IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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IN THIS ISSUE

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IRBs can learn from the experiences of early SCROs

California ESCRO follows NAS guidelines

As funding barriers are slowly being chipped away in California and some other parts of the country, increasing numbers of institutions are forming stem cell research oversight committees (SCROs), or embryonic stem cell research oversight committees (ESCRO), which often have some overlapping responsibilities with IRBs.

IRBs and institutions could learn from the California pioneers in this area of human subjects research and be prepared for the day when stem cell research, which has public support, is funded federally beyond the approved cell lines.

"Because stem cell research is a new and very promising field, a lot of institutions and universities are going to be looking at protocols to do this kind of research," says **Bernard Lo**, MD, professor of medicine and director of the Program in Medical Ethics at the University of California, San Francisco. Lo co-authored a paper on establishing procedures for oversight of stem cell research, which was published in the January 2007, issue of *Academic Medicine*.[1]

"It is clear IRBs are not really set up to address and oversee stem cell research," Lo notes. "So setting up SCRO committees is very important to make sure the research is carried out under strict oversight."

The National Academy of Sciences (NAS) of Washington, DC, defined ESCROs and published guidelines in 2005.

These were the guidelines adopted in California by the California Institute for Regenerative Medicine, which is the agency formed after the passage of proposition 71, which allowed the state to sell bonds to provide funding for research using embryonic stem cells, says **Steven Peckman**, an associate director for the Institute for Stem Cell Biology & Medicine at the University of California, Los Angeles. Peckman spoke about ESCROs and IRBs at the 2006 annual Human Protection Program Conference of Public Responsibility in Medicine & Research (PRIM&R), held Nov. 15-18, 2006, in Washington, DC.

"The first thing we did was meet with IRB members and staff and talk about how to interface between our [ESCRO] program and theirs, Peckman recalls.

"California has a unique law that requires IRB review of all stem cell research, regardless of whether it has human subjects," Peckman notes. "So when we developed the ESCRO mechanism, we had to develop some kind of interface for the IRB committee and IRB staff, and the members have been helpful in the process."

While previously there were at least two review committees reviewing all embryonic stem cell research, this changed in January, 2007, Peckman says.

This was when a new California law designated that IRBs only will review stem cell research that includes human subjects, while the ESCRO committee will handle reviews of all human embryonic stem cell research, Peckman adds.

Studies that will continue to need both IRB and ESCRO review are those in which cells have direct or indirect identifiers of the donor, and studies in which there is a direct donor interaction, such as collecting embryos from an in vitro fertilization clinic for the purpose of deriving embryonic stem cells, Peckman explains.

"There will always be some overlap of compliance committees," Peckman says. "If you take embryonic stem cells and put them in animals, then you have animal committees involved; if there is radiation, you have a radiation committee involved."

The SCRO oversight is required in California by state law, but other institutions in other states may follow suit because of recommendations by the National Academies panel, Lo says.

Since IRBs have a lot of experience with consent forms, stem cell research oversight committees might defer to the IRB's recommendations when certain issues are considered, such as when embryos are donated for new stem cell lines, Lo notes.

"We have deferred details of consent to the IRB, but they are not set up to think about the science of stem cell research and go into depth [like the SCRO committee]," Lo adds. "So we try not to duplicate reviews but will partition various aspects of the protocol, according to the expertise of the committee."

Several members of the ESCRO and IRB overlap at UCSF, and the institution has a process that facilitates effective communication and convenient timing between the IRB and SCRO committee, Lo explains. **(See story with suggestions for starting an ESCRO, p. 52.)**

"That's important because researchers already are concerned that the review process adds time to their work," Lo says. "So we try to schedule the committees to meet during the same week."

At UCLA, the IRB and ESCRO committees share the same application form, simplifying the process for investigators.

"That cuts down on the paper and application burden for investigators, and at the same time it ensures information flow between two compliance

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committees," Peckman says. "It promotes collaboration and a relationship between the two committees."

At UCLA, the ESCRO committee has the responsibility for doing a scientific review, and the ESCRO committee members are available to attend IRB meetings in order to answer IRB members' questions about the science aspects of a proposed study.

The IRB won't review a protocol until the ESCRO committee approves the study's scientific basis, Peckman says.

"We won't waste IRB resources on something that's not scientifically adequate," Peckman says. "So once the ESCRO committee says the science is sound, the IRB will review it immediately."

The IRB committee meets every other week, and the ESCRO committee meets when needed, he adds.

ESCRO committees look at the ethics of human subject participation, and they're responsible for a list of oversight items, according to the NAS guidelines, Peckman says.

Also, the ESCRO committee is charged with making sure a protocol receives oversight review from all other applicable committees, including the IRB, conflict of interest committee, etc.

"So the ESCRO committee makes sure all committees have done their review before the investigator does research," Peckman says. "The ESCRO committee is responsible for maintaining registries for embryonic stem cell research, as well as the cells at the institution."

ESCRO committees also educate the research community about embryonic cell research.

At UCLA, the ESCRO office shares two full-time employees, including Peckman, with other departments. The office will be expanded once more stem cell research is underway, Peckman says.

Although proposition 71 was passed in November, 2004, by 59% of voters, several opposition groups immediately filed lawsuits to stop its implementation, basing their claim on the state's constitution, he explains.

"The bonds can't be sold until those suits are resolved, and this has created significant delays for the funding agency," Peckman says.

As an interim measure, the agency handling the stem cell research funding created bridge notes to sell to individuals or organizations in support of the agency and its research mandate, he says.

"If the lawsuits are resolved in favor of the state, then the bridge notes will be repaid," Peckman says. "If the plaintiffs are successful, then the donor notes will be considered a gift to the state."

So far, $81 million in bridge notes were sold, and the state government also has agreed to lend the state agency $150 million. UCLA was awarded $3.75 million over three years from this initial round of funding, which is earmarked for training five pre-doctoral fellows, five post-doctoral fellows, and six clinical fellows in stem cell science, Peckman says.

The plaintiffs lost in the first round, and the case is now in the appellate court and may ultimately end up in the California Supreme Court, with a decision expected by the summer of 2007, he adds.

If the state wins the case, then bond sales can take place, and the enterprise may raise up to $3 billion dollars, Peckman says.

The money raised must be distributed within 10 years of the bill's passage, according to the law, and at least two of those years have been used up by the lawsuit, he adds.

Despite the delay, research institutes already are seeing benefits to the state's passage of the proposition.

"One thing that has been a great benefit for academic centers is it has helped to recruit young faculty," Peckman says. "UCLA recruited five young, very creative and motivated stem cell faculty members, and that's been absolutely wonderful."

By California law, the ESCRO committee includes members with scientific, medical, and ethical expertise, as well as non-affiliated/non-scientific members, which makes it a little different from the IRB, which is not required to have an ethics expert, Peckman notes.

"The ESCRO committee is required to have members who are biologists, assisted reproduction specialists — which is a more explicit roster than the IRB membership requirement," he says.

Since there is no federal law governing the process, there is some flexibility in the establishment of an ESCRO committee at institutions in states without applicable local law, Peckman says.

"We focus on two elements: members come with expertise in stem cell science and expertise in ethics and the community perspective," Peckman says. "By California law, the ESCRO committee has to have community members."

UCLA's ESCRO committee's community

members include people who have been involved in the HIV/AIDS community, as well as a person who is involved with the Parkinson's disease community, he says.

Unless the lawsuit prevails, the future is bright for the state's embryonic stem cell research.

"People need to see this as a creative opportunity, and it's important to ensure that through the process of stem cell science and oversight, we have the highest quality science and achieve the highest ethical standards," Peckman says.

While California cannot compete with National Institutes of Health funding, the expected $3 billion in bond money will provide a good start in this research, Peckman says.

"We hope in the future the federal government will change its policy and other monies will be available to help scientists conduct stem cell research," Peckman says. ■

Reference

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Learn start-up differences of SCRO committees and IRB

Expert offers this advice

As stem cell research increases in California and elsewhere, IRBs and institutions are investing time and resources in establishing new oversight committees and writing new policies and procedures.

"Setting up a stem cell research oversight (SCRO) committee is very important for making sure research is carried out under strict oversight," says **Bernard Lo**, MD, professor of medicine and director of the Program in Medical Ethics at the University of California, San Francisco (UCSF). Lo co-authored a paper on establishing procedures for oversight of stem cell research, which was published in the January 2007 issue of *Academic Medicine*.

A special SCRO committee will come up with questions that might not occur to the average IRB, Lo suggests.

For instance, at UCSF there was a protocol before the SCRO that didn't involve human beings directly, but it raised major ethical concerns.

A scientist wanted to use an existing stem cell line that couldn't be linked to its original donors for the purpose of coaxing the cells into human bone cells, Lo explains.

"He proposed to inject these cells into chicken embryos to see if human cells appeared with all of the characteristics of human bone cells," Lo says.

"One of the basic scientists on the committee had concerns about how long human cells would be allowed to grow," Lo says. "He thought they should not be allowed to grow to the point where they would have any structures resembling human characteristics."

The scientist who raised the question pointed out that as early as 12 days, one could see basic limbs of chicken embryos, so he didn't want to see human structures like a human hand rather than a wing, Lo adds.

"This issue wouldn't normally come before an IRB because it doesn't involve potential harms to humans," Lo says. "But it was about creating animals that have characteristics that are uniquely human, so we struggled with this concern."

It's also a concern that wouldn't have been raised except when a committee has scientists who have the knowledge necessary to know what to ask, he adds.

This is one example of why institutions that anticipate even a handful of stem cell research protocols in the near future should consider establishing a separate board to review the studies, Lo says.

"All IRBs need to look to the future because it might be one protocol this month, but it could be a much larger number next year," Lo says.

Lo offers these suggestions for how institutions can establish an effective SCRO that would meet the 2005 National Academy of Sciences (NAS) guidelines, as well as California's state requirements:

1. Find the right people to form the committee.

"Membership is very important," Lo says. "It became clear to us that there were three very different members needed."

The first type of member is the scientist who understands the science of stem cell research because before a committee can understand the ethics, it needs to understand the science, Lo explains.

"We have a lot of scientists from different fields, including developmental endocrinology," Lo says.

Other scientific members include experts in cell biology, stem cell biology, developmental biology, human genetics, and assisted reproduction.[1]

The second group includes people who have experience in research ethics and the regulations for research, and these might include law professors, ethics faculty members, and IRB members, Lo says.

"Finally, we think it's very important to have public members because this is the type of research the public has been very interested in," Lo says. "We think having people who are not affiliated with UCSF could help us not lose sight of what the public thinks."

Other qualities to seek in SCRO members are the desire to work hard, as well as having an open mind about new scientific and ethical issues, Lo notes.

"We don't want people coming to the committee with preconceived ideas of what research is," he says.

2. Establish policies regarding when informed consent would be needed.

Even if states don't establish guidelines or regulations regarding the source of stem cells for research, institutions need to consider having guidelines in place.

Many people would find it acceptable to allow embryos created through in vitro fertilization processes to be donated to research once they are no longer of use to the infertility couple and are set to be destroyed, Lo says.

"But we need a careful consent process to make sure the woman and couple in IVF understand the implications of what they're doing," Lo says.

"We have argued in other papers that if there is an egg donor or sperm donor in the original creation of the embryo, then those donors also need to have consented to allow the embryo to be used for stem cell research," Lo adds. "So it's not as straightforward as it might appear."

Institutions need to be very careful with their policies regarding informed consent because of the sensitivity of the issue, he says.

An institution's policy might require that the informed consent process take place at the IVF clinic, but will also require the researchers who will be using the embryos to make certain the policies and procedures have been followed, Lo says.

"You have to make sure contractors follow their own policies," he adds.

Studies have shown that of the women who donate oocytes for IVF, about one-fourth of them would not want their embryos to be used for stem cell research, Lo says.

"This is different from other types of research because the donor's DNA is in the laboratory for a long time, and there's a possibility that the cells might be used for transplantation," Lo says. "For example, it's different from a cancer operation in which there is tissue obtained that could be used for research or thrown away, so the general consent is not suitable."

Embryos have special symbolic and emotional significance to people, and so these can't be treated like discarded tissue," Lo explains.

3. Thoroughly analyze potential solutions to ethical dilemmas in research.

"The researchers at UCSF are extremely interested in deriving new stem cell lines, so they've presented several proposals," Lo says. "One is to allow frozen embryos that are not needed now for infertility treatment, but they've also proposed to use two other sources of materials from IVF clinics."

One other potential source would be oocytes, which don't fertilize and can't be used for reproductive purposes, Lo says.

The second category is embryos that were created in the IVF setting but didn't develop sufficiently and, therefore, would not be used for implantation for IVF treatment, Lo says.

"Those embryos also would be discarded, and the proposal was to ask for permission to use those failed-to-develop embryos for research," Lo says. "We approved those ideas, and there was a lot of discussion and concern about the consent process and also about how the determination process would work for deciding whether the oocytes had fertilized or developed."

The SCRO committee asked that the different types of scenarios be mentioned separately in the consent document. Consent for donating oocytes that don't fertilize and embryos that don't develop would have to be obtained at the time the woman is undergoing treatment, whereas the consent for frozen embryos would be obtained after she's completed treatment, Lo explains.

"When it's consent for embryos that haven't fertilized, it should be brought up beforehand," Lo says. "Most women will agree that these can be used for research if there is no way they'll turn into little children, and it's less problematic than frozen embryos."

But the timing of obtaining informed consent is important, and women shouldn't be asked for this informed consent at a time when it's very stressful for them, Lo says.

Also, the SCRO committee wanted to make sure the decisions were entirely impartial and

Best Practice Report

Create how-to booklet to be used when IRB administrator is gone

Little black binder is 30-40 pages

Small IRB offices often do not have cross-trained or back-up staff in the event the IRB administrator is unexpectedly absent. So what happens when the people filling in cannot find the right forms or records or schedules?

IRB Administrator **Paulette M. Vandzura**, MA, CIP, of Memorial Medical Center in Johnstown, PA, first gave this dilemma serious thought as she was preparing for an international vacation.

"The vacation triggered for me to think about what would happen if I never came back to this desk," Vandzura says. "It's just me and the IRB chair, who is very busy and is also a PharmD and director of the PharmD residency program."

It occurred to Vandzura that there was no one else who could easily step into her shoes at the office without receiving guidance that would help them get through the first four to six weeks of work.

"When we talk about a larger IRB there usually are several staff members," she says. "Even if they aren't purposely cross-trained to each other's work, they at least have some familiarity or exposure to it."

But at small IRB offices, the replacement would be someone who has never ventured into the office, she notes.

Once Vandzura realized there might be a problem, she took action. First, she opened a new file called "day-to-day procedures," and each time she did a new task or procedure, she typed in a brief description of that activity, including why she did it, how it links to the next step, and where the activity was located on the computer, Vandzura says.

She filled this new file with information over a week's time, eventually organizing it by daily, weekly, and quarterly activities.

Some of the items she included were:

- How to organize and prepare for an IRB meeting;
- What transpires at the meeting; and
- What has to be accomplished following the meeting;

"Then I took an even broader look at things," Vandzura says.

So she came with initial instructions, which include advice to familiarize her replacement with files and folders on the computer.

The collected information was organized into a how-to booklet (a black binder) that provides an overview and day-to-day instructions on the IRB administrator's duties.

For example, the replacement person is instructed to ask the information technology department to access Vandzura's portion of the server.

"Within the black binder, I have certain key documents and hard copies of items like in-and-out logs," Vandzura says. "I have a hard copy of my currently active studies log, so that if someone called up and said, 'I want to talk about study 0640,' they could go to that log, look up the study by number and see who the principal investigator is, as well as other basic information."

There is another listing for annual reviews, and the rest of the binder contains key regulatory documents, including a memorandum by the Office of Human Subjects Protection (OHRP) about what constitutes human subjects research. Other included items are, as follows:

- Exempt review categories;
- Expedited review categories; and
- HIPAA information and how it impacts research.

"Those are just the documents I look at on almost a daily basis," Vandzura says. "Almost everything else is on the computer in a word processing file or spread sheet format."

The how-to booklet contains 30-40 pages, including three type-written pages of instructions and the supporting documents, she says.

Instructions cover how to assign IRB tracking numbers, meeting preparation, information about meetings and follow-up, as well as how to present quarterly reports.

"There's a section on how to track, follow, and achieve all the continuing review deadlines, and then there's a short description of end-of-the-month items," Vandzura says.

Each week, Vandzura updates the hard copy of the log of active studies, which also is filed on the computer as a spread sheet.

"The regulatory documents can all be found on the Internet, but I find it so much easier to have a hard copy at my fingertips," Vandzura says. ■

scientifically-sound, he says.

"We put in some additional safeguards in terms of the laboratory embryologist who makes the decisions about whether the oocytes had been fertilized," Lo explains. "He would not know whether those failed-to-develop embryos or oocytes would be discarded because we wanted those decisions to be absolutely unbiased."

Also, SCRO members wanted to make certain that no one involved in collecting embryos or studying them would have conflicts of interest, or even the appearance of a conflict of interest, Lo says.

"The embryologist could not derive any financial interest in stem cell research," Lo adds. "We arrived quickly at the decision to make the process beyond reproach and bias."

For example, if there was a researcher who had financial interest in a company that makes growth media that is used by stem cell investigators, then that would be very damaging to the stem cell research work, Lo says.

"This area is both new and controversial and complicated, and unless you spend a lot of time thinking about it, you won't get all the nuances," Lo says. ■

Reference

1. Zettler P, et al. Establishing procedures for institutional oversight of stem cell research. *Acad Med*. 2007;82(1):6-10.

Rule creates headaches for historical medical archives

Archivists and IRBs deal with the fallout

The archives of medical colleges and hospitals can be a rich source of information for historians interested in how health care has been delivered throughout our nation's history. Old case files, collections of physicians' personal papers, even old photographs were donated to archives so that others could learn from them decades later.

But historians have run into a roadblock at some archives, as archivists, lawyers and IRBs apply the privacy rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The documents so full of fascinating details about health care in the past century are also scattered with individuals' protected health information (PHI) — sometimes in unanticipated places.

As a result, institutions that hold archival documents face difficult decisions. Do they close the files to researchers, or spend valuable staff time redacting them so that they pass HIPAA muster? Or do they allow access, gambling that any disclosures are for people long dead and unlikely to complain?

For now, institutions are taking different approaches — some restricting access, some involving IRBs or privacy boards in decisions about waivers of authorization to disclose PHI. Some are allowing access to parts of their archives, but not to other sections.

"It's about the interpretation of the lawyers, and lawyers think differently," says **Jim Gehrlich**, head archivist for Cornell University Medical Center in Ithaca, NY. "There's no case law out there [on this topic], and so some institutions will say since there is no case law, we'll be strict constructionists and hold to HIPAA exactly as it is. Others will be loose constructionists."

While institutions appear to be making these differing interpretations of HIPAA work, the inconsistencies in access are frustrating some researchers who complain that records available at one medical archive might be closed at another.

Karin Rosemblatt, PhD, an associate professor of history at Syracuse University, Syracuse, NY, described her difficulty in gaining access to records of psychological and educational tests conducted on American Indian children during World War II. The records were held at the Smithsonian Institution, which withheld the records, citing HIPAA concerns.

"I should say that I have worked with similar, if not exactly the same type of documents at other archives that handle it differently," she says.

Rosemblatt, who was researching the anthropologist who conducted the tests, offered to sign a confidentiality statement, and asked to see only the questionnaire involved in the testing but still was denied access.

She says the refusal to allow researchers access to these types of collections ignores the wishes of the scientists who donated them to the institutions. And she worries that closing historical medical records can keep important issues from coming to light.

"For example, would we ever know, under the HIPAA regulations, about Tuskegee?" Rosemblatt says, of the infamous Tuskegee Syphilis Study. "The researchers who uncovered that did so by having access to those records."

Stephen Novak, head of archives and special collections for the Augustus C. Long Health Sciences Library at Columbia University, New York City, has a different fear.

Novak notes that larger institutions such as his own have the money, staff and expertise to deal with HIPAA.

"But a lot of smaller places are holding records that, in some ways, may be much more representative of the type of medical care that was administered in late 20th and early 21st century United States," he says. "Those [documents] could be destroyed because these places don't have that kind of infrastructure, and they just don't want to have to deal with it. Patient records don't need to be kept permanently and they are a pain in the neck to keep. This may be just one more reason to get rid of them."

In 2005, Novak testified before a privacy subcommittee of the U.S. Department of Health and Human Services, asking for more clarity in the HIPAA ruling regarding historical medical records. Among his requests was an expiration date that would clearly identify when older records would no longer fall under HIPAA's privacy requirements.

"It looks as if that's not going to go anywhere," he says. "HHS does not seem to be interested in modifying HIPAA on those lines, and I'm not sure it ever will be."

PHI hiding in old files

To get an idea of why the issue of PHI in historical records can be so thorny, consider some of the types of documents held by the archives of the Johns Hopkins Medical Institutions, in Baltimore, MD:

- Log books dating back to the very first admissions to and discharges from the hospital. Entries ordinarily would include names, addresses, birthdates, and diagnoses.
- A collection of more than 80,000 photographic images, including formal portraits of physicians and students, photos taken on the wards, and a large number of individual patient photos, linked to patient records. These photos may illustrate injuries or genetic anomalies.
- Personal paper collections donated by faculty and staff, often physicians who have been eminent in their fields. The papers normally would include case files, research files, and correspondence files.

Nancy McCall, director of Hopkins' Alan Mason Chesney Medical Archives, says these personal papers can be important tools for physicians and researchers.

McCall says that while PHI can be found throughout much of the personal papers donated by physicians, it's the correspondence files that can be the most troublesome when it comes to the privacy rule.

"Whatever the reason for the letter, health professionals writing to each other seem inevitably to talk about their health, the health of their families, as well as discuss a patient. It's all over the place," McCall says.

She says some of the information can be extremely personal.

"We find things like euphemisms for abortion from the 1930s that students studying the documents may not always recognize," McCall says. "And some of these people are still living."

Novak agrees, saying problematic information can turn up in unexpected places.

"You're processing these papers and, in the middle of it, the doctor will write: 'I have seen Mrs. So-and-so, whom you referred to me, and she's suffering from paranoid schizophrenia.'

"The researcher using those papers is not looking for Mrs. So-and-so, almost certainly. They're looking because they're interested in the doctor."

Novak asks researchers using the collections to sign a form agreeing not to identify people whose information they run across in this way.

"If they want to use a pseudonym, it's fine," he says. "Usually most researchers don't have a problem with that. Does it satisfy HIPAA? Well, we're not absolutely sure, but it's the best we can do. Otherwise, we couldn't use any of these things."

Novak notes that in many cases, the people described in the archive documents are almost certainly dead, and HIPAA does have provisions for dealing with PHI from deceased subjects.

"What most archives have generally done is set an arbitrary date," he says. "We assume people to be deceased if it's 100 years after date of birth, if that's included in the record, or the date of record creation, whichever occurs first. Records of people who received care 100 years ago or more we consider dead, and they have a different procedure to follow than those whom are considered to be living.

"That still doesn't mean that the researcher can use the name, it just means that the access is different, the procedure, the forms are different."

To IRB or not to IRB?

Novak says his archive currently does not involve the IRB in decisions about what to release to researchers.

"When HIPAA first came up, we did talk about that and, at one point, there was some discussion about having a historian on the IRB in case these requests came up," he says. "Eventually, it was decided that this was not a problem dangerous or sensitive enough that the IRB had to be involved. That was a possibility I was completely comfortable with, but the lawyer decided it wasn't necessary."

At Cornell, researchers seeking to do work involving individuals who are deceased (or whose records are 100 years old or more) must simply sign a form, Gehrlich says. Anyone with a proposal to investigate files of people who are still living must go through the IRB.

Gehrlich says that HIPAA actually has made such requests at his institution less complicated.

"I have the simple form, the person signs the form, says that they're doing research on decedents and, once they sign that form, I don't have any other worries," he says.

At Hopkins, the institution's lawyer determined that it would be best for a privacy board to review any requests for research that would require access to documents containing PHI.

"The applicant fills out a form that requires an abstract of the research protocol and their [curriculum vitae] and that is reviewed by the privacy board and a decision is made about whether to issue a waiver of authorization to conduct research," McCall says. "An institutional body (an IRB or a privacy board) would have to issue the waiver — the archives itself could not issue the waiver."

That interpretation of HIPAA has not been universally popular, she says.

"A number of historians have essentially blamed us, the archives, for this, because we did the interpretation at Hopkins," McCall says. "We've had to take a lot of grief that it's all our fault, that it's our screwy interpretation."

She says the experience implementing HIPAA in the archives has been educational, both for her and for the privacy board.

"I would say that each case brings up different issues that we had not anticipated," she says. "We have some really good people on the privacy board, but they don't know much about the older documentation and how this applies.

"It's a very good group — we learn a lot from each other," McCall says. "But this is the kind of thing that could never be put into a cookie-cutter process. That's what's so difficult with privacy issues because they're seldom issues that are simply black and white. We've never had a ho-hum meeting."

Novak points out that institutions such as his at least have the infrastructure to deal with these complicated issues. At a smaller institution, which may be served by a single reference librarian and an IRB unfamiliar with historical medical documents, things could be more difficult.

"If an historian or biographer or sociologist comes to them, they're going to say, 'What are we going to do with this?'" ■

How should IRBs approach privacy in medical archives?

Archivist recommends focusing on the living

In the absence of changes to HIPAA that would clarify the use of the privacy rule in historical medical archives, institutions, archivists and IRBs are left to sort through the complicated issues themselves.

While much of the decision-making may be in the hands of an institution's lawyers, Cornell University Medical Center Head Archivist **Jim Gehrlich** says there are some practical points that IRBs should consider when faced with this issue.

"My suggestion is that the IRB not be involved with anything that involves decedents and HIPAA," he says. "The privacy rule allows for that. It specifically says that if a researcher is dealing exclusively with PHI (protected health information) of decedents, it doesn't have to go to the IRB."

Gehrlich says that at some institutions, IRBs have insisted on taking responsibility for these requests, without proper background in historical research.

"It would be better if they let go of it — that would be the best of all worlds," he says.

If an IRB is put in a situation of reviewing such privacy waiver requests, Gehrlich says the board needs to seek out the necessary expertise, ideally from the institution's archivist, but also in allowing historians on the IRB who can offer the perspective of those conducting research in medical archives.

At Johns Hopkins Medical Institutions in Baltimore, MD, head archivist **Nancy McCall** says she's trying to figure out new ways of accommodating research requests while holding strictly to HIPAA's privacy requirements.

McCall says colleagues in medical informatics have found that historical case files and operative notes that used some kind of standardized form can be de-identified in a similar way to contemporary electronic files.

"The identifiers can be stripped without diminishing the intellectual content of the body of the document," she says. "That's what we found very exciting." She says this type of technology could make it possible for an archive to put up older, de-identified case files on the Internet for scholars to study.

For biographical and personal papers that would be more difficult to redact, McCall says she's considering offering a paid service to researchers, in which her staff could comb through the necessary documents, remove the information a researcher needs and prepare a report for the researcher.

"Our staff are all HIPAA certified — we've taken courses, passed exams, and are in a category to be working with this kind of information," she says. "When somebody is really interested in some intellectual dialogue in the correspondence of [eminent physicians], then we could go into that series and quote all the material that has nothing to do with PHI. The onus would be on our staff to demonstrate that we just provide the researcher with the [proper] information."

Archivists at many institutions are also having serious discussions with those intending to donate collections, to explain the HIPAA implications of their gift.

"Quite often, the children turn over the materials," McCall says. "We have to ask them whether they want their parents' health information, or their own health information, revealed. And they are startled that we would even be thinking about this. We have to show them, here is where [the documents show] you broke your leg at this age."

Because HIPAA's privacy protections apply only to covered entities such as hospitals and medical schools, some archivists have even suggested to donors that their collections may be better off in the hands of a non-covered entity such as a state historical society.

"If it's an individual physician who wants to donate his office records, which include patient case records to an institution, I've explained the implications — that the records would be handled differently if they came to us than if they went to a historical society, because the historical society is not covered," Gehrlich says.

Members of the Society of American Archivists Science, Technology and Health Care Roundtable and the Archivists and Librarians in the History of the Health Sciences have compiled a Web site to address the impact of HIPAA on medical archives. Access the site at: http://www.library.vcu.edu/tml/speccoll/hipaa.html ■

Incentives for surveys — Can they be coercive?

Sociologist says that IRBs should focus on risk

When researchers are attempting to persuade subjects to answer questions about themselves, whether on the phone or by filling out a form, sometimes the altruism of participating in research isn't enough.

So they resort to incentives — cash, or a non-cash gift, as a reward for participation. IRBs can become concerned about these incentives, and whether they manipulate people into participating in surveys they wouldn't have answered otherwise.

But a sociologist at the University of Michigan argues that such IRB concerns can be overblown — that incentives don't generally induce subjects to work against their own interests, particularly when the study involved simply requires that they answer questions.

Even when the questions involved are difficult ones about violence, or high-risk or stigmatizing behaviors, studies show that subjects don't tend to take on higher actual risks in exchange for money, says **Eleanor Singer**, PhD, adjunct professor of sociology at the Population Studies Center at the University of Michigan, Ann Arbor, MI.

"Honestly I don't think that incentives are usually an ethical issue," Singer says. "I don't know why IRBs need to concern themselves with them as much as they do. It is a benefit that respondents can be given. I don't see anything wrong with giving it to them, frankly."

Singer recently wrote about the issue of incentives for survey participation for the *American Journal of Preventative Medicine*. Her paper was part of a larger look at survey work, particularly in the area of violence and violence prevention.

Prepaid vs. refusal-conversion

Singer says there isn't a lot of information about how much researchers, in general, are paying to convince respondents to participate in surveys, but there are a few general ways in which cash incentives are offered:

- **Prepaid incentives,** money that is promised before the subject has decided whether to participate and which is paid up front.
- **Promised incentives**, which are offered beforehand, but not paid until after the subject completes the interview.
- **Refusal-conversion incentives,** which are offered to a potential respondent after he or she already has declined to participate, in an effort to change his or her mind. These may be prepaid or promised after the interview is completed.

Singer says it's hard to know how often refusal-conversion payments are used, since they're often used simultaneously with other forms of payments. She says some ethicists disagree as to the appropriateness of refusal-conversion payments, which, in effect, reward subjects more for being less cooperative. But they can be helpful in raising survey participation rates.

In her own work, Singer says she deals with that issue by offering a small prepaid sum to everyone contacted for a survey, with a refusal-conversion incentive offered to those who initially decline.

But the larger issue for IRBs tends to be the effect of the incentive on a person's autonomous decision to participate. Does the prospect of payment coerce a subject into responding?

'Influence,' not 'coerce'

Singer argues that it doesn't, using the Belmont Report's definition of "coercion" as an "overt threat of harm. . .intentionally presented by one person to another in order to obtain compliance."

Another issue raised by the Belmont Report is that of "undue influence," or "an offer of excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance."

"You should never think of incentives as coercive but, obviously, you can think of them as influencing people," she says. "The question is, are there situations in which the size of the incentives raises some questions about the amount of influence that may be exerted on the subjects? Is that ever bad?"

Singer says that several studies looking at the cost-benefit decision-making process of respondents show that individuals do not exchange risk for money — they don't accept greater risk as the compensation offered increases.

There are some concerns that people wishing to participate in a survey might give false information to meet eligibility requirements. But she notes that this can be dealt with through rigorous screening of applicants.

Singer says that if IRBs are concerned about incentives and their effects, they should attack the problem on two fronts:

- **Ask subjects' opinions about incentives.** Singer says IRBs should do research on what size incentives are considered excessive by the people who are offered them.

"The IRB tends to substitute its own very subjective judgment in these matters and every IRB comes up with a different amount," Singer says. "I think that's wrong, because it subjects research being done by different institutions to very different standards."

She says it would be useful to get the public's input into these issues: Given a certain type of situation, what kind of incentive is excessive? What is considered insufficient?

"You can do it locally, you can do it nationally," Singer says. "You can have discussions about what would be the most appropriate kind of sample to get this kind of opinion from. But there should be at least some input from the populations who are actually affected by the incentives."

Some researchers argue that IRBs, or a federal agency, should monitor levels of incentives being used in survey research to get a better idea of what is being offered to whom. This type of empirical information could help better identify real potential ethical problems.

COMING IN FUTURE MONTHS

- Expert offers advice on how IRBs can handle investigator non-compliance
- Study offers insight into obtaining exceptions to informed consent in ERs
- New OHRP guidance addressing social-behavioral research could be coming this year
- Research with undocumented immigrants: What IRBs should know

• **Focus on risk, not incentives.** Singer argues that the IRB should focus on reducing risks, such as the nature of the questions asked or the possibility that personal information might be disclosed, rather than worrying how much people are being paid.

"The issue isn't whether you can offer incentives in exchange for risks, the issue is can you protect people against risks," Singer says. "If you can't, there are some questions as to whether you should be doing the research at all.

"And if you are protecting them against risk in every reasonable way, then the offer of an incentive is not, to me, unethical."

Even in situations that may give some IRBs pause (for example, surveys dealing with vulnerable populations such as children), incentives are not as important as the risks being asked of the respondents, Singer says.

"What are you influencing these kids to do?" she asks. "Is this against their own interests? If it isn't, if there's no risk to them or if they're protected against the risks such as confidentiality issues, then it's really not the IRB's business to decide what incentives may be offered." ■

Reference

Singer E, Bossarte RM. Incentives for Survey Participation: When are They "Coercive?" *Am J Prev Med* 2006 Nov; 31(5):411-418.

CE/CME *questions*

15. California recently passed a law regarding stem cell research oversight. Which group is charged with its oversight?
A. IRBs when it's human subjects research and animal protection committees when it's animal research
B. A stem cell research oversight committee will handle reviews of all human embryonic stem cell research, and IRBs will provide a review of only the stem cell research that involves human subjects.
C. A government panel called the Human Embryonic Stem Cell Oversight Board will be the only body to review all human embryonic stem cell research.
D. None of the above

16. Stem cell research oversight committees should include members with which type of expertise and backgrounds?
A. A. Scientists, particularly those with biological, genetic, and reproductive expertise
B. Professors with medical ethics expertise.
C. Former patients in assisted reproduction programs, law professors, biology teachers.
D. All of the above

17. Which of the following would be an example of a 'non-covered entity' for purposes of the Health Insurance Portability and Accountability Act (HIPAA)?
A. The historical archives of a medical school or hospital
B. A state historical society.
C. Neither, both are covered entities.

18. True or False: Studies have shown that survey respondents are willing to accept more risk in a research study in exchange for higher cash incentives?
A. True
B. False.

Answers: 15. (b); 16. (d); 17. (b); 18. (b)

The CE/CME objectives for *IRB Advisor* are to help physicians and nurses be able to:
- **establish** clinical trial programs using accepted ethical principles for human subject protection;
- **apply** the mandated regulatory safeguards for patient recruitment, follow-up and reporting of findings for human subject research;
- **comply** with the necessary educational requirements regarding informed consent and human subject research.