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IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

INSIDE

SEPTEMBER 2001

VOL. 1, NO. 3 (pages 25-36)

HIPAA's effect on clinical trial info causes worry for researchers

Some ask HHS for an amendment to privacy rule

If the government gets its way, your IRB could be forced into making value judgments on what patient identification data can be disclosed as part of research.

Fourteen professional health care organizations and various representatives of hospital- and university-based research facilities say the new privacy regulations could impair clinical trials, place onerous burdens on IRBs, and restrict the number of health research studies conducted in the United States.

Organizations that oppose the Health Insurance Portability and Accountability Act (HIPAA) of 1996 voiced concern in a letter written to **Tommy G. Thompson**, secretary of the U.S. Department of Health and Human Services (HHS). The group is calling for substantial amendments to the proposed rules published in the Aug. 14, 2001 *Federal Register*.

"Our concern with HIPAA is it creates a parallel regulatory structure with much greater liability associated with any breach of the very complicated privacy rules," says **Jennifer Kulynych**, JD, PhD, director of

OHRP moves offices

The Office for Human Research Protections has moved its offices. All correspondence, either through direct mail or overnight services, should be sent to the new address. OHRP now is located at The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. The main telephone number is (301) 496-7005. Staff telephone numbers and e-mail addresses can be found at the following link: http://ohrp.osophs.dhhs.gov/phonstf.htm. ■

the division of biomedical and health sciences research for the American Association of Medical Colleges in Washington, DC.

Breaches of the privacy rule could result in civil fines and criminal penalties for researchers, medical schools, hospitals, and others directly involved in maintaining patient health data, Kulynych says.

The portion of HIPAA that is of specific concern to IRBs and researchers is Section 164.514, which discusses requirements relating to uses and disclosures of protected health information. **(See overview of HIPAA requirements, p. 27.)**

This section explains the definition of "de-identification of protected health information," which relates to information that does not identify an individual and cannot reasonably be used to identify an individual.

There are only two methods for determining that health information is de-identified. The first method requires a statistician to determine that the risk of identification is very small and to document the methods and results of that conclusion. The second method requires that 18 pieces of information be entirely removed from the health care data. **(See list of 18 identifiers, p. 29.)**

"We believe the two methods are unworkable," states **Melissa Bartlett**, JD, legislative counsel for the American Medical Group Association in Alexandria, VA.

"First, a safe harbor of relying on a statistical expert would be very difficult to rely upon," she says.

The second method contains too many identifying characteristics for medical facilities to remove, Bartlett adds. "There are four of the 18 characteristics that we believe would properly put into place privacy protections but would still allow for meaningful research."

Some personal data on charts should remain

Bartlett says these four characteristics should be allowed to remain in the research data because some research will be meaningless if these are entirely removed:

- zip codes;
- dates;
- unique identifying number characteristic or code;
- serial numbers.

Serial numbers, for example, might be used to identify a patient who used a particular medical device. When a physician reports to a medical device company that there was a defect involved with a particular pacemaker, the manufacturer will be unable to investigate whether similar pacemakers also had a problem unless that serial number was included, Bartlett explains.

Bartlett and others opposed to HIPAA's final rule say that research entities already are subject to the common rule, and that research that is subject to an IRB review should be exempt from additional privacy rule requirements.

And that's where another chief concern about HIPAA resides. The rule contains so much ambiguity and complexity that it's unclear how medical facilities, researchers, and IRBs may adhere to them, Kulynych says.

The regulation provides for IRBs or a privacy board to conduct a waiver analysis to see if a particular research project may be exempted from the de-identification standard or from the requirement for specific patient consents for research.

However, to be eligible for a waiver of authorization, the research has to be of minimal risk and the privacy board or IRB must look at it and decide whether the risk of losing privacy is outweighed by the importance of the potential research, Kulynych explains.

"And it's not clear how this is intended to function," she says.

Kathleen Kline, IRB coordinator at the University Medical Center of Southern Nevada in Las Vegas, says the new privacy rule could result in the IRB or a privacy board having to meet on a weekly rather than monthly basis to

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- Is there a viable future in stem cell research?
- Training essentials for new research investigators
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- Understanding the differences between adult consent and pediatric assent

HIPAA requirements in a nutshell

Here's a brief overview of privacy requirements under the Health Insurance Portability and Accountability Act (HIPAA) of 1996:

• **Compliance schedule:** The final rule took effect on April 14, 2001. Most covered entities have to fully comply with the rule's provisions by April 14, 2003.

• **Covered entities:** The regulation covers health plans, health care clearinghouses, and health care providers who conduct certain financial and administrative transactions electronically.

• **Information protected:** All medical records and other individually identifiable health information used or disclosed by a covered entity in any form, whether electronically, on paper, or orally, are covered by the final rule.

• **Consumer control:** Patients will have significant new rights to understand and control how their health information is used. Providers and health plans will need to give patients a clear written explanation of how the health information might be used and disclosed. Patients also will be able to see and obtain copies of their records, and they can request amendments. Also, health care providers who see patients will be required to obtain patient consent before sharing their information for treatment, payment, and health care operations. Separate patient authorization must be obtained for nonroutine disclosures and most nonhealth care purposes. Patients will have the right to request restrictions on the uses and disclosures of their information. If patients believe their rights have been violated, they may file a formal complaint with the covered provider or health plan or with the U.S. Department of Health and Human Services (HHS) about the violations.

• **Boundaries of medical record use:** An individual's health information may be used only for health purposes, with few exceptions, including an exception for appropriate law enforcement needs. In general, disclosures of information will be limited to the minimum necessary for the purpose of the disclosure, but this provision does not apply to disclosure of medical records for treatment purposes.

• **Ensure the security of the information:** Covered entities may design their own policies and procedures to meet security standards, but in general they will have to adopt written privacy procedures. Issues include who will have access to protected information, how it will be used within the entity, and when the information may be disclosed. Covered entities also must take steps to ensure that their business associates protect the privacy of health information. And they must train employees and designate a privacy officer who will be responsible for ensuring the procedures are followed.

• **Establish accountability for medical records use and release:** Congress has provided penalties for covered entities that misuse personal health information, including civil penalties that can be applied to health plans, providers, and clearinghouses that violate HIPAA standards. Penalties are $100 per violation up to $25,000 per person, per year for each requirement or prohibition violated. Under HIPAA, covered entities that knowingly violate patient privacy are subject to criminal penalties up to $50,000 and one year in prison for obtaining or disclosing protected health information, plus they are subject to up to $100,000 and five years in prison for obtaining protected health information under false pretenses, and up to $250,000 and 10 years in prison for obtaining or disclosing protected health information with the intent to sell, transfer, or use it for commercial advantage, personal gain, or malicious harm.

• **Balancing public responsibility with privacy protections:** In limited circumstances, the final rule permits covered entities to continue certain existing disclosures of health information without individual authorization for specific public responsibilities. These permitted disclosures include research, but is generally limited to when a waiver of authorization is independently approved by a privacy board or IRB. Other permitted disclosures are for emergency circumstances, identification of the body of a deceased person, or for finding the cause of death; public health needs; oversight of the health care system; judicial and administrative proceedings; limited law enforcement activities, and activities related to national defense and security.

• **Special protection for psychotherapy**

notes: Psychotherapy notes (used only by a psychotherapist) are held to a higher standard of protection because they are not part of the medical record and are never intended to be shared with anyone else. All other personal health information is considered to be sensitive and protected consistently under this rule.

• **Equivalent requirements for government entities:** The final rule applies equally to private sector and public sector entities.

• **Cost of implementation:** The projected implementation costs are $17.6 billion over 10 years.

• **Preserving existing state confidentiality laws:** Stronger state laws like those covering mental health, HIV infection, and AIDS information, continue to apply. These confidentiality protections are cumulative; the final rule will set a national floor of privacy standards that protect all Americans. In circumstances where states have enacted laws to require certain disclosures of health information, the final rule does not preempt these mandates.

• **Compliance and enforcement:** The final rule will be enforced by the HHS Office for Civil Rights (OCR). Before covered entities must comply with the rule, OCR will provide assistance to providers, plans, and health clearinghouses in meeting the requirements of the regulation. A web site on the new regulation is available at http://www.hhs.gov/ocr/hipaa/. ■

review research projects proposed by medical and pharmacy students. The teaching hospital typically has about 10 students working on any given day.

"They're only here for six weeks and can't be waiting a month for all the paperwork to go through," Kline says.

Resident, student projects face same scrutiny

These resident and student research projects typically have involved retrospective studies that are approved by medical faculty and hospital physicians. Now these same small projects will have to be reviewed by the IRB to make certain they meet all of the HIPAA requirements, Kline explains.

"It's going to take a lot of staff time," Kline adds. "And our medical staff donate their time for research committee work, and all they get is a free lunch or a donut and cup of coffee."

HIPAA imposes more requirements on IRBs to review protocols and other investigator documentation in order to make value judgments on whether certain patient health information is needed for the research, says **Lisa Murtha**, JD, chief audit and compliance officer for The Children's Hospital of Philadelphia.

"It's a huge culture shift for academic medicine," Murtha notes. "Academic freedom gives researchers the opportunity to do what they need to do within the auspices of their academic pursuits, one of which is clearly research, so for an institution to place controls and requirements on how researchers use their data will create a rippling effect on institutions."

IRBs have burden of deciding privacy issues

While its a good idea to have a privacy standard that applies to research, HIPAA places a burden on IRBs to make ad hoc decisions on a case by case basis of which information is appropriate to release under various circumstances, says **Robert M. Nelson**, MD, PhD, associate professor of anesthesia and pediatrics for The Children's Hospital of Philadelphia.

Medical facilities and universities involved in research could become victims of unintended consequences of HIPAA, suggests **Clyde Evans**, PhD, vice president of the Association of Academic Health Centers in Washington, DC.

"We would be much happier if we could find a way to safeguard the right of patients to protect their privacy and to give permission when they're willing to, but to balance that against circumstances in which the usefulness of the data could be compromised," Evans says.

Not everyone agrees with HIPAA criticism and concerns regarding research.

"I don't think HIPAA will change things substantially," says **Jon Merz**, MBA, JD, PhD, assistant professor at the University of Pennsylvania Center for Bioethics in Philadelphia.

"It altered standards for waiver and consent, but I think it's filled in some gaps in the common rule with ethical considerations of what should be done," Merz says.

The Center for Bioethics conducted a survey a few years ago asking the admissions departments of 202 large U.S. hospitals in the what kind of forms or consent papers were given to patients discussing the release of information for research purposes, Merz says.

Most hospitals reported only obtaining general patient consent forms when patients were admitted. Out of the 202 hospitals, only 33 had forms that mentioned research uses of the medical record, Merz adds.

"That is pretty absurd," Merz says. "We're doing a large interview study of patients and doctors, looking at confidentiality concerns, and we're finding that patients have very vague ideas about who has access and who should have access to their health information."

Merz says that every single study that uses a medical database should obtain a new waiver from the IRB, and if anything he'd make HIPAA tougher than it is.

For example, he would have IRBs decide against a waiver in research cases where it's unreasonable to expect that patients would not be concerned about their privacy.

"Drug abuse researchers did a study of alcoholics and talked about a waiver of consent because they knew the alcoholics were suspicious of physicians and hospitals," Merz says. "The IRB said they could waive consent from these people because they'd say 'No' if they were asked to sign a consent form." ■

Privacy rule lists these 18 research identifiers

Take these off charts, and the coast is clear

The final rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) says that medical research must protect confidentiality of research subjects by de-identifying protected health information.

The rule lists these 18 identifiers often listed in medical charts that should be removed for the purposes of research:

A. Names.

B. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of a ZIP code, if according to the current publicly available data from the Bureau of Census:

1. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people.

2. The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000.

C. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of 90 or older;

D. Telephone numbers.

E. Fax numbers.

F. Electronic mail addresses.

G. Social Security numbers.

H. Medical record numbers.

I. Health plan beneficiary numbers.

J. Account numbers.

K. Certificate/license numbers.

L. Vehicle identifiers and serial numbers.

M. Device identifiers and serial numbers.

N. Web Universal Resource Locators.

O. Internet Protocol address numbers.

P. Biometric identifiers, including finger and voice prints.

Q. Full face photographic images and any comparable images.

R. Any other unique identifying number, characteristic, or code. ■

NCQA: Standards for VA IRB accreditation finalized

Debut doesn't come without IRB concerns

In the ongoing race to develop accreditation standards for IRBs, the National Committee for Quality Assurance (NCQA) in Washington, DC, has reached the finish line. On Aug. 16, the NCQA published its final standards for the Veterans Affairs (VA) Human Research Protection Accreditation Program standards (VAHRPAP).

The new standards have elicited both praise and concern among the IRB and research communities.

"I believe the final set of standards developed by the VA and NCQA is an excellent beginning in the VA's efforts to standardize and improve the

IRB process," says **John D. Burke**, MA, RPh, chairman of the human studies subcommittee at the VA Medical Center in Louisville, KY.

"It is obvious that we who are responsible for ensuring protection of human subjects in research are expected to be very diligent and proactive in our efforts to ensure this protection," Burke says. "Therefore, I am concerned that we will require more resources and support than we have previously had."

Burke's sentiments are seconded by **Steve Belknap**, MD, assistant professor of clinical pharmacology and medicine at the University of Illinois College of Medicine in Peoria.

"I think the NCQA accreditation program that was developed for the VA has a lot of value," Belknap says. "My concern is that very likely many IRBs will be unable to meet the standards set by the VA Human Research Protection Accreditation Program," he says.

VA standards could be guidelines for all IRBs

Whether or not VA IRBs agree with the new standards, they will need to be prepared for surveys immediately. The first surveyors were dispatched in September, says **Sandra Sanford**, RN, MSN, CCRC, CIP, director of Human Research Protection Accreditation Program for NCQA. **(See story on changes made to the VAHRPAP final standards, p. 31.)**

The Louisville VA Medical Center should have no difficulty meeting the new accreditation standards, provided that a few areas are addressed and several documents are created or revised, Burke says. "I can't honestly say I'm looking forward to this review, but I don't fear it either."

Burke says the only difficulty he anticipates is in providing continuing education for the IRB and researchers.

"While I have been a member of both of our research committees for a number of years, membership does change frequently on the committees," Burke explains. "Often, committee members are just beginning to fully comprehend the responsibilities of the IRB when they have to rotate off the committee."

It's also possible that the new standards will lead to some smaller VA medical centers closing their IRBs, but this should not result in those institutions stopping their research, Burke says.

The smaller VAs might resort to using the IRB of a university affiliate or the IRB of a larger VA.

One of the chief concerns private IRBs and researchers might have is that the VA standards will be used as a basis for a national standard for all IRBs, Belknap says.

If that occurs, one of the likely effects would be that many marginal IRBs would stop functioning, and their function would be turned over to national IRBs that might not encourage input from local communities, Belknap adds.

For example, IRBs need to know the competence and experience of people conducting research, and some of the information IRBs need to assess competence is derived from personal contact with the researcher. Smaller, community-based IRBs typically do not rely entirely on a researcher's curriculum vitae (CV), Belknap explains.

"So if you had a national IRB they wouldn't know that investigator personally and might make a judgment based only on the researcher's CV," he adds.

Smaller IRBs also have the flexibility of speaking directly with researchers to discuss the protocol, and this way the IRB can resolve many minor research issues without having to delay the project due to paperwork changes, Belknap says.

Sanford says that it isn't NCQA's intent to create IRB standards that mirror the VA human research accreditation standards.

"There are clearly pieces that are pertinent only to the VA," Sanford says. "We fully recognize that these standards are not immediately transferable or generalized to the outside world."

NCQA now is engaged in a process to develop a potential business plan and feasibility study to determine whether the organization will develop non-VA IRB standards, Sanford adds.

Burke says that the NCQA VAHRPAP standards are an excellent beginning for standards to be developed for IRBs in the private sector.

"Very minor parts of the VAHRPAP differ from IRB requirements currently applied in many universities or private IRBs," Burke notes.

Also, it will be easier for other organizations to develop new IRB standards because the VA standards can serve as a set of guidelines, Burke says.

Everyone involved in human research would like to prevent problems, Burke adds.

"We need to suppress the very large egos of individuals and institutions and admit that we have sometimes become careless and arrogant in our conduct of research," Burke says. "We are dealing with human beings and they deserve our respect, our vigilance, and our concern when we ask them to submit to research." ■

Major changes to the final VA standards explained

Changes were prompted by VA comments

IRBs that have reviewed the preliminary Veterans Affairs (VA) Human Research Protection Accreditation Program standards, created by the National Committee for Quality Assurance (NCQA) in Washington, DC, should keep in mind that several changes were made in the final version, partly in response to comments made by VA employees.

"There are three major changes from what was put out in March," says **Sandra Sanford**, RN, MSN, CCRC, CIP, director of human research protection accreditation programs for NCQA in Washington, DC.

Also, there are two issues that received comments but did not result in big changes to the final standards. Those issues were about research involving children or prisoners. VAs typically do not engage in that type of research, Sanford notes.

"There is potential for someone to do prisoner research if a subject is enrolled and then later becomes a prisoner," she adds. "But the VA does have a policy of not doing research on children because veterans are not children, although Congress did instruct the VA to conduct a study that has to do with the effects of Agent Orange in children of veterans."

Nonetheless, these areas were not among the major changes that were made to the final standards. The three changed areas are as follows:

1. Research and development (R&D) committees: The final standard refers to an institution's R&D committee and states that the R&D committee will conform to VA policy regarding human subjects research, with the following responsibilities:

- The R&D committee is responsible for the scientific quality and appropriateness of all research involving human subjects.
- The R&D committee re-evaluates, at least annually, the scientific quality of all research studies involving human subjects to assure protection of human subjects.
- The R&D committee membership, supplemented as needed by advisors or consultants, possesses the expertise required to perform the scientific review.
- The R&D committee cannot alter an adverse report or recommendation, such as disapproval for ethical or legal reasons made by the subcommittee on human studies.

To be scored 100%, the R&D committee must meet all four factors. Otherwise the committee receives 0% in scoring.

Initially the R&D committee requirements were not included in the standards, Sanford notes.

"That came from public comments," she explains. "The VAs have a unique reporting system; unlike other IRBs they may report to different individuals or departments, but are freestanding committees, and the VA felt it was important the standards represent their unique structure."

Everything in the standards about the R&D committee is drawn from VA policy, Sanford adds.

2. Pharmacy: The final standards include a specific requirement for pharmacy services, including a distinct policy on the control and dispensing of investigational products.

This change was also in response to VA comments about existing policies on pharmacies, Sanford says.

The requirement is INR6, which reads, "The institution ensures that the use of investigational products in research with human subjects is consistent with VA and federal regulations."

The requirement further instructs the institution's pharmacy service to have policies and procedures for handling investigational drugs that address five factors: receipt, storage, security, dispensing, and disposition of unused stock.

Scoring is graduated with 100% given when all five factors are addressed in the policies and procedures; 75% when four factors are addressed; 50% when three factors are addressed, and 0% when less than three factors are addressed.

Pharmacy service must maintain an investigational drug log, which includes the name of the drug, manufacturer or other source, date of receipt of the drug, quantity received, expiration date, control number, date the protocol is approved, and name of authorized practitioner signing the prescription.

There are five other elements to the requirement, and the last one is that the results of pharmacy service evaluations are reported to the R&D committee or other institutional official with responsibility for oversight of the research pharmacy.

3. Continuing review: The third major change from the preliminary standards involves a clarification of the distinctions between two

types of continuing review that IRBs conduct, Sanford says.

"One type is the continuing reviews that occur at pre-established time frames set by IRBs," she adds. "When they review a project they say it needs to be reviewed in 'X' period of time, a minimum of one year, and the other is a review that goes on during the life of a research study."

Requirement IRB7 states, "The IRB uses required and relevant information to conduct continuing review of research at specified intervals and requires changes as appropriate."

The first element of this requirement states that the IRB has policies and procedures for the conduct of continuing review that include consideration of the following: changes to the research; adverse event reports; safety reports, including IND, IDE, and MedWatch; protocol violations and/or deviations, and investigator noncompliance, including noncompliance with IRB requirements for frequency of periodic continuing review.

Policies and procedures must address all five factors to receive a 100% score or receive a 0% score.

Comments about the standards' first version expressed concern about how continuing reviews are handled during the life of a trial and as amendments are made, so the final version makes these distinctions clearer, Sanford says.

"It appeared that when people read our first version, they thought we had not addressed that ongoing research issue," Sanford says. "We thought we had addressed it and that we had written it clearly, but obviously we had not; so we made some clarifications in that." ■

Can cash motivate patients to volunteer for trials?

Ensure risk levels do not determine monetary value

Would you participate in a medical research project that required you to periodically give blood, undergo invasive diagnostic screenings and tests, and spend significant parts of each week at a local hospital undergoing these procedures? What if the results of the research project would provide no benefit to you, but could one day lead to a cure for a fatal disease?

What if researchers offered to pay you $50? Or $500?

What amount of compensation is needed to encourage people to participate in research projects? Does compensation for participation violate the principles of informed consent by "coercing" someone to participate when they would ordinarily refuse?

These are questions that many IRBs are struggling with as pressure from the private sector mounts to recruit more and more people to participate in medical research projects. Pharmaceutical companies, in particular, are eager to get their drugs through required clinical trials — and they have the financial capital to "recruit" as many people as they need.

"Concern has been expressed that the offer of money could compromise the voluntariness of someone's decision, in essence influencing them to do something contrary to their interests or values," explains **Christine Grady**, RN, PhD, a researcher in the department of clinical bioethics at the National Institutes of Health.

Grady recently published a paper examining this topic in the Spring issue of the *American Journal of Bioethics*.[1]

In fact, Grady concludes, money is just one of a number of factors that might influence a person's decision to participate in a research project. Other factors might include the availability of a medical procedure or product not otherwise available or the chance to receive free medical care.

As long as the amount of money offered is not excessive, the payment can be seen as just compensation for the time and contribution that subjects made and an indication of respect for the subject, she says.

The question is, at what point does simple compensation end and coercion begin?

"IRBs or their institutions should establish guidelines for determining when and how much should be offered to participants in a study," Grady says. "Guidelines would provide a rationale for payment, and preferably a formula or a basis for calculations. This way, decisions would be standardized within an institution (and thus fair), and IRBs have some framework for their particular decisions."

Decisions made on case-by-case basis

Many institutions that sponsor research, particularly those who receive federal grants, do have guidelines on payments made to research

participants. These guidelines are published, along with other requirements investigators must meet, in the respective institution's research guidelines and on their web sites.[2,3]

However, establishing a standard formula for paying participants would be difficult, says **Ada Sue Selwitz**, director of the office of research integrity (ORI) at the University of Kentucky in Lexington. The ORI oversees all research conducted at the university and supervises three medical IRBs and one nonmedical, scientific IRB.

"IRBs have to look at a number of variables in trying to decide, first of all, is it appropriate to pay subjects, and, if so, how much is appropriate and when is it too much?" she says.

For example, if the study group is primarily people living in a third world country, even a small dollar amount of cash compensation could be coercive. Yet, a similar amount of money would not be a significant incentive to a study group drawn mostly from middle-class people living in this country, she says.

"That is the first criterion you look at: What is the study population? And, in that context, is the proposed amount appropriate," she explains.

The IRB at the University of Nebraska Medical Center in Omaha tries to focus its compensation on reimbursing participants for the time they must spend participating in the various parts of the research, says **Ernest Prentice**, PhD, vice chancellor for academic affairs and IRB co-chair.

The amount might vary from study to study based on what was asked of the people involved.

"We base our compensation levels on what would be a reasonable hourly rate for the time spent in preparation for, participation in, and recovery from a particular research intervention," he explains.

For example, if participants must undergo a bronchoalveolar lavage, they would have to come to the hospital, undergo anesthesia, undergo the procedure, recover from the procedure at the hospital, and most likely be accompanied home by a companion, he says. "They probably wouldn't recover from the anesthesia for a couple of hours. They probably would have a sore throat and maybe a little bit of fever. Clearly, it is inconvenient."

The researchers should come up with an amount that compensates those participants for the time they must spend involved in the research from beginning to end — in this instance, the time spent going to the hospital, undergoing the procedures, recovering from the procedures, plus compensating the person who is needed to accompany them.

"We usually use the reasonable hourly rate figure of around $10 per hour," he says. "Obviously, if the person is a CEO making $300, this is not his or her normal hourly compensation, but we aren't going to go there. This is a reasonable compensation for the time spent."

The focus, he says, is really to eliminate any disincentives to research participation rather than really "compensating" them for the service, he says. "We don't want anyone to assume financial liabilities for taking part."

The IRB would like to move toward having a set compensation amount for every procedure that a research study might perform, Prentice adds. "We would like to have more standard, definitive guidelines in place. And we are trying to work on what would be a reasonable dollar amount for performance of a whole series of procedures — from bronchoscopy with lavage all the way to a skin biopsy."

Don't link payment amounts to risk

One benchmark that should not be used to determine the level of compensation, both Prentice and Selwitz say, is the level of risk involved.

"The level of payment must *never* be based on the level of risk," says Prentice. "You do not elevate the amount of compensation you deem acceptable."

In the past, some IRBs considered this an acceptable way of compensating participants, but this is now thought to be clearly coercive, Selwitz says.

"Some used to say, in approving a protocol, if it is really risky you get, say, $1,000," she says. "If there is less risk involved, $50. I don't think anyone is doing that anymore."

You don't want payment to be the reason that people agree to participate in, and remain in, a very risky study, she explains. "If it is a high-risk study and there is no potential benefit to the participants — no chance of a medical benefit — then the IRB is going to look very closely at the dollar amount."

Payments should be prorated

Both Selwitz and Prentice also recommend that IRBs require payments to subjects to be prorated, if the project involves multiple appointments or

tasks over days or weeks.

"The payment schedule can make a difference in whether the payment is coercive or not," says Selwitz. "We don't allow there to be a lump sum at the end of the project, conditional upon the person completing the project. They must feel free to withdraw at any time."

The University of Kentucky IRBs require that subjects be paid for each portion of the project they complete, whether they remain in the study to the end or not.

Prentice encourages investigators to pay subjects a selected portion at each visit, and that the amount be tied to the amount of time involved.

"Say you have five visits. The first visit is pretty extensive, so you pay the person $50," he says. "The second visit involves significantly less time so you pay the person $25."

Under no circumstances, should there be a "bonus" for completing the project — such as a payment schedule that lists the last visit as worth twice as much as the previous visits, Prentice says.

Should children be compensated?

A major controversy in payment of research subjects has been the question over whether children should be given compensation for participation in research, or whether their parents should receive compensation.

"What happens when the person you are enrolling is a child?" asks Selwitz. "That is a different issue. "If you offer cash compensation to the parents, you can run into situations where the parent says, 'My child will participate whether he wants to or not.' Because the parent wants or needs the money."

Should you pay the children directly? Even a small amount of money could be coercive to a child, she says. "Many IRBs have chosen not to offer compensation for children involved in research at all."

Instead of cash, some investigators offer the child a small coupon to a toy store or small gift certificates, she says. "Sometimes, an IRB will be OK with that and sometimes they won't."

The University of Nebraska IRB does not compensate children at all, but will make cash reimbursements to parents for their time in taking the child to and from the medical center, says Prentice.

"We are not going to hand $10 to a child. Anything, whether it is money, pizza, gift certificates, we are very concerned about that," he adds.

Some IRBs, deciding that cash is inherently coercive, will allow compensation only in other forms, says Selwitz.

"Some IRBs allow payments, but not cash payments," she explains. "Particularly with vulnerable populations like children, or with [college] students. Some IRBs feel that students are already in a coercive situation. So, if you give them a free pizza or gift certificate, as opposed to $20, is that less coercive? Some IRBs say yes, and some do not."

Prentice agrees with Grady that there are issues other than compensation for participation that have more potential to be coercive. And, IRBs have to be sure to be aware of these, as well.

"You have to look at why people participate in research," he says. "The first reason is usually to get a particular drug or procedure that they feel may offer them some hope, but they may not have access to outside a research trial. Second, they may not have health insurance and may see the research as a way to get free medical care."

The second issue, in particular, has the potential to be very coercive and the IRB must be extremely careful to look at the planned study population and how investigators intend to recruit participants.

Ask for details

"We ask for a rather detailed description of the target population," he says. "In terms of demographics, we want to know what the age range is, the gender, ethic minority status, where they are going to recruit subjects from, and how they are going to recruit them," he says.

It is important that poor people and minorities, who traditionally have less access to health care, are included in research efforts. But, it is important to ensure that these populations are not targeted because they will be less likely to refuse, or less likely, once enrolled, to leave the project.

"If the investigators say, we're going down to the Last Chance Clinic in north Omaha, which has a high percentage of poor African-American people, and that's where we're going to get our people, that is a red flag to us. We need to have balance. You have balance access to the benefits of research participation, without coercing people into a project and accepting risk that they would not ordinarily do so. It is a hard balance to achieve."

Need More Information?

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- **Christine Grady**, RN, PhD, Department of Clinical Bioethics, Building 10/Rm1C118, National Institutes of Health, Bethesda, MD 20892.

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Few med students trained in adverse drug events

Only 16% of internal medicine clerkship programs include formal lectures about adverse drug events, according to a new study published in the Sept. 5 issue of the *Journal of the American Medical Association*. Study results indicate that medical students in the United States have little exposure to information on adverse drug events in the curriculum used during their internal medicine rotation.

The study, sponsored by the U.S. Agency for Healthcare Research and Quality (AHRQ), with additional funding from the Food and Drug Administration, also found that 35% percent of clerkship directors had little or no familiarity with the 1999 Institute of Medicine report on medical errors, "To Err is Human: Building a Safer Health System." After reading a brief summary of the report, 83% of clerkship directors said that heightened surveillance and training should occur to help decrease adverse drug events.

Sixty-five percent of the clerkship directors said that they would incorporate one or two hours of educational materials on adverse drug events if slide shows or Internet-based educational modules were available. Only 41% of clerkship directors would welcome an outside speaker to lecture on the topic.

The study was carried out by AHRQ's Center for Education and Research on Therapeutics (CERTs) at Georgetown University in Washington, DC, and was based on a survey of 79 U.S. internal medicine clerkship programs that was conducted in the spring of 2000. Internal medicine clerkship programs were chosen for the survey because medical students spend an average of 12 weeks on this rotation, more than any other required clinical experience during their medical training. The study did not assess the impact of the lack of information on adverse drug events on their training overall. ■

IRB Advisor (ISSN 1535-2064) is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **IRB Advisor**, P.O. Box 740059, Atlanta, GA 30374.

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Subscription rates: U.S.A., one year (12 issues), $299. With CME: $299. Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $269 per year; 10 to 20 additional copies, $239 per year. For more than 20, call customer service for special handling. **Back issues**, when available, are $50 each. (GST registration number R128870672.)

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Hospital closures higher this year

During the first half of this year, 24 hospitals with 4,088 staffed beds have either closed their doors — partially or entirely — or announced plans to do so, compared with 20 for the same six months last year, according to an Ohio health care consulting firm.

Dynamis Healthcare Advisors of Cleveland said the closure trends this year are similar to those exhibited in 2000. Five of the 2001 closures have been in rural communities, and 19 were urban hospitals. Seven of this year's closures were for-profit and 17 were not-for-profit facilities.

Geographically, most of this year's closures were in the Midwest, followed by the East Coast. Ohio led the list of closures with four closures or announcements. At the same time last year, Ohio also led the list with five. Closures to date in 2001, according to the report, have affected 4,203 staffed beds and approximately 13,000 employees. For more information, go to www.dynamis-hc.com. ■

CME*questions*

The CME objectives for *IRB Advisor* are to help physicians be able to:

- establish clinical trial programs using accepted ethical principles for human subject protection;
- understand the regulatory qualifications regarding human subject research;
- comply with the necessary educational requirements regarding informed consent and human subject research;
- apply the necessary safeguards for patient recruitment, follow-up, and reporting of findings for human subject research;
- have an understanding of the potential for conflict of financial interests involving human subject research;
- understand reporting adverse events during research.

9. Health care organizations and representatives of hospital and university-based research facilities say the privacy regulations proposed under the Health Insurance Portability and Accountability Act of 1996 will:
   A. impair clinical trials.
   B. place onerous burdens on IRBs
   C. restrict the number of studies conducted in the U.S.
   D. all of the above
10. According to Melissa Bartlett, JD, legislative counsel for the American Medical Group Association, which of the following characteristics should be allowed to remain in research data?
   A. Patient's names
   B. Dates
   C. Patient's address
   D. All of the above
11. Among those who share concern over the new (Veterans Affairs) VA Human Research Protection Accreditation Program standards is Steve Belknap, MD, assistant professor of clinical pharmacology and medicine at the University of Illinois College of Medicine, who feels:
   A. the VA program standards are too lenient for non-VA-related programs.
   B. the time line set by the accrediting body for compliance is unrealistic.
   C. many IRBs will likely be unable to meet the standards set by the VA program.
   D. all of the above
12. A recent study authored by Christine Grady, RN, PhD, of the department of clinical bioethics at the National Institutes of Health, concludes that there are several coercive factors that influence a person's decision to enroll in a clinical trial. The biggest factor is:
   A. money.
   B. availability of a medical procedure otherwise not available.
   C. availability of receiving free medical care.
   D. all of the above