PROTECTING HUMAN SUBJECTS

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Is anonymization a real possibility?

Computer scientist Paul Ohm says reidentification of data is relatively easy

Paul Ohm

We can no longer assume that if we try hard enough data can be anonymized so that privacy is assured, Paul Ohm told DOE's Human Subjects Working Group during its San Diego workshop.

"Until a decade ago, many people thought anonymization was a one-stop shop for protecting privacy, something that would be easy to accomplish with a few basic data changes," he said. "This would allow researchers to freely share information with the assurance of confidentiality. It seemed so easy and powerful, we all came to rely on it."

No longer. He says the word *anonymize* should be abolished. While it should mean, "try to achieve anonymity," instead it has been used to mean, "achieve anonymity." *Deidentify* might be a better word, he said, but even that might also tend to confuse the accomplishment of privacy with the attempt to accomplish privacy.

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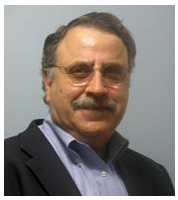
Should informed consent forms be abolished as a hinderance?

In these two summaries of a debate at the last PRIM&R meeting, Leonard Glantz and Jerry Menikoff debate the proposition that informed consent forms are a hindrance and should be abolished. Glantz, an attorney and professor, argued for abolishing them; Menikoff, director of OHRP, said the forms are a useful tool that should be improved.

Abolish them



Leonard Glantz

Obtaining informed consent from subjects is an essential condition for performing ethical research, but there is a distinction between the consent process and the forms.

The complaint about forms is that they are too long, too complicated, almost nobody likes them, and they are not truly useful to potential subjects. Despite widespread efforts to improve them, most research professionals agree the problems continue.

Is it time to consider a new approach.

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No, keep them

Jerry Menikoff

Are there problems with consent forms? Absolutely. There are two approaches to thinking about these problems.

One is to say that the nature of the information you're trying to convey is such that forms have no useful role. It is complicated information and what is needed is a discussion process to help people understand.

In my book, *What the Doctor Didn't Say: The Hidden Truth About Medical Research*, I write about two prominent bioethicists who said forms are largely irrelevant. They said it is the integrity of the investigator that

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Abolish consent forms

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We have spent 35 years trying to make them work and they don't. They've gotten longer and more complicated, and I don't think they actually matter. This is because the forms are not for the people who sign them; they are for the people who write them.

The sad truth is that we don't actually do informed consent. We do informed consent forms. We focus on forms because bureaucrats love forms. If they see a signed form, they're happy.

Documentation is not ethics

But the documentation doesn't tell you anything about what people know. Documentation has nothing to do with the ethics of explaining to potential subjects the implications of their choice.

Look at the problems we've had with some research. The problems with Tuskegee or Guatemala weren't related to forms, they resulted from the kind of research being done.

The forms don't educate. They are supposed to document that a process has occurred, but they don't do that. The system encourages researchers merely to get a signature so that the research can proceed.

The alternative to forms is to think of the process as an educational discussion intended to help people understand the implications of their choices. The forms can distract from the discussion.

Abandoning forms would mean we would have to train investigators to talk to people. If documentation is needed, we can digitally record the conversation. This would allow us to focus on the person. That is not what forms do. They merely allow us to escape from having a real discussion.

Proponents of the forms argue that they are needed and can be improved, but if that is true, why haven't they been improved? We've been trying for 35 years.

A full and honest talk

I agree that there are useful things that can be put into writing, but that is different than making sure people understand what they are getting into. For too long we have had the attitude that we're doing a good job with the consent process and that if the potential subject doesn't understand, it's because they can't understand. No, it's more likely that if they don't understand, it's because nobody has sat down with them for a full and honest talk about what they're getting into.

I think that the most productive way to begin the consent process is with a face-to-face conversation that begins, "I'm here asking you for a favor." It should continue with, "This research is for me and for science, not for you."

It's time to think about the alternative to forms largely because when the primary concern is documentation, we are not focusing on the real issue, which is the question of whether we should be doing this particular study or not and whether this person should become a research subject or not.Δ

Keep consent forms

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ultimately protects the subject, not the form. So they take the position that getting consent is a process involving not just the form but also the discussion about what will happen if a person participates in the study.

No idyllic understanding

The problem is that evidence out there thus far indicates that moving away from forms and toward discussion processes doesn't improve understanding all that much. So if you think getting rid of forms is going to get us to an idyllic understanding, there is not a lot of evidence that this is going to happen.

The other approach is to say that consent forms have lots of problems, including that they're written badly and are too long. But these are manageable problems that can be corrected.

In those problem studies that make headlines, the issue is usually that specific information about risk was not conveyed. That information wasn't conveyed in discussion or in forms, so discussion processes alone are ineffective if we're not giving the information that is needed.

The advantage of forms used in conjunction with a discussion is that a form can clearly and concisely spell out the information a person should know and it can be written in a way that people can understand. The form documents that this is key informa-

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Keep consent forms

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tion we think a person needs to know before participating in a study.

Language matters here. If the form actually says something useful, it is a good starting point.

For example, do consent forms tell people that they can often get the same treatment from a doctor outside the study? People often enroll in a trial hoping to get a new treatment. But it's often the case that the study's purpose is to examine a drug's off-label use, which means nothing is preventing doctors not involved in the study from providing it.

If we want better forms, this is one of the things we could say in a box on the front page of the consent form: you have only a 50% chance of getting the drug in this study, and your own doctor can give it to you anyway.

Some colleagues and I at the National Institutes of Health did a study in which we asked people in hospital waiting rooms to read the provisions of a fake study and make a guess about the likelihood of their being benefitted by participating in the study.

We did this because the therapeutic misconception, especially in phase one oncology studies, is that research subjects tend to mistakenly think they will be benefitted by participating. We may unknowingly encourage this by including ambiguous language in consent forms, language such as "you may or may not benefit" or "we're not sure."

Diminish unrealistic expectations

We wanted to know if clear statements in a consent form would diminish this unrealistic expectation.

When we told them in the form that their likelihood of benefiting is near zero, they reported back that they would not expect any benefit, which suggests that clarity can at least minimize the misconception.

I am not belittling the need for a conversation between investigators and potential subjects, but I do think the written word provides a tangible way for people to see specifically the information they need to make a good decision. The form is also something they can take with them for later reference.

It is not time to abandon consent forms. They can be an efficient, clear, and useful way to begin the conversation.Δ

Research ethics publication

The evolution of consent forms—A quarter century of research

Authors Ilene Albala, Margaret Doyle, and Paul S. Appelbaum have compiled a history of changes in informed consent forms by examining 215 of the forms, discovering two trends.

Their article, "The Evolution of Consent Forms for Research: A Quarter Century of Changes," is in *IRB: Ethics & Human Research* vol. 32, 7/11/2010.

They say that institutional review boards (IRBs) and researchers have struggled to ensure that subjects receive sufficient information to make knowledgeable decisions about study participation.

But the quality of the consent forms has rarely been evaluated. One trend they found was greater consistency in the description of risks, and the second was an increase in the length of consent forms.

However, despite data indicating that length and comprehension are inversely related, length of consent forms increased linearly.

They say the findings demonstrate the dilemma in attempting to provide information on consent forms that is simultaneously accurate and concise.

See:
http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=4673&utm_source=constantcontact&utm_medium=email&utm_campaign=mktg20110308.

Following up on results of San Diego meeting

Community member workshop ideas

Elizabeth White

Susan Rose

Among the ideas generated by the San Diego workshop "Enhancing Contributions of Community IRB Members," was an idea for IRBs to join with others in their region to hold meetings where community members could be recognized. The meetings would be an opportunity to share existing resources and also to provide additional forums for community members nationwide to interact, to exchange ideas and experiences, and to learn.

Elizabeth White, Manager of DOE's Human Subjects Protection Program, and **Susan Rose**, the University of Southern California Executive Director for the Office of the Protection of Research Subjects, are working with others on implementing this idea and some others.

The purpose of their workshop, sponsored by DOE and the USC, was to brainstorm ideas about how to engage community members in the IRB's work and enhance their contribution to the endeavor.

Teleconference seminars

As a follow-on to the workshop, USC and DOE have initiated a series of biannual 1-hour teleconference seminars, to be led by Community IRB members **Argelis Ortiz** of the USC IRB and **Bill Nebo** of the DOE Lawrence Livermore National Laboratory IRB.

The purpose of these community member seminars is to share information on topics of interest, become a national voice, and provide a platform for community member communication. Each will feature at least one presentation from an expert in the field of human subjects protection.

The first such teleconference seminar was held on June 22 featuring a presentation by **Paula Knudson** of the University of Texas Health Science Center on Community Consultation for FDA Emergency Research.

Webinar

Additionally, PRIM&R offered a webinar on "Community IRB Members: Supporting Their Involvement to Enhance Research." It was held on July 12th. Information about other programs can be found at: **http://www.primr.org/Conferences.aspx?id=56**.

During the webinar, participants heard from an IRB chair, a community member, and a federal representative. Their topics included: the roles of the community member and the IRB, the experiences of one community member, and some strategies suggested by participants of a recent workshop to enhance community member participation as well as existing resources available to community IRB members.

Susan Rose also agreed at the December 2010 workshop to conduct a survey designed to yield, among other things, insight about the best use of resources for community members. The survey asked about ways to best utilize the skills and knowledge of community members and sought ways to encourage their active involvement in the process of studying proposed research.

Rose's survey has been completed. The results will be made available to IRBs and community members when they have been compiled and a report has been written. The USC survey results included the following :

90% of IRB community members believe that more training is needed for community members.

88% said they were motivated to serve on the IRB because of their interest in research.

76% said they were interesting in getting in touch with community members at other institutions.

One of the issues discussed at the workshop was what to look for when IRBs want to add community members to their panels. **William Nebo**, a theologian and community member for the Lawrence Livermore National Laboratory's IRB, describes his view of the qualities of an ideal community member in the article on page 20.Δ

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What regulatory changes are needed

Ezekiel Emanuel asks for ideas about where we should go from here, given that they should be practically possible, politically realistic, and likely to have good effect.

Given the criticism of and inconsistencies in regulations related to human subject research, what changes are needed and which are most important?

Ezekiel Emanuel, Special Advisor for Health Policy to the Director of the U.S. Office of Management and Budget, outlined both the criticisms and the inconsistencies of regulations and has asked the human subjects protection community for ideas about "where we should go from here."

Ezekiel Emanuel

Emanuel discussed the issue at the last PRIM&R meeting in San Diego.

Meeting the test

The problems endure, he said, because few suggestions for change have met the tests that they be practically possible, politically realistic, and likely to have good effect.

"I have been thinking hard about this," he said, "and I would like to hear what the research protection community thinks would improve the system."

The list of criticism is long, he suggested, and there is a sense that the frequency and vehemence appear to be growing over time.

"I'm concerned that there is a de-legitimization of regulations that may lead to and may increase the neglect or conscious avoidance of the research regulations and protections of human subjects," he said.

> *I'm concerned that there is a de-legitimization of regulations that may lead to and may increase the neglect or conscious avoidance of the research regulations and protections of human subjects.*

Nine areas of criticism

There are nine main areas of criticism, he said, the first being the scope of regulations. For example, regulations apply to federally funded research or those seeking FDA approval. "While many institutions apply federal protections to all research conducted in their institution, not all do, and neither is it required by regulation or statute. And as you know, there has been a movement not to apply them because of their perceived onerousness."

Not all federal agencies funding, conducting, or reviewing research have signed onto the Common Rule, which means that some human subjects research is not covered by federal protections even though "many august bodies . . . have called for extending Common Rule protections to all human subjects research conducted in the U.S.," he said.

"So one question is, is this necessary and feasible?" To extend the Common Rule would require legislation, which is a difficult endeavor, and many people wonder whether it would even matter.

Another criticism is repetitive IRB reviews. "The Common Rule requires that each institution engaged in a multicenter research study obtain IRB approval of the study. In multicenter studies, scores of IRBs might review the same protocol."

The process can take months or even more than a year for large studies, he said, and there are data suggesting that "multiple reviews lead to minor changes in informed consent documents but not necessarily greater protection for research participants."

The argument on the flip side is that local IRB review allows for local input on important local factors. So, would the streamlining of multicenter study reviews jeopardize important protections provided by local review?

Annual reviews needed?

Another issue, Emanuel said, is that studies reviewed by a full IRB usually require annual review by a full IRB. Does the annual review contribute to human subjects protections if subjects are only being monitored—without any additional experimental interventions—or when the research is at a point where the data are being analyzed and written up?

Critics also say there is inconsistent application of exempt and expedited review. Some survey or social science research is deemed expedited by some IRBs, whereas other IRBs require a full IRB review of the same types of research.

"It has been suggested that minimal risk research with adults be exempt from IRB review," Emanuel said, "and they make an impassioned argument that

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Usage of stored nonidentifiable biological samples and existing medical records seems to be exempt from IRB review. So why does so much research done with stored biological samples receive full IRB review?

Ezekiel Emanuel: Where do we go from here?

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it would save money without compromising safety. It's a radical proposal and it's an interesting question, whether it's the right way to go or a step too far."

So, can minimal risk research be safely exempted from IRB review? The last update of the list of procedures that can be used in expeditable studies was over a decade ago and IRBs have "widely differing interpretations of what constitutes minimal risk research," he said.

Consent documents do not necessarily disclose information that is relevant.

Knotty problem

Another knotty problem stems from uncertainty about research requiring review. For example, does research with stored biological samples or medical records require IRB review? "IRB review does not add to protections since there are no physical or psychological risks from such research. Or are there?"

Also, usage of stored nonidentifiable biological samples and existing medical records seems to be exempt from IRB review. So why does so much research done with stored biological samples receive full IRB review? "Does it provide useful protections for people, human subjects?" he asked.

"One of things we might say about storage samples," he said, "is that while the risks are not physical, there are risks of disclosure of data on an identifiable individual. The main risks from research with stored biological samples are informational risks—the inappropriate and unauthorized disclosure of data on an identifiable individual. Further, are IRBs constituted to have the knowledge, skills, and competency to implement the best protections from information risks? And is there a better way than IRB review to protect human subjects from information risks?

Is it OK not to understand?

"And then there is the informed consent mess," Emanuel said. "There is an overwhelming amount of data indicating that many subjects do not understand the studies they are enrolled in. The question is, is that all right? Many of us have signed up for things we didn't fully understand, and we were perfectly content with that.

In addition, informed consent documents are often written at too high a reading level, often written by researchers who have no skill in writing clear English. The documents have also grown more and more lengthy over the years and do not necessarily disclose information that is relevant to making an informed decision about participation in research.

Inconsistent federal guidelines also continue to be troublesome. "Different federal agencies provide different guidance on how to interpret and implement the federal research regulations, which have differences.

Different definitions of adverse events

"For example, different agencies have different definitions for adverse events and different requirements for reporting adverse events. Similarly, FDA and HHS have different exemptions from informed consent requirements, which raises questions.

"But while differences exist, are they really a problem? Does this variation actually impede research? Or, is this variation legitimate because different agencies have different duties—sponsoring research, reviewing research, etc.?

"So, what to do?" he said. "And as you are thinking about what advice to give me, keep two objectives in mind. First, we clearly need to protect people who even consider enrolling in studies, and we must minimize their risks if they do enroll. Simultaneously, we need to allow for the efficient conduct of research and an easy process for getting the protections in place.

"Sometimes these seem contradictory, but I think they can be accomplished simultaneously with revisions that lead to a more efficient review process that also protects."Δ

Eva Mozes Kor: "I am a human being who was treated as subhuman, a disposable human subject. If I died I knew I would be replaced by twins arriving on the next transport."

Remembering the death camp experiments

"I hope what was done to me is never done to another human being. Those of you who do research must make a moral commitment never to violate human rights and dignity."

Eva Mozes Kor

Eva Mozes Kor and her sister Miriam were one of 1500 sets of twins used by Nazi doctor Joseph Mengele for grotesque medical experiments he and his staff conducted at the Auschwitz death camp during the Holocaust.

"I am a human being who was treated as subhuman, a disposable human subject. If I died I knew I would be replaced by twins arriving on the next transport," Kor said during a presentation at the San Diego PRIM&R meeting.

Cautionary tale

The research Mengele conducted on death camp prisoners was the worst form of using human beings in medical studies, Kor said, and it is an important cautionary tale for scientists today.

"I remember the injections, the tests, the dead bodies, and the smell of human flesh."

In early 1944 Kor was 10 years old when her family was rounded up in their village near Transylvania, Romania. They were loaded into a cattle car and taken to Auschwitz where she and Miriam were kept alive only because Mengele believed that twins would be the best subjects for his genetic experiments. She and Miriam never again saw their mother, father, or their two older sisters.

"There were 13 sets of twin girls on that transport, from 2 to 16 years old. They marched us to a huge building and made us sit naked on benches. They gave us short haircuts and gave us our clothes with a huge red cross painted on the back identifying us as human subjects. Then they lined us up for registration and tatooing," she said.

"I remember the injections, the tests, the dead bodies, and the smell of human flesh. The first night, when I went to the latrine, on the floor were the scattered corpses of three children.

"In the barracks all the children huddled in filthy bunks crawling with lice and rats, starving for food, for human kindness, for our mothers and fathers.

"Three times a week we were placed naked in a room where they measured every inch of our bodies. That part of it wasn't dangerous, but it was demeaning. We were reduced to a lower form of existence, just a mass of cells, and our lives depended on being cooperative. Our childhood was gone.

"Three times a week we were also taken to what I called the blood lab. They took blood samples and gave me five injections," she said.

"After one of the injections I became ill with a high fever, but I tried to hide it because the rumor was that anyone taken to hospital never came back. But I got worse and they put me in the hospital. People there looked more dead than alive.

"I remember Mengele coming to my bed, laughing sarcastically. He said, it's too bad, she probably has just two weeks to live," she said.

Expected to die

Kor hovered between life and death for the next two weeks. She was not treated, not given medicine, because when prisoners were taken to the hospital they were expected to die.

"But I refused to die."

For months Kor stole potatoes so she and her sister would live, and on January 27, 1945, "four days before my 11th birthday," Auschwitz was liberated by allied troops.

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Kor said the scientific community must remember that research is done for the benefit of people, not purely for science.

Remembering the death camp experiments

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"I hope what was done to me is never done to another human being. Those of you who do research must remember the Nurenburg Laws and make a moral commitment never to violate human rights and dignity."

Research is for people

Kor said the scientific community must remember that research is done for the benefit of people, not purely for science.

After she was liberated from the camp, Kor and her sister lived in refugee camps, then returned to Romania, and eventually emigrated to Israel. She met an American tourist there, married, and moved to Indiana. Her sister stayed in Israel and died there several years later from a combination of kidney failure and bladder cancer that may have been the result of Mengele's injections.

"I hope that my message is one of hope, of healing, of forgiveness, of peace," she said. "Always remember, never forget that you are dealing with human beings and that when you cross the line by forgetting that, you're heading in the direction Mengele went. We cannot do that again."Δ

Research ethics publication

Viewing research participation as a moral obligation: In whose interests?

An article in the *Hastings Center Report* (March–April 2011) asks how we should think about participation in health-related research. It's not just a praiseworthy option, some say. Over the past few years, a growing number of people have called for reconceptualizing participation in health research as a moral obligation.

Philosopher **John Harris**, for example, argues that seriously debilitating diseases give rise to important needs, and since medical research is necessary to relieve those needs in many circumstances, people are morally obligated for reasons of justice, beneficence, and self-improvement "because we all benefit significantly from modern medicine, we are all required to do our part in advancing the state of medical knowledge."

The article is a critique of the position taken by **Stuart Rennie**, a philosopher at UNC-Chapel Hill, who argues the idea that research participation is valuable but not obligatory.

Recasting research participation as obligatory is therefore not a minor philosophical quibble about the moral status of an action. Viewing research participation in this way would constitute an ethical paradigm shift with global ramifications, analogous to other efforts to promote particular religious or secular moral views around the world.

See:
http://www.thehastingscenter.org/Publications/HCR/Detail.aspx?id=5166

Public health emergencies will require rapid research responses to identify who is at risk for consequences, whether it is infectious disease or environmental exposure.

NIH Director: Ethical issues in new technologies

Francis Collins on anonymization, genetic research, health reform, and IRB responsibilities

Francis Collins

The human subjects research community must resolve a variety of ethical difficulties in biomedical research stemming both from new technologies and from long-simmering issues that have not been adequately addressed, according to Francis Collins, Director of the National Institutes of Health (NIH).

A physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the Human Genome Project, Collins addressed problems with sharing genomic information, confidentiality, conflicts of interest, genetic nondiscrimination, and streamlined approaches to ethical review for research during health emergencies.

Collins, who was keynote speaker at PRIM&R's Advancing Ethical Research Conference in San Diego, said that when the oil spill in the Gulf of Mexico occurred in 2010, there was no mechanism for multiple investigators to get ethical reviews accomplished quickly enough to do needed research.

Public health emergencies

"Public health emergencies will require rapid research responses to identify who is at risk for consequences, whether it is infectious disease or environmental exposure. Without a plan in place, that response can take a very long time," he said. "But we want to be able to collect data as quickly as possible after an exposure."

Now, he said, mechanisms are in place to establish public health emergency research review boards to provide a streamlined approach by "using established protocols that are already written and reviewed so they can quickly be put into place."

Collins said genomics has resulted in the ability to survey the entire human genome and find risks associated with common disease. And whereas the mapping of the first human genome cost about $400 million, in the next three or four years the cost will be down to about $1000.

Cures for genetic diseases

This technology is a boon to researchers and to those hoping that their studies will lead to cures for various genetic diseases. But the research itself has created unresolved questions. "When complete genome sequencing becomes the norm, how do we share information among researchers and at the same time honor confidentiality for participants? What do we do about returning information to people when we learn something about them during the course of a study, when identifying those people compromises confidentiality?"

When complete genome sequencing becomes the norm, how do we share information among researchers and honor confidentiality for participants?

If a person has given permission for tissue to be used in a study about diabetes, he said, what do we do when we get information about other conditions such as cancer? "What is the researcher's obligation to share that information, and how do you talk about it in the original consent?"

Human tissue and confidentiality

When studies use human tissue obtained with the promise of confidentiality, is it possible to prevent the identification of the donor, and if identification is prevented, what should researchers do when they get information that the donor may need to know?

"A small amount of information about a variation in my DNA would make it possible to match that up with a sample that is identifiable and thereby make a connection that I as the donor might not approve.

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The research community must still develop ways to avoid conflicts of interest that cast a cloud over the whole enterprise.

New research challenges

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How do we deal with that?" he asked. "When we pool together large data sets, it is possible to determine whether an individual is in that pool by making a comparison to a small amount of their data in another source."

One way these questions may move toward being resolved, he said, is by establishing data access committees and requiring approval for investigators to gain access to data.

Health care reform

Collins said the 2010 health care reform legislation went a long way toward solving ethical issues related to providing justice and fairness. "People can now get preventive services, including smoking cessation. There can be no lifetime limits on coverage, no denying of claims without appeal, and no denying of coverage for children with genetic conditions."

Similarly, he said, the Genetic Information Nondiscrimination Act of 2008 better allows science to work for the benefit of health care by prohibiting the use of genetic information to harm people in ways such as health insurance or employment discrimination.

Reducing threshhold for conflicts

On the other hand, he said, the research community must still develop ways to avoid conflicts of interest "that cast a cloud over the whole enterprise." Although real conflicts may not be common, he said, "we need to be sure we have a review system" that ensures complete transparency.

"We at NIH have proposed rules about this, and the final recommendations will be coming soon," he said. "They will reduce the minimum threshold for reporting from $10,000 to $5,000, and we will be asking institutions to review their staff's interests and to devise a plan for managing conflicts and for training.

"This might be seen by some investigators and institutions as burdensome, but the credibility of the scientific community is at risk if we don't get our house in order," he said.

$100,000 in royalties?

Collins said the acceptability of being able to patent DNA sequences is also unresolved. "For the last 20 years the U.S. Patent and Trademark Office has been issuing patents on human genes. As a result of a lawsuit, a U.S. District Judge ruled that DNA sequences in their natural state ought not be patentable material. The case is now before an appellate court that has not yet ruled.

The question has serious ethical implications, he said, because "in the era of the $1000 genome we could get to the point that we would be required to pay royalties on patented genes and could end up spending $100,000 in royalties" for a $1000 genetic scan. Among other consequences, the added cost would inhibit research and stall the search for new treatments.

"It seems to me that our technology is advancing at a terrific pace, and we should celebrate that, but we must keep in mind that our goal is to benefit people suffering from very real diseases. It is them for whom we offer hope, but hope couched in reality, and this has to be put into a framework of ethical research behaviors," Collins said.Δ

Bioethics blogs

Bioethics blog, written by the editors of The American Journal of Bioethics
http://blog.bioethics.net/

The Hastings Center bioethics forum
http://www.thehastingscenter.org/BioethicsForum/Default.aspx

Women's bioethics project
http://womensbioethics.blogspot.com/

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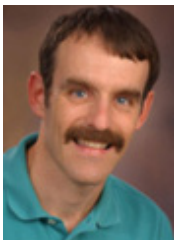
Were potential subjects told they could get the same information from health care providers outside the research study? There is "room for improvement."

Examining informed consent documents

Concern about the quality of information provided about alternatives to research

Discussion of alternatives to research participation is a key legal and ethical requirement for clinical research informed consent, but little is known about how investigators communicate this information.



David Resnik

A study by David Resnik and his colleagues found some concern about the quality of information about alternatives to research in consent documents.

Resnik is a bioethicist and IRB Chair for the National Institute for Environmental Health Sciences, National Institutes of Health.

"We found that only 17.4% of consent forms for oncology randomized controlled trials (RCTs) in which all of the treatments being investigated were available to the subjects without participating in the study actually informed subjects that they could receive these treatments off-study," Resnik said during a PRIM&R panel discussion.

Quality of information

"The aim of our study was to evaluate the quality of information about alternatives contained in informed consent documents, Resnik said.

The question was, were potential subjects told they could get the same information from health care providers outside the research study?

They acquired 104 consent forms from a random sample of oncology RCTs in which treatment was available off-study.

Resnik said they found room for improvement.

"One reason why disclosure of alternatives in consent forms is often deficient is that these documents already contain so much information that there is not enough space to include a more lengthy discussion of alternatives," he said.

"While we recognize the space constraints inherent in consent forms, we think there should be enough room for a better discussion of alternatives than found in many of the documents we examined. There are ways of economizing space in consent forms other than omitting important information that subjects need to decide whether to participate."

Resnik said they found that local forms are better than model forms.

Different standards

"One possible explanation for this result is that IRBs may appeal to different (i.e., higher) standards for informed consent than research committees that develop informed consent documents for multisite clinical trials.

"Another possible explanation is that IRBs may have access to information about the local availability of alternatives that committees that draft consent forms lack."

Their finding may have implications for the debate concerning local IRB review, since it suggests that local IRBs do better at a particular task than cooperative groups, which are similar in some ways to multicenter IRBs.Δ

Their finding may have implications for the debate concerning local IRB review, since it suggests that local IRBs do better at a particular task than cooperative groups, which are similar in some ways to multicenter IRBs.

It is both imperative that we conduct research with adults who lack consent capacity and possible to do so in an ethically sound way.

These cases are the prototype for why IRB review matters.

Research with cognitively impaired subjects

Research using people who are cognitively impaired as subjects can be ethically appropriate, but IRBs have special responsibilities to ensure their protection.

Nancy Dubler

David Strauss

"When the protections ordinarily provided by a subject's consent are lacking, an IRB is responsible for crafting additional safeguards," said Nancy Neveloff Dubler, professor Emerita, Albert Einstein College of Medicine, and David H. Strauss, Deputy Director for Research, New York State Psychiatric Institute, and Vice Chair for Research Administration, Ethics and Policy, Columbia University Department of Psychiatry.

Flaws in informed consent

Dubler said that finding appropriate ways to conduct research with people who are unable to protect themselves or give consent is especially difficult given the flaws in the informed consent process even for people who are not impaired.

"So these cases are the prototype for why IRB review matters," Strauss added.

They said it is both "imperative that we conduct research with adults who lack consent capacity" and possible to do so in an ethically sound way.

Just because the proxy is legally authorized doesn't necessarily mean the proxy is ethically appropriate.

"We are dealing with disorders that include the most common and devastating," Strauss said. "There is a pressing need to address the needs of those with the most ravaging disorders. The notion that we are unable to conduct needed research because of the failure to conduct ethical review would be deeply troubling."

In general, they said, calling upon a "legally authorized representative" (LAR) to make a consent decision does not alone provide the necessary protections. The extent to which a surrogate or proxy provides protection varies widely depending upon the situation and upon the surrogate.

"Everything you owe to the research subject you owe to the LAR," Dubler said. "The problem is that we often ask them to make a decision as if that alone fulfills our obligation. It doesn't."

"Just because the proxy is legally authorized doesn't necessarily mean the proxy is ethically appropriate," Strauss said.

In these cases more than almost anywhere, Strauss said, the interests of science and the interests of the subject are not the same. The entire research protection industry rests on the idea that we need to intervene because the researcher wears two hats, one serving the needs of the subject and the other serving science.

"The history of research with incompetent and institutionalized individuals is such that all too often the needs of science were placed ahead of the needs of the individual," Strauss said. "In subtle and not so subtle ways we still have problems of that sort."

"Barriers to understanding"

Dubler said it is never enough to rely upon informed consent forms. "I think they are barriers to understanding. The form primarily serves the purposes of the institutions that sponsor, or they think it does. I think they're wrong." They said the IRB's task is to raise the question, is it reasonable to ask people to participate in this study? How will this affect the subject's life?

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IRBs come in all varieties, some very courageous, others not so much. What one thinks is sufficient protection another IRB may not. It takes courage to say to your principal investigator, more is needed.

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When free and informed consent from the subject is not possible, who "stands in the shoes of the subject?" they asked.

"This is a hard task," Dubler said. "IRBs come in all varieties, some very courageous, others not so much. What one thinks is sufficient protection, another IRB may not. It takes courage to say to your principal investigator, more is needed."

Research with people who have Alzheimer's disease is especially important, they said, because one in eight people 65 and older have it and there is no treatment. More research is needed because "we need to offer more than palliative care," Strauss said.

Similarly, treatment for schizophrenia is palliative rather than curative because it is probably the most poorly understood of the common cognitive disorders. About 2.4 million American adults have schizophrenia, and it first appears when people are young. "So it devastates the brain and personality and then stays with them for their entire adult life, having a massive impact on them and everyone around them," Strauss said.

Regulations are not a lot of help, they said. The Common Rule calls for "additional safeguards" when participants are likely to be "vulnerable to coercion or undue influence ... such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons." There is no such subpart, Strauss said, "for those unable to consent for themselves. No regulatory language to accommodate them."

How much assessment?

They said it is important that IRBs provide some assessment of consent capacity for impaired people "to be sure the subject understands the consent they've made," Dubler said. "Simply passing the form across the table and receiving a signature does not count as consent. How much assessment is required depends upon degree of risk to the subject."

One of the trickiest things to do when dealing with impaired human subjects is to define an upper level of risk.

"We know that the IRB is offered large latitude in determining risk acceptability," Strauss said, but in these cases the upper limits of risk can best be established by involving reviewers who are knowledgeable, by determining when a special subject advocate is needed, and by clearly defining the advocate's role.

Protecting vulnerable populations becomes especially difficult if it involves a double blind study in which half the people get a drug and half get a placebo. If their condition makes them aggressive and violent, it is essential, Strauss said, to ensure that "no one stays on a protocol to the point of harm. The IRB needs to be very aggressive in addressing the justification and value of the research and to establish clear criteria for dropping out of the study."

Study less-burdened groups first

They said availability, ease of recruitment, and study cost should never alone justify the inclusion of individuals who lack consent capacity. "Instead, IRBs should consider whether the scientific questions are answered by research with people who do have the capacity to consent. In general, they said, study "less burdened" groups first.

IRBs should also take care to define the capacity to consent, which is always protocol specific. "Consent capacity for what?" Strauss said. "The usual requirement is, do you have the ability to understand the design, risks, benefits, alternatives, and impact on you, and to communicate your choice." In the case of impaired subjects, those requirements have to be transferred to an LAR or be met in some other way that is best understood as occurring along a continuum. It is task specific, they said, and will vary by the risk of the protocol and its complexity.

Dubler and Strauss said that research involving the kinds of issues they discussed are where IRBs can "prove their mettle by finding ways to stand in the shoes of impaired subjects.

"The refusal of the IRB to so act abandons these patients to their illness with no possibility of improvement," Dubler said.Δ

Even when we think all identification has been removed, little bits of identifiable data have usually been left behind. It is not difficult to tease out individual people from the larger group.

Is anonymization a real possibility?

(Continued from page 1)

An associate professor of law and telecommunications at the University of Colorado Law School, Ohm's research focuses on information privacy, computer crime law, and intellectual property—bridging the disciplines of law and computer science.

Chipping away at trust

Computer scientists a decade ago began to chip away at the trust in anonymization, he said. "Lots of people got funding to analyze reidentification techniques, and they soon realized that it is surprisingly easy to restore identity to databases that were supposed to have been anonymized."

The findings are an indication, he said, of "how really different we are from one another. Even when we think all identification has been removed, little bits of identifiable data have usually been left behind."

With powerful enough computers, he said, it is not difficult to tease out individual people from the larger group.

Governor's data revealed

This was graphically demonstrated in the mid 1990s when Massachusetts governor William Weld released supposedly anonymized data about all state employees, which was intended to help researchers who needed the data for various studies.

A Boston computer scientist, Latanya Sweeney, used the information to identify not just Governor Weld's identity, she also found hospital records specifically identifying conditions for which he was treated and the records of the treatment.

"She packaged up the information and sent it to him," Ohm said.

Sweeney had used only three pieces of data, a 5-digit zip code, gender, and a birth date including the year.

"This was surprising at the time because these were types of information being released regularly. People mistakenly thought there was safety in numbers, that they would be anonymous because they would be hidden in a crowd of other people," Ohm said.

Sweeney determined that by using the released "anonymized" data, 87 percent of the people represented were identifiable. "People were surprised to learn there was that much identifying power in just three pieces of information," he said.

Netflix study

Twelve years later the video distributor Netflix released "anonymized" information about the movies its customers were watching. Its business success rested in part on being able to recommend movies to customers based on what they previously watched.

"But their in-house computer scientists had run out of steam. They could use their algorithms to squeeze only so much predictive ability about what people would want to see in the future.

Netflix wanted more, so it released the data—100 million ratings representing more than 480,000 users and 18,000 different movies. Included were four pieces of information: the date of the rating, the movie, the rating on a scale of 1–5, and an anonymized identification.

The company offered a $1 million reward to the first person who could advance the predictive ability by 10 percent beyond what they had been able to do.

"Lots of academic and corporate teams banded together to go to work and this intense burst of work resulted in various new techniques developed to analyze information.

Graduate student

"Two weeks after the release of data, a University of Texas graduate student reported finding a surprising amount of uniqueness in individual users' ratings. Turns out there is very little information needed to be able to pluck an individual user out of that large a database. If I know six movies you've seen, I can find

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Is anonymization a real possibility?

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you in the database 84 percent of the time and can find every other movie you've rated in Netflix."

The result confounded expectations, he said, and with one more piece of data, knowing when you rated the six movies, "I can do even better," he said.

Uncovering patterns in social networks
Other researchers have looked at social networks like Twitter and Facebook, specifically analyzing shape of networks of friends to learn more about the limits of anonymization.

Computer scientists at MIT, for example, studied the pattern of friending on social networks to see if they could find patterns in city neighborhoods.

"I haven't seen the data, and it has not been published, but they claim amazing success about predicting whether someone is gay, and they say they have been able to identify closeted gay people, those who had not yet come out."

Ohm said "we have all been raised to think that information can be separated in such a way that it's OK to have some information be public and other information must be kept private. But it turns out the two different pools of information have more in common than you think, which is the problem because it means they may not be separable."

However, there may be limits to the harm that can be done.

Information releases worsen problem
"In each of the studies I've talked about, a public release of information exacerbated the problem. Researchers involved in human subjects studies are not going to release data to the public.

"This lowers the risk," he said, "but only lowers.

"And I haven't yet given up entirely on anonymization. A scientist in California has developed a new technique, differential privacy, which seems to provide a more robust form of privacy assurance that theoretically won't reveal identity. But it's still expensive and can be used only in limited ways," Ohm said.

The important thing to remember is that the uniqueness of human behavior and the relative uniqueness of human genetics may become more of a problem over time.

"So when a researcher tells you that the protocol will anonymize the data, you should realize that a claim of anonymization is only the beginning of the conversation, not the end," he said. "Find out what they mean by that. How are they doing it and what do they think they are accomplishing."Δ

Research ethics publication

Changing the research landscape

Ann Freeman Cook and **Helena Hoas** write in "Protecting Research Subjects: IRBs in a Changing Research Landscape" that, given the many changes in the research environment since the model for the institutional review board (IRB) was codified in 1981, tensions may arise as IRBs try to fulfill their obligation to protect human subjects while confronted with competing goals to advance science and support the interests of researchers and their institutions.

The report is in *IRB: Ethics & Human Research* 33, no. 2 (2011): 14-19. The study was designed to learn how different types of IRBs carry out their basic functions in overseeing human subjects research and to discover how IRB members perceive their obligations in light of competing goals and the resulting tensions.

Access to the full text of this article requires a subscription to this journal.

See:
http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=5234&terms=ann+freeman+cook+and+%23filename+*.html

Issue No. 22

Research during humanitarian emergencies

"There should be some demonstration required that shows how the data we're gathering is going to produce some benefit for the population from which the data is coming. Doing basic research just to increase knowledge is questionable."

Jon Hubbard

Jon Hubbard has been working in war zones, disaster areas, and various other places troubled by humanitarian emergencies for 20 years and is still grappling with how to do ethical research in such unpredictable and often chaotic conditions.

Hubbard is the director of research and a psychotherapist at the Center for Victims of Torture (CVT) in Minneapolis.

It is that much more difficult for the flood of young investigators who are finding it increasingly manageable to get to trouble spots but do not have the experience to do the work in a way that doesn't worsen problems for people.

Studies should include local populations in the design and in the interpretation of data.

Evaluating effectiveness

Hubbard works to strengthen the capacity of international torture treatment organizations to evaluate the effectiveness of their mental health interventions and consults with researchers exploring the consequences of exposure to torture and other massive trauma in cross-cultural populations.

He has worked with CVT's mental health programs in Guinea, Sierra Leone, Liberia, the Democratic Republic of Congo, and Jordan and has provided training and consultation to independent torture treatment programs in many other countries.

He noted a variety of problems that can arise when working in conflict and disaster zones. For example, data are being collected in situations that are contextually different—politically, socially, religiously—than where they will be analyzed.

"So studies should include local populations in all phases of the research, from design to the interpretation of data. It is hard for somebody outside the situation to look at numbers, responses, and answers and know what meaning is connected to them for the local population," he said.

Unintended consequences of research

Another difficulty is unintended consequences of research. For example, "No matter how well the study is explained, it will create expectations on the part of subjects and communities that they will get something from it.

"In extremely resource-poor places under times of distress, anyone from outside is seen as hope. This means they will pass along things in their answers they believe might get them help. So interpretation can be difficult," Hubbard said.

When researchers study specific war-affected populations, such as child soldiers or survivors of gender-based violence, one of the problems is funds are rarely available to allow the researchers to return and do anything to help the problems they find.

"I think we should be working with a higher standard than merely collecting data in these situations. There should be some demonstration required that shows how the data we're gathering is going to produce some benefit for the population from which the data is coming, like leveraging resources or informing intervention. Doing basic research just to increase knowledge is questionable," he said.

Don't reinforce divisions

Hubbard said investigators should be cautious they don't reinforce existing identities and divisions in communities.

"For example, we should be careful when targeting specific groups like child soldiers because it can highlight and isolate a particular group and consolidate their identity around one part of their experience.

One of the results is that a lot of kids who were never soldiers will say they were because it will get them access to the study's resources. At the same

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"If one side is getting attention and help when the other side isn't, it's an indication that people from the outside care about one side more than the other. So the divisions you might be hoping to heal are instead being reinforced."

Research during humanitarian emergencies

(Continued from page 16)

time other young people who were not soldiers but were severely affected by the war can be overlooked.

It could be more effective to study war-affected adolescents and then examine differences at the analysis and interpretation stage, exploring the various problems represented by the groups," he said.

When working with torture survivors, investigators should remember that they are only one side of the equation in a conflict zone. "Unless someone is working with the other side—combatants, perpetrators—it tends to encourage repetition of the problem. That's because if one side is getting attention and help when the other side isn't, it's an indication that people from the outside care about one side more than the other. So the divisions you might be hoping to heal are instead being reinforced."

How to question victims

IRBs should be mindful, Hubbard said, to scrutinize carefully the questions being asked of people who have been traumatized. In a study of Cambodian youths, kids were asked whether they had turned in their parents or relatives to the Khmer Rouge. "But there was no real purpose for the question other than to gather miscellaneous data. The question itself was likely to worsen whatever trauma already existed. The risk for those kids, with no therapeutic resources available to them, wasn't appropriate.

Scrutinize carefully the questions being asked of traumatized people.

"Investigators must be careful that what they do doesn't undermine or get in the way of other humanitarian processes, and they should be prepared, when they see that happening, to change things in midstream from what they initially set out to do," Hubbard said.

Ten years ago Hubbard rarely encountered other researchers when he was in the field. "That has changed because of easier access to remote areas. Often the lead investigators fly in for a few days, make arrangements with a non-governmental organization (NGO), or a hospital administrator, then fly home leaving behind a few students to gather data or monitor studies," he said.

Young people managing unfamiliar dilemmas

"This means we have a lot of enthusiastic young people stuck trying to manage unfamiliar ethical dilemmas—coercion of clients, bribery, stories of severe trauma with nobody to refer clients to for help, nobody to supervise or advise the students as these dilemmas arise.

"Last week I was consulted by a colleague with concerns about a team of researchers from Europe who were quickly copying data from a local NGO, entering years' worth of client information that they wanted to take home for study. There was no research design, no hypotheses, just an opportunity to get some interesting data to analyze and publish."

Hubbard said some of the increase in disaster and conflict zone research is driven by the desire of funding agencies to get evidence that the work being done with their money is effective. "So they ask the NGO to produce data using control groups and random assignment of clients when the NGO has little or no experience doing research." The intentions are good but there is often little understanding of the skills and resources needed to do this work in any meaningful way.

Informed consent especially difficult

Informed consent is especially difficult in field research because there are often no criteria to determine whether you really have it.

When American IRBs are asked to approve research in situations where there is little understanding of research practices or ethics and people have been traumatized, they should consider going beyond getting informed consent from clients or subjects and to think more broadly about consent by requiring that the organizations and their staff fully understand the study, its benefits and consequences.Δ

Jerry Jacobs: "I have been disturbed at how frequently I've heard researchers say, 'I don't need IRB approval because I'm working overseas, I'm doing international research."

Conducting ethical research in disaster zones

Jerry Jacobs

Researchers gathering data after disasters such as the earthquakes or tsunamis in Haiti, Sri Lanka, and Japan too often think they can leave their codes of ethics in the United States, according to psychologist Jerry Jacobs.

American IRBs have the responsibility to ask questions to determine whether investigators really understand the enormity of what has taken place, that things which might not strike us as doing harm in South Dakota may cause enormous harm elsewhere.

"I have been disturbed at how frequently I've heard researchers say, 'I don't need IRB approval because I'm working overseas, I'm doing international research,'" he said.

Director of the Disaster Mental Health Institute at The University of South Dakota, Jacobs discussed his work at the PRIM&R meeting in San Diego. He was involved in disaster responses after the September 11, 2001, attack on the World Trade Center; the 2001 Gujarat, India earthquake; the 2004 Indian Ocean tsunami; and New Orleans after Hurricane Katrina.

Study group

The American Psychological Association formed a study group to examine ethical considerations in research undertaken during disasters, war, and other complex emergencies.

No cohesive code of conduct has yet emerged from the group's discussions, but some recommendations are emerging.

For example, not only should disaster research be cleared by an investigator's home IRB, he said, it should be cleared by whatever stands as an IRB in the community being studied.

"It might not be called an IRB in Sri Lanka, but there is a local research council. In India there might be a group of elders that needs to give approval, and in Africa a local chief might be the one who determines whether you are allowed to work in his village," he said.

American IRBs have primary responsibility to ensure their researchers have done their homework and are working with the local structure, he said. "They should ask questions to determine whether investigators really understand the enormity of what has taken place, that things which might not strike us as doing harm in South Dakota may cause enormous harm elsewhere."

It might not be called an IRB in Sri Lanka, but there is a local research council. In India there might be a group of elders that needs to give approval.

Social norms, religious beliefs

Too frequently, Jacobs said, researchers fly into a disaster area, rent a car, hire a translator, and start asking questions without any consideration for whether they have understanding of the community's social norms, its religious beliefs, or its language.

"I had a South African researcher tell me that even though he had lived all of his life in the country, he would never try to go into a neighboring township to conduct a study because he would not feel sufficiently familiar with the culture or the language. He said to me, 'what makes you people think you can come into our country and immediately start doing this kind of work?'"

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"I wonder whether it's even possible to get informed consent in the aftermath of a disaster."

Conducting ethical research in disaster zones

(Continued from page 18)

Similarly, investigators should understand that informed consent means different things in different places and circumstances, Jacobs said. "If you're doing research in a place where a non-governmental organization (NGO) is providing food, housing, and other services, people might feel coerced into answering your questions because they fear that refusing to cooperate might mean they will lose the food and housing being provided by the NGO."

Getting in the way

Related to that, investigators should have knowledge of the structure of the humanitarian response being undertaken by NGOs and others. "If you don't, it is very easy to get in the way of the people who are trying to keep people alive.

Further, traumatic stress affects people's ability to think clearly. Just as serious illness affects people's decision-making capacity, so does experiencing a disaster. "I wonder whether it's even possible to get informed consent in the aftermath of a disaster. I wonder if we should instead be doing more observational research, more qualitative research, instead of working directly with people."

Jacobs said some researchers believe it's not a question of whether researchers are doing harm because in one way or another all research does some harm in disaster settings. Instead it's a question of whether the benefits outweigh the harm. Others say we can't afford not to do the research. The key is to do it properly, he said.Δ

News note

Reforming the regulations governing research with human subjects

The U.S. Department of Health and Human Services is contemplating various ways of enhancing the regulations overseeing research on human subjects. Before making changes to the regulations, which have been in place since 1991, the government is seeking the public's comments on the following:

1. Revising the existing risk-based framework to more accurately calibrate the level of review to the level of risk.

2. Using a single Institutional Review Board review for all domestic sites of multi-site studies.

3. Updating the forms and processes used for informed consent.

4. Establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data.

5. Implementing a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all trials to harmonize the complicated array of definitions and reporting requirements, and to make the collection of data more efficient.

6. Extending federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from the Common Rule agencies.

7. Providing uniform guidance on federal regulations.

Comments are due on October 26, 2011. More information can be found at http://www.hhs.gov/ohrp/ and also at http://healthpolicyandreform.nejm.org/?p=14979&query=OF

You will want someone who is not angry, who can see from lots of different perspectives, and who is empathetic to others' positions. Look for someone who doesn't have axes to grind, someone who is not racist, homophobic, or sexist.

How to pick a community member

Find someone who knows the business community, churches, schools, town politics

William Nebo

by William Nebo,
Community Member
Lawrence Livermore National Laboratory

Some principal investigators (PIs) think the least important person on an IRB is the community member.

If asked, these PIs say that what they want on the IRB is someone "who really understands my work." But the code behind that, what they really mean is, they want someone who will let them do what they want.

Because that way of thinking exists in the research community, I am glad we have IRBs that say to that PI, "I know you don't like it, but you still have to do it."

Outside the family

An important part of achieving an effective IRB, one that is best able to ensure the integrity of the research process and to protect human subjects, is finding the right community member. Your IRB needs someone from outside the institutional family who brings a good mix of personal strengths along with the perspective of the wider community.

What follows are several ideas about what to look for in selecting that person.

Look for someone with wide community involvement. It's not going to be especially helpful if you have someone who is involved with their kids' schools but has very little to do with other parts of the community. Find someone who knows the business community, churches, schools, and has an understanding of town politics.

You should seek someone who is mature, and we all know what that means. We have friends whom we love dearly, but we're not going to trust them with judgments about our life or our finances because they don't seem to have the ability to make mature choices.

You need someone who can manage their ego, their anger, and who knows how to keep confidences.

Look for the ability to be diplomatic but with the self-assuredness to still be able to say what they think.

You need someone who can manage their ego, their anger, and who knows how to keep confidences. Look for the ability to be diplomatic but with the self-assuredness to still be able to say what they think.

The person you need should exhibit rational and clear thinking. This doesn't mean an absence of emotional feeling, it means that the ability to think and speak clearly is essential to this task.

Sound judgments

It should be somebody who has sensitivity to the needs of a variety of people, who makes sound judgments, and who speaks up when they have something to say.

Look for someone who can handle scientific data, who isn't necessarily a scientist, but who can objectively sort through complex ideas and information.

You will want someone who is not angry, who can see from lots of different perspectives, and who is empathetic to others' positions.

It is very important that this be someone who can follow discussions about ethics without being consumed by personal biases that unduly predispose them to a position that they get stuck in. So try to avoid people who have strong biases that are likely

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The best community member is able to balance various interests and perspectives, who is not always pro-management or pro-labor or locked into any extreme position.

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to cloud their thinking. These are people, and we all know some of them, who seem to explode when certain topics are being discussed.

Also avoid people who can't keep confidences.

Avoid people who can't handle authority well. Remember, your IRB is an authority and an important quality is understanding the need for appropriately exercised authority.

Look for someone who doesn't have axes to grind, someone who is not racist, homophobic, or sexist.

The best community member is able to balance various interests and perspectives, who is not always pro-management or pro-labor or locked into any extreme position.

So, finally, if you ever find this perfect individual I am describing, make sure you recruit them for your IRB.Δ

Related disaster resources

USC IRB community member information and education
http://www.usc.edu/admin/provost/oprs/training/cm.html

Community IRB member news—Oak Ridge Associated Universities
http://www.orau.gov/communityirb/news.htm

USC community member resource manual
http://www.usc.edu/admin/provost/oprs/private/docs/oprs/brochures/community_member_web.pdf

Yale University Center for Bioethics: IRBs and personal conflicts of interest
http://www.yale.edu/bioethics/irbcase2.htm

Ethics publication

(Mis)Understanding exploitation

A standard concern is that researchers exploit research subjects for the benefit of future patients, especially when participants in clinical trials are drawn from vulnerable social groups and when research takes place in developing countries.

In the feature article of the March–April 2011 issue of *IRB: Ethics & Human Research*, Erik Malmqvist responds to a group of influential authors who have proposed a so-called non-exploitation framework for randomized controlled trials that appears to address these concerns.

This article challenges one basic assumption of that framework: the idea that nonexploitation requires participants to be protected from excessive risks, which are understood to be risks that are not outweighed by the anticipated benefits of the research.

See:

http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=5232

News notes

Criticizing the Belmont Report and recalling Albert Reiss

A discussion of criticisms of the 1978 Belmont Report is in The Hastings Center bioethics forum. The original posting was 0n November 30, 2010, followed by commentary in 2011.

Zachary M. Schrag, of George Mason University, examines Albert Reiss's condemnation of the report as reducing "people" to "subjects" and required procedures—such as risk-benefit analysis—that were inapplicable to research that did not resemble medical experiments.

See: **http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4999**

International Research Panel of the Presidential Commission for the Study of Bioethical Issues releases report

The International Research Panel of the Presidential Commission for the Study of Bioethical Issues has just released its report:

http://bioethics.gov/cms/sites/default/files/IRP-Proceedings%20and%20Recommendations_0.pdf

The panel made 5 major recommendations:

1. Researchers must demonstrate respect for human subjects and their communities, especially through ongoing dialogue between U.S. and international bodies, and by clarifying the U.S. provisions for equivalent protections.

2. Research funders should support ethics training for researchers.

3. Greater efforts are needed to enhance transparency, monitor ongoing research, and hold persons responsible for violations. One way to achieve transparency is to require registration of all greater than minimal risk research.

4. The U.S. should implement a system to compensate subjects for research-related injuries.

5. Harmonization of existing rules merits higher priority than creating new rules.

Deadly South African research and U.S. investigators

A clinical trial in South Africa studying how to treat patients with both HIV and tuberculosis resulted in questions about whether the deaths of 10 participants were justified.

Authors Sean Philpott and Udo Schüklenk said that the study demonstrated that integrated HIV and TB treatment is more effective than sequential treatment. The article is discussed in the September-October, 2011, issue (Vol. 41, No. 5) of The Hastings Center's Bioethics Forum.

The question, they said, is whether obtaining that data justified the 10 or more preventable deaths that occurred among trial participants.

"Even before the study began, years of observational data had shown that the risk of HIV-related death among patients not receiving ART therapy was highest during the first few weeks of TB treatment, calling into question the need to conduct a randomized, controlled trial in which ART was delayed by as long as 11 months for some study participants," Philpott said.

See: **http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4626&amp**

Meetings

Ethical Considerations in Research Collaborations
Sept. 22–23, 2011
Seattle, Washington
For information, http://courses.washington.edu/oriconf

Strengthening the Future of Community-Based Participatory Research
Sept. 27, 2011
Nashville, Tennessee
For information, see http://researchintegrityconferencenashville.org/

Western Michigan University Medical Humanities Conference
Sept. 28, 2011
Kalamazoo, Michigan
For information, see http://www.wmich.edu/medicalhumanities/files/MedHum_CfA.pdf

American Society for Bioethics and Humanities 13th Annual Meeting
Oct. 13–16, 2011
Minneapolis, Minnesota
For information, see http://www.asbh.org/meetings/annual/index.html

3rd Annual Community Engaged Research Conference
Oct. 27–28, 2011
Houston, Texas
For information, see http://www.csuhayward.edu/JERHRE/conference/index.html

Conflicts of Interest in the Practice of Medicine: A National Symposium
October 27–28, 2011
Pittsburgh, Pennsylvania
For information, see http://www.aslme.org/Calendar

PRIM&R Advancing Ethical Research Conference
Dec. 2–4, 2011
National Harbor, Maryland
For information, see http://www.primr.org/Conferences.aspx?id=11065

Protecting
Human Subjects

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

DOE Human Subjects Protection
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This newsletter is available electronically at no cost to anyone interested in or involved in human subjects research or the protection of human research subjects. To receive e-mail notification of new issues of the newsletter, please send an e-mail to:
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http://humansubjects.energy.gov/doe-resources/newsletter/