of the University of Southern California.

Among the first

As one of the first people in Los Angeles County to serve as a nonaffiliate member of an IRB, I would like to describe my work and make some proposals for improving the system.

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Patient privacy rules ok'd

First comprehensive federal standards

Sweeping new rules to protect the privacy of medical records took effect in April. The Web site for the rules is www.hhs.gov/ocr/hipaa/.

The rules establish the first comprehensive federal standards for medical privacy. They will affect virtually every doctor, patient, hospital, pharmacy, and health insurance plan in the United States.

The rules require that health care providers obtain written consent from patients before using or disclosing medical information for even routine purposes. Patients would have a federal right to inspect and copy their records and propose corrections.

The rule does not supercede or conflict with the Common Rule on protection of human subjects or the federal privacy act. It uses the same definition for research as the Common Rule. Covered entities must comply by April 14, 2003.Δ

Being white, educated, and financially comfortable poses difficulties in representing people who are ill, frightened, depressed, too trusting to ask questions, often poor, and very often desperate.

Committees will be strengthened if their composition reflects the diversity mandate of the federal regulations.

The value of difference
The value of difference is crucial because human subject research involves people in many different roles. Appreciating these differences is central to the successful functioning of the committee.

I am referring to the difference between biomedical researchers and the patients they study, the difference between participants in research and the reviewers of research design, and the difference between the reviewers who are part of the research institution and the nonaffiliated members of the committee. I refer to the difference between being outside and being inside the structures of power that conduct research.

I try to stand in for the patients and to guard their autonomy, their safety, and their rights. But being white, educated, and financially comfortable poses difficulties in representing people who are ill, frightened, depressed, too trusting to ask questions, often poor, and very often desperate.

Despite these obvious differences, I have been a wife, a mother of a child with disabilities, and a teacher. I have suffered from depression and survived cancer. I have lived with fear and the oppression it produces, and I have an innate (or at least deeply assimilated) resistance to authority. I employ all of this personal history to honor the role I accept as a representative for research subjects.

Education
(1) IRBs can foster education about ethical responsibility. Both the National Institutes of Health and the Office of Inspector General of Health and Human Services have said ethics training should be a central focus.

Our society faces increasingly complex issues in biomedical research, and I believe we must include more instruction to ensure that everyone involved understands both the protocol and the implications of research studies.

This instruction is especially needed by the non-scientist and the nonaffiliated members of review committees, but it also applies to the medical members.

Who will protect patients as we proceed into the age of genetic research? Who will ensure subject access to genetic counseling and full disclosure about what it means for research participants to have their genetic material stored in a bank? The best hope is well-informed and ethically astute researchers and IRBs.

Reflect diversity
(2) Committees will be strengthened if their composition reflects the diversity mandate of the federal regulations.

The best way to broaden membership is to involve the population directly served by the institution. This is a radical and frightening prospect for most committees because they do not always trust the people they represent.

Nonaffiliated representation
(3) IRBs can institute proportional representation for nonaffiliated members. Federal regulations mandate that the five-person minimum for a review committee must include at least one nonscientist and one nonaffiliate.

Consequently, committees have grown larger while the number of nonscientists and nonaffiliates has often remained at the bare minimum. IRBs today ought to interpret the federal mandate as requiring a ratio of at least 20% nonaffiliate members.

Voting
(4) IRBs can insist that accepted standards for decisionmaking require the presence of nonaffiliated members during votes. Although regulations require one nonaffiliate

on each committee, they do not require their presence to constitute a quorum for voting.

The nonaffiliates on my committee have succeeded in changing this practice. Now, a nonaffiliate must be present or a vote cannot take place.

More than scientific merit
(5) All IRBs must reaffirm that our major responsibility is ethical review. The science in research studies should meet professional standards, but scientific standards alone are not sufficient.

We need a revolution in thinking about ethical principles in human subject research. We can move from the present approach of protecting subjects to an approach in which they become active participants.

Only when protection means ensuring the human rights of research participants will the knowledge we gain from research truly advance the interests of all members of our society.

Informed consent
(6) IRBs can put much more effort into the processes involved in obtaining so-called informed consent. Reviewers may become so concerned with the advancement of science that they lose sight of the overriding mission, which is human subject protection.

Truly informed consent requires more than an explanation of the research. We need to ask for reassurance that the timing is appropriate, that the setting is conducive to thoughtful consideration, and that there is a declaration of who will administer the informed consent. Informed, obviously, means that the consent form be translated into the patient's primary language.

It means that patients should be invited to discuss their concerns with an ombudsman who is not affiliated with the institution. An ombudsman can explain the possible benefits, the possible risks, and the patient's rights.

In a now famous case, the father of a young volunteer who died in a gene therapy procedure said he wished that he and his son had been able to talk with someone outside the institution, someone not involved in or invested in the science or profits of research.

Organization
(7) Nonaffiliate members should take the lead in educating all involved about the contribution we make as representatives of the research participant. We can organize ourselves locally and nationally, redefine our responsibilities, and emphasize our difference as outsiders.

A group of us recently invited community members across the country to join us as we attempt to build a national organization to help both the research world and the public recognize the value of community representation. Through organization we can gain the strength needed to help both the research world and the public recognize the value of community representation on the IRB.

Possibilities for nonaffiliates
We can lobby for more training. We can identify issues around which we can develop expertise. We can broaden the diversity of IRB membership.

We can insist on attending and participating in federally sponsored meetings and conferences. We can seek relationships with individuals and organizations around the world that have common concerns about the future of biomedical research.

I believe that nonaffiliates can best fulfill their role when ethical review of human research is viewed as essential. I am optimistic that the increasingly visible activity of nonaffiliates is a major step in this direction.Δ

IRBs can insist that accepted standards for decision making require the presence of nonaffiliated members during votes.

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Research intermediaries

Position created to protect vulnerable people who might not have capacity to consent

By Janet Allen

The intermediary works primarily with inpatients hospitalized with schizophrenia, bipolar disorder, and other conditions.

It is important that the people being approached for the research understand that the intermediary is independent of the clinical and research teams.

Concerns persist about whether research participants truly understand the research and whether they know their options.

A wide range of approaches have been proposed to allay the concerns, especially those related to monitoring informed consent. The "research intermediary" is one method of IRB oversight of informed consent.

The intermediary position was created in 1993 by the University of Texas–Houston (UTH) IRB Executive Coordinator Paula Knudson as a way to provide liaison among the IRB, the research staff, and the research volunteers. The intermediary's job is to ensure that informed consent communication remains intact throughout a research participant's involvement in a study.

The intermediary works primarily with inpatients hospitalized with schizophrenia, bipolar disorder, and other conditions. The intermediary has also been dispatched to serve others for whom the IRB finds the need for additional assistance in informed consent. For example, the IRB has determined that people facing experimental surgery and device placement sometimes warrant this added protection, especially when children or people with few treatment options are involved.

In their own words

After the initial informed consent discussion, the intermediary visits with research participants to get them to describe the study in their own words. Alternatives to participation in the study are also discussed. The intermediary then determines whether the participant understood the consent. If the consent seems truly informed, the intermediary assures the IRB that it is valid. If there are questions about the consent's validity, the intermediary suggests that it be reconsidered.

The initial consent discussion is not observed by the intermediary. The process was designed in this way for three reasons. First, research staff members are the primary source of the information about the project and the presence of the intermediary might distract from

Janet Allen meets with Joel Steinberg, M.D., associate professor of psychiatry and behavioral sciences, to discuss research at the Harris County Psychiatric Center. Allen served for several years as a liaison between patients and physicians conducting research at the center. (Photo by Fran Dressman)

communication between the investigator and the prospective subject. Second, primary responsibility for the quality of the consent process lies with the principal investigator. Third, it is important that the people being approached for the research understand that the intermediary is independent of the clinical and research teams. Being present during the initial consent discussion could interrupt the communication and make the roles unclear.

Protecting against coercion and misunderstanding

People with severe forms of bipolar disorder, addiction, or schizophrenia may have had experiences before and during hospitalization that felt coercive and oppressive.

Empowering volunteers

Even patients with conditions that are not typically related to emotion and behavior can feel as if they are powerless in the medical system. If the research intermediary is seen as "one of them," the opportunity to help empower the volunteer to communicate with investigators can be lost.

The investigators notify the intermediary when a person has volunteered. The timing of the intermediary's first visit occurs reasonably soon after consent was received. The visit is structured as a conversation rather than a structured questionnaire.

Experience with the process has shown that even non-verbal signals are important. When the intermediary arrives, she should wait in the patient/visitor areas rather than staff lounges or nursing stations.

It is also helpful to let patients make decisions about such things as where to sit for the discussion and whether family or friends should be involved. The intermediary asks for permission to speak to staff members about the patient's care, an effort designed to communicate that the patient has decisionmaking control.

The goal of the intermediary's visit is (1) to elicit a description of the study in the volunteer's own words, (2) to answer questions that can be answered by the informed consent document, and (3) find qualified staff to answer any questions not found in the document. Every effort is made to assure the volunteers that they may ask any question or change their minds at any time.

Evaluating reasons

Because one concern is that some volunteers may lack the decision-making capacity to make an informed choice, it is important for the intermediary to evaluate the volunteer's reasons for enrollment. One criterion for this evaluation is whether the volunteer can cogently describe the study.

One patient had agreed to participate in a low-risk study that involved periodically drawing blood samples during her hospitalization. When asked to describe the study in her own words, she said she was helping the FBI solve crimes committed by the Mafia. When this information was given to the investigator, the person was removed from the study.

When a person does not seem to be describing the study in a clear way, the investigator is informed of this by being given the exact words used by the volunteer, rather than a clinical determination from the intermediary.

— Continued on page 9

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Historic preservation

An unusual way to protect human subjects in research

By Ellen Prendergast,
Pacific Northwest National Laboratory

HCRL staff conduct interviews with people who have contributed to the cultural landscape.

One doesn't usually consider historic preservation as having anything to do with living people, or as "research" having to do with human subjects.

However, the Hanford Cultural Resources Laboratory (HCRL) at the Hanford Site interacts with human subjects in a variety of ways, some of which constitute human subjects research.

Ellen Prendergast

A key element in this work is determining what constitutes "research" and thus requires application of special measures to protect human subjects.

Federal requirements

Along with archaeological surveys and examination of historic buildings, ethnographic and oral history interviews are among the many ways that DOE complies with federal historic preservation requirements. HCRL staff also hold meetings with tribes and the public to get their advice on cultural resource decisions.

To document and record the rich culture that comprises the Hanford Site, HCRL staff conduct interviews with people who have contributed to the cultural landscape.

Local tribes

We have interviewed members of local tribes who lived along the shores of the Columbia River. We also interviewed Euro-Americans who settled and lived in towns that were well established at the time of the Manhattan Project in 1943. Some of these are former workers who contributed to the making and operating of Hanford's reactors and associated facilities.

The information provided by these people contributes greatly to our

Interviewees include members of local tribes who lived along the shores of the Columbia River.

Filming an oral history interview with tribespeople who lived along the shore of the Columbia River.

understanding of cultural resources at the Hanford Site and makes the past come alive.

Because we participate in a variety of human subjects interactions, some of which are and some of which are not in the actual context of research, we had to find a way to determine when it is "research."

Clarifying the process

HCRL has tried to do this by developing a policy that clarifies the process for addressing human subjects issues.

At right is the table developed by HCRL staff to determine the need for informed consent and review by the IRB. Once the need is determined, required documents are submitted to the IRB for review and approval.

When human subjects regulations do not apply, but "persons" are involved, HCRL's "Best Practices" procedures are employed.

Requiring informed consent

I recently joined the HCRL to help develop the ethnography program. As part of that program, I conduct interviews twice a month. All interviews require informed consent from the person being interviewed, and the IRB approval process has become routine.

For many people associated with the Hanford Site, their experiences, stories, and way of life are very personal and sensitive. The informed consent process helps to establish an open and trusting atmosphere, which helps create a rapport and trust that extends beyond the interview itself.

For information

Call (509) 376-4626 or e-mail: ellen.prendergast@pnl.gov. Δ

Table 1. This table was developed by the Hanford Cultural Resources Laboratory to determine the need for informed consent and review by the Institutional Review Board.

Hanford Cultural Resource Project • Interactions with Human Subjects

Type of activity	Example	Human Subjects Research?	Action/Permission
Discussions/comment resolutions/ stakeholder involvement	DOE tribal issues meetings, issues exchanges, and special meetings related to HCRL project activities	No	None
Tribal notifications	Notification of cultural resource reviews, planned site surveys, and/or monitoring trips	No	None
Field trips	Site surveys, monitoring trips, construction monitoring, project-specific trips, site-specific trips	No	None
Discovery of human remains		No	Procedure CR-10
Subcontractors	Participation in project activities that do not involve human subjects	No	However, these individuals must be trained to applicable project policies and procedures.
Taking photographs, slides, videotapes, etc.	Pictures, slides, videotape, etc., of participants during field activities not related to research	No	However, any non–PNNL staff of whom photographs, videotape, or other media will be taken must sign a Photographic Release Form.
	Pictures, slides, videotape, etc., of participants during research activities	Yes	If the photos, video, etc., are related to information that is personal and identifiable, a Photographic Release Form must be signed.
Conducting research	Interviews/oral histories taken from Native Americans, former residents, former Hanford workers, current Hanford workers	No	If the information is general in nature and not identifiable to an individual.
		Yes	If the information is personal and identifiable, the human subject(s) must sign an Informed Consent Form.
	Documentary information taken from Native Americans, former residents, former Hanford workers, current Hanford workers	No	If the information is publicly available and not identifiable to an individual.
		Yes	If the information is NOT publicly available and the information is personal and identifiable, an Informed Consent Form must be signed by the human subject(s).
Taking notes	Notes taken from interactions with Native Americans, former residents, former Hanford workers, current Hanford workers	No	If the information is general in nature (e.g., information about site events or processes that are not personal) and not identifiable to an individual.
		Yes	If the information is personal and identifiable, the human subject(s) must sign an Informed Consent Form.

Oak Ridge sets up new IRB

Replacement for previous board has more funding and wider authority

From left, Jeffrey Smith, ORNL Deputy for Operations; Betsy Ellis, new IRB chair; Susan Rose, DOE Human Subjects Program Manager; Ron Townsend, president of Oak Ridge Associated Universities; and Shirley Fry, outgoing IRB chair.

An Institutional Review Board (IRB) has been established to cover research at all of the Department of Energy's (DOE's) Oak Ridge operations, including those in Paducah, Kentucky, and Portsmouth, Ohio. Its purview includes studies of past and present workers.

The Oak Ridge Site-wide Institutional Review Board (ORSIRB) replaces an IRB that for many years has reviewed and provided guidance to research activities at Oak Ridge National Laboratory and Oak Ridge Associated Universities (ORAU).

Former IRB "exemplary"
DOE's Human Subjects Protection Program director, Dr. Susan Rose, said the former IRB was for many years an exemplary board but was limited in funding and did not have authority to oversee all Oak Ridge sites. The new IRB has more funding and wider authority.

As the lead organization for the new IRB, ORAU will provide an information clearinghouse on Oak Ridge human subject studies, including studies funded by agencies other than DOE.

In the near future this IRB will also encompass a new centralized DOE-wide IRB specifically established to oversee Beryllium research.

The IRB's administrator, Richard Toohey, said protecting the safety, welfare, and privacy of research subjects is the board's top priority.

Shutdowns highlight need
DOE's proposal for the IRB said, "By protecting the interests of human subjects, a properly functioning IRB also protects the interests of the researchers and sponsoring institutions.

"The need for a well-administered and adequately supported IRB is highlighted by recent shutdowns of human research protocols at several nationally recognized research institutions.

"It is imperative that (DOE's Oak Ridge Office) and its contractors be proactive in their assurance of protection of the subjects of such studies. The ORSIRB, managed by ORAU, will be a major step forward in providing this assurance."

The board will have term limits on membership in an effort to ensure more turnover and diversity of membership. No one will serve more than two three-year terms consecutively.Δ

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ORO's Chung gets "Time Off" Award

Regina Chung

Regina Chung, coordinator of the Oak Ridge Operations (ORO) Human Subjects Protection Program, has won a "Time Off Award" in recognition of her contributions to the Program.

As the ORO coordinator, she was instrumental in establishing the ORO site-wide Institutional Review Board (IRB).

The IRB has been recognized as a DOE-wide model by DOE's Office of Human Subjects Protection.Δ

Mallon gets one of five BNL awards for 2001

Darcy Mallon

Brookhaven National Laboratory (BNL) has recognized Darcy Mallon for outstanding achievements as Human Subjects Protection Program Administrator. She received one of this year's five "Brookhaven Awards."

Mallon helped create the Office of Research Administration (ORA) within the BNL Director's Office. The ORA has administrative responsibilities for the Institutional Review Board, the Institutional Animal Care and Use Committee, and the Radioactive Drug Research Committee.Δ

LLNL managers support IRB effort

New position funded after review suggestion

Lawrence Livermore National Laboratory (LLNL) is expanding its support of the lab's IRB by creating the position of IRB Office Secretary.

Ann-Marie Bucaria Dake

The position will be filled by Ann-Marie Bucaria Dake, who has been with LLNL for 10 years.

In announcing the appointment, Bree Klotter, IRB Administrator, said the new position is a direct result of last summer's performance review of LLNL's human subjects protection program by DOE and an outside expert panel.

One of the review team's recommendations was that additional administrative support of a half-time person was warranted. Klotter said LLNL's management responded quickly by providing special funding to give the IRB its needed assistance.

Dake has had considerable experience working in a regulatory environment. She will interact with principal investigators in the protocol submission process and will assist in all phases of the IRB office.Δ

Research intermediary

(Continued from page 5)

With few exceptions, each time information about a lack of understanding was relayed by the intermediary, the investigator was unable to continue to confirm the volunteer's informed consent.

Other participants have found that having someone outside the research and clinical teams to encourage their questions and to provide answers have made participation easier. This is also true for those whose cultural or language barriers may prevent easy communication.

Many investigators have come to understand that what the research volunteers say to investigators is often not the whole story. Those who have been involved in the process have agreed that a better-informed and supported volunteer is one who is better able to follow the often rigorous requirements of participation in research.Δ

Janet Allen served as research intermediary for the University of Texas–Houston Health Science Center from 1993 until early 2001. She is now research auditor for Baylor College of Medicine.

Protecting Human Subjects wins newsletter award

DOE's *Protecting Human Subjects* newsletter won a Merit Award in the 2000–2001 publication competition of the Society for Technical Communication's (STC's) East Tennessee Chapter.

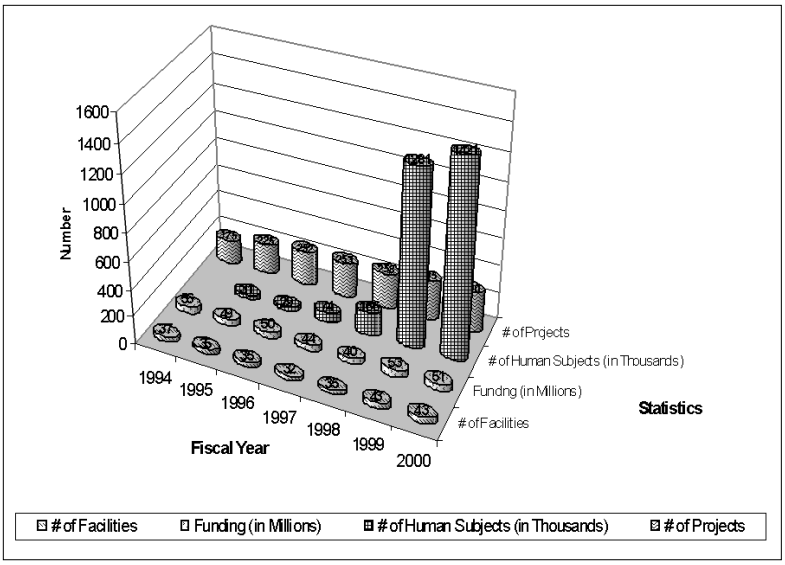
The newsletter, published since 1992 has a primary circulation of about 5,000. It focuses on emerging bioethical issues and regulatory changes important to human subjects research.

Some 43 entries competed in this year's publication competition sponsored by the STC's East Tennessee Chapter.

Past issues are available on the web at www.science.doe.gov/ober/humsubj/newslett.html.Δ

Human subjects database

FY 2000 update shows dramatic increase in number of subjects reported



The chart depicts trends in the number of reporting facilities, funds directly associated with tasks or portions of projects involving human subjects, total number of human subjects, and number of projects reported.

The FY 2000 update of the DOE Human Subjects Research Database (HSRD) is now on the World Wide Web at http://www.eml.doe.gov/hsrd/

In 1999 the database had 10,925 visitors. In 2000 that number increased to 29,004—a rise of 165%.

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

By Ethel Jacob, Richard Larsen, and Camille Marinetti

300 projects

The FY 2000 database includes 300 projects, of which 73% were conducted at DOE facilities and 27% at non-DOE facilities (such as hospitals and universities).

There are 43 reporting research facilities—12 are DOE laboratories and 31 are non–DOE facilities.

Funding from DOE that was directly associated with tasks or portions of projects involving the use of human subjects was about $39 million; funding from other federal and private sources at DOE facilities was about $12 million. A total of 1,420,988 human subjects were reported, 98.8% of whom are from registries, questionnaires, surveys, and epidemiological studies.

Trends and funding

The chart pictured above presents trends in the number of reporting facilities, the funding that is directly associated with tasks or portions of projects involving the use of human subjects (in millions), the total number of human subjects (in thousands), and the number of projects reported.

Most evident in these trends is the explosive increase in the number of human subjects reported after 1998. This dramatic increase resulted from the addition of epidemiological studies to the database from the Former Worker Projects and from the National Institute of Occupational Safety and Health.Δ

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The database includes 300 projects, of which 73% were conducted at DOE facilites.

IRB roles & responsibilities

An outline of duties for institution, IRB, administrator, and investigator

By Jeffrey Cohen

The following article is an overview of a comprehensive discussion about ensuring the effectiveness of IRBs, which was presented at a PRIM&R/AAMC workshop by Jeffrey Cohen, Associate Director for Education in the U.S. Department of Health and Human Service's Office for Human Research Protection (OHRP). His talk provides a detailed job description for all those involved with IRBs. It can be used as a check list for your site.

Institutions bear full responsibility for all research involving human subjects covered under their Assurance, including meeting all requirements of 45 CFR 46 for all federally sponsored research.

The Office of Human Research Protection (OHRP) strongly encourages institutions to embrace Department of Health and Human Services (HHS) regulations, regardless of sponsorship. After establishing an IRB, institutions should provide sufficient space and staff to support the IRB's review and record-keeping duties. They should also ensure the appropriate Assurances and certificates of IRB review are submitted.

The following describes job responsibilities and procedures that many institutions follow to ensure effective administration and compliance with regulations. Not all institutions follow these procedures exactly. For example, some do not have the Institutional Official appoint the IRB chair or members; they may have that done by another body.

The Institutional Official

- is authorized to act for the institution and assumes on behalf of the institution the obligations in the Assurance
- sets the tone for an institutional culture of respect for human subjects
- is the knowledgeable point of contact for OHRP
- is responsible for appointing IRB members and chair
- provides IRB with necessary resources and staff
- supports IRB decisions
- ensures effective institution-wide communication and access to human subject information
- encourages participation in human subject educational activities.

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"Education Summit" calls for training in responsible research

By Jeffrey Cohen

In February, 2001, representatives from government, public and private research institutions and organizations, professional societies, and businesses met in Rockville, Maryland, for what was called an "Education Summit."

The summit was called to discuss education and training in the responsible conduct of research and the protection of human subjects.

After a day-long brainstorming session, the group proposed formation of an "Education Council."

The draft charter of the Council said, "The mission of the Education Council is to facilitate and promote the development, sharing, and adoption of appropriate and effective educational programs related to responsible conduct of research (RCR) and protection of human subjects at or amongst institutions, organizations, businesses, and government agencies that perform research."

The Council is designed to be a public/private partnership. The participants in the summit will meet again in August to adopt a final charter and to develop an organizational structure for the Council.Δ

The IRB Chair

- ensures that the IRB carries out its responsibilities
- conducts expedited review of delegates
- keeps institutional official informed
- educates IRB members and investigators.

The administrator often makes preliminary determinations regarding exemptions and eligibility for expedited review.

The IRB Administrator

- receives all research protocols and communicates IRB decisions to investigators
- often makes preliminary determinations regarding exemptions and eligibility for expedited review
- schedules IRB meetings
- prepares and distributes the agenda and review material for IRB members
- records the minutes of IRB meetings
- ensures that IRB decisions and requirements for modifications are promptly conveyed to investigators in writing
- maintains the IRB records and arranges access to the records when requested by federal authorities
- forwards certification of IRB approval of proposed research to the appropriate federal department or agency
- acts as designated institutional contact for receipt of communication from federal or other policymakers concerning human subject research issues
- reports promptly to the appropriate institutional officials, OHRP, and other sponsoring federal department or agency heads:
  1. any unanticipated injuries or problems involving risks to subjects or others
  2. any serious or continuing noncompliance with the regulations or requirements of the IRB
  3. any suspension or termination of IRB approval for research
- ensures constructive communication among research administrators, department heads, investigators, clinical care staff, human subjects, and institutional officials
- arranges for and documents distribution of a copy of the institution's Assurance to each person who conducts or reviews human subject research
- provides ready access to copies of pertinent federal regulations, policies and guidelines, as well as institutional policies and procedures.

Action items

1. All faculty and staff are to receive a memo that includes
   - statement of institution's obligation to protect human subjects
   - definition of "research" and "human subject"
   - name and telephone number of contact person
2. Institutional leaders should mandate adequate training and education for IRB members and all faculty and staff involved in human subjects research.
3. Institutional leaders should sample IRB records for review. This should include the minutes, protocols, and grant applications.
4. Institutional leaders should survey IRB members, administrators and staff to determine their unmet needs for resources. This is especially important because inadequate institutional support is the root cause of compliance problems.

Inadequate institutional support is the number one root cause of compliance problems.

The IRB has authority to suspend or terminate previously approved research.

The investigator has primary responsibility for protecting the rights and welfare of human research subjects.

The IRB

- reviews and approves, requires modification in, or disapproves all research activities, including proposed changes in previously approved human subject research
- conducts continuing review of approved research at intervals appropriate to the degree of risk, but not less than once a year
- has authority to suspend or terminate previously approved research not being conducted in accord with the IRB's requirements or that has been associated with unexpected serious harm to subjects
- must be familiar with
    1. ethical principles of human subject research
    2. requirements of federal regulations
    3. applicable state laws
    4. institution's Assurance
    5. institutional policies and procedures for the protection of human subjects
- must have effective knowledge of
    1. subject populations
    2. institutional constraints
    3. differing legal requirements
    4. other factors that may contribute to a determination of risks and benefits to subjects and subjects' informed consents.

The Investigator

- has primary responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of their institution's Assurance
- must be familiar with
    1. ethical principles of human subjects research
    2. requirements of federal regulations
    3. applicable state laws
    4. institution's Assurance
    5. institutional policies and procedures for protection of human subjects
- conducts all research according to IRB-approved protocol and complies with all IRB determinations
- ensures that each potential subject understands the nature of the research and of the subject's participation and takes whatever steps are necessary to gain that comprehension
- provides a copy of the IRB-approved informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement
- retains all signed consent documents according to institutional policies, but at least three years beyond completion of the research
- promptly reports proposed changes in previously approved human subject research activities to the IRB
- does not initiate changes without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects
- reports progress of approved research to the IRB, as often as and in the manner prescribed by the IRB on the basis of risks to subjects, but not less than once a year
- promptly reports to the IRB any unanticipated injuries or problems involving risks to subjects or others.

Exam for IRB professionals

Three DOE working group members pass test with flying colors

More than 160 people have passed the newly created Certification Exam for IRB Professionals. The exam has been given twice at several locations in the United States. The next exam is scheduled for October.

Among those who stepped up to the challenge of taking the first exam, which was given in October, 2000, were three members of the DOE Human Subjects Working Group (HSWG): Darcy Mallon (Brookhaven National Laboratory), Chris Byrne (Lawrence Berkeley National Laboratory), and Terry Reser (Sandia National Laboratories).

HSWG members

Fewer than half of the test takers passed the first exam; however, all three HSWG folks did, and Darcy was even selected to sit on the review panel for the next exam, scheduled for March 2001.

Developed by the Applied Research Ethics National Association (ARENA) and conducted by Professional Testing Corp (PTC), the 4-hour, 238-question exam covers a lot of territory.

There is no study guide, but PTC offers a short "Handbook for Candidates" that provides eligibility requirements and general topics one needs to know.

Some questions get into arcane and picayune detail, and some test your reading skills, but most questions deal with issues that IRB Administrators confront every day.

"CIP"

If you pass, you earn the right to add the initials "CIP" (Certified IRB Professional) after your name for the next three years. You also receive a certificate.

This certification process should help promote professional recognition for the legions of dedicated, hardworking IRB Administrators. Now if we can just work on commensurate salaries . . .

A copy of the Handbook and information on future exams is on the PTC web site at http://www.ptcny.com/.Δ

Darcy Mallon, Chris Byrne, and Terry Reser provided information for this article.

Three members of the Human Subjects Working Group passed: Darcy Mallon, Chris Byrne, and Terry Reser.

If you pass, you earn the right to add the initials "CIP" (Certified IRB Professional) after your name for the next three years.

Human subjects protection Web sites

Association of American Medical Colleges—Research Compliance Resources
The site's focus is research with human subjects.
http://www.aamc.org/research/dbr/compliance/startcom.htm

National Human Research Protections Advisory Committee
http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm

Professional Testing Association (This vendor works with ARENA/PRIM&R.)
http://www.ptcny.com

CDC, Protecting Human Research Subjects, IRB Guidebook (NIH, OPRR)
http://www.cdc.gov/od/ads/irbguide.htm

Protecting Human Subjects

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

DOE Human Subjects Research Program Manager
Dr. Susan L. Rose

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This newsletter is available at no cost to anyone interested or involved in human subjects research at DOE. Please send name and complete address (printed or typed) to the address below. Please indicate whether information is to
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Fax (301) 903-8521

Meetings

HEALTH, LAW, AND HUMAN RIGHTS
September 28–October 1, 2001
Philadelphia, Pennsylvania • Sheraton Society Hill Hotel
The health and human rights movement has become a dynamic force in international public health. This three-day conference will use plenary sessions, case studies, and small, interactive workshops to examine key questions about the movement and its conceptual foundations. It is designed to bring together lawyers working in the fields of human rights and public health, physicians, public health officials, health advocates, social scientists studying the role of law in society, epidemiologists, and behavioral scientists in public health. The conference is sponsored by the American Society for Law, Medicine and Ethics (ASLME), the Beasley School of Law of Temple University, the University of Connecticut Health Sciences Center, and Georgetown University Law Center, in cooperation with the Francois-Xavier Bagnoud Center for Health and Human Rights at the Harvard School of Public Health.
Contact: Sarah Quilty, ASLME Conference Director, by phone: 617-262-4990; fax: 617-437-7596; or e-mail at: squilty@aslme.org

PRIM&R CERTIFICATION EXAM FOR IRB PROFESSIONALS
October 20, 2001
The registration deadline for the October 20 exam is September 1. The exam is offered in various locations. *For testing centers, visit the Professional Testing Corporation Web site: http://www.ptcny.com/.*
For more information about this and other events, visit the PRIM&R Web site: http://www.primr.org/conferences.html

AMERICAN SOCIETY FOR BIOETHICS AND HUMANITIES
October 24–28, 2001
Nashville, Tennessee • Renaissance Nashville Hotel
Contact: *http://www.asbh.org*

ARENA 2001 IRB MEETING
December 2, 2001
Boston, Massachusetts • Sheraton Boston Hotel
Contact: http://www.primr.org/conferences.html

PRIM&R 2001 IRB CONFERENCE
December 3–4, 2001
Boston, Massachusetts • Sheraton Boston Hotel
Contact: http://www.primr.org/conferences.html

DOE HUMAN SUBJECTS PROGRAM/INTERAGENCY MEETING
April 2002
Location & contact information will be announced later.
The focus of this meeting will be unaffiliated/community members.
Sponsored by the U.S. Department of Energy
Contact: http://www.science.doe.gov/ober/humsubj/

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