AMERICAN HEALTH CONSULTANTS®

IRB ADVISOR

*Your Practical Guide To Institutional Review Board Management*

## INSIDE



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# IRBs often have questions about dealing with student research

*When should it be reviewed, how to educate*

Student research sometimes falls between the IRB cracks usually because faculty and physicians may not be aware of the importance for an IRB review of all research involving human subjects.

As IRBs face increasing scrutiny and research institutions are finding that all research conducted by their faculty, staff, and students can be at risk for legal and regulatory problems, IRBs are beginning to take a closer look at student research.

"The regulations that IRBs are expected to follow are silent on making a distinction on what happens in school settings and pedagogy and student research," says **Moira Keane**, MA, director of research subjects protection program at the University of Minnesota in Minneapolis.

So it's left to individual institutions and IRBs to decide the answer to the question: What constitutes real student research?

"The question is whether or not it's really being done for research purposes or training purposes," says **John M. Cavendish**, EdD, JD, CRA, an associate professor of occupational therapy at the Shenandoah University in Winchester, VA. Cavendish is a member of the university's human subjects review board.

"Say you have a research class, and they'll administer each other surveys and the process is to learn how to construct a survey and analyze results," Cavendish says. "Then you have something different from if you have a graduate student doing a thesis and who is surveying middle school students and analyzing their attitudes about drugs and alcohol."

That type of pedagogical research will never be published, only involves fellow students in a common setting, and is not intended for any purpose other than to help students learn the process. That would appear to be a place where an IRB could draw a line and say that such projects do not require IRB review. Yet, not all IRBs would agree.

"Other colleagues will say that students' research does not contribute to generalizable knowledge, and therefore, IRB rules don't apply, but we

take the opposite stand," Keane says. "We believe that we are training the next generation of research scientists; these students should be fully versed in the requirements for conducting research, and one of those requirements is IRB review."

One way to handle IRB reviews involving student pedagogical research would be to have the faculty advisor/instructor submit a research proposal for approval and then use that very same project for all students, so the one review will suffice, Keane suggests.

"If students do an independent project as part of a master's thesis or undergraduate senior thesis or graduate project, then it should be handled separately," Keane adds.

### Decide where to draw the line

Student research is a gray area that each IRB should consider, says **Miguel Roig**, PhD, associate professor of psychology at the Notre Dame division of St. John's College in Staten Island, NY.

"Technically, as I understand the regulations, if the activity is not for research purposes, then it should not be sent to an IRB," Roig says.

However, unpublished student research that was conducted for research purposes should be reviewed by an IRB, Roig adds.

For example, at St. John's University, there are some master's-level research projects that conceivably could be testing novel hypotheses, although they most likely will end up in a professor's slush pile, Roig explains.

"But if they are implemented as if they are research, actual research, then in those cases the projects ought to be reviewed by an IRB, in my opinion," Roig says.

IRBs should decide where it draws the line in defining research that requires an IRB review, whether it's at the dissertation, master's thesis, or undergraduate level, and then it could set a policy so that faculty and students will have some idea of what will be required. Otherwise, there often is some confusion and varying interpretations.

For instance, Cavendish recently asked members of IRBs on an IRB Internet list service whether they thought this particular scenario constitutes research and whether it should require an IRB review:

- "A class data set consisting of blood pressure, resting pulse, height, weight, and a few similar variables is collected at the beginning of the term from students in a research course. These data will be used in class to demonstrate how to conduct various statistical analyses. No further use will be made of the data, and results will not be published."

While some IRB members wrote Cavendish to say that this scenario should not result in an IRB review, others said the opposite.

Keane and Roig note that this particular pedagogical exercise should not be conducted as written, and therefore it might require an IRB review.

"You can do all kinds of things inside the classroom that represent experiment studies that are pedagogical exercises that perhaps should not be done in class," Roig says. "What occurred to me about that scenario is the question of whether we should have students ask peers personal information about their weight and blood pressure."

Faculty should be sensitive to these types of issues because weight, height, and other personal physical information can be highly sensitive to certain individuals and therefore are unsuitable data to be collected in a classroom setting, Roig says.

"Weight is not a low-risk question among young women particularly," Keane says in agreement. "Body image and weight and all encumbrances of those issues can have an effect on developing eating disorders."

Keane says her IRB would have approved part of the research, but not the collection of data on weight and height.

From an alternative perspective, students who conduct research often believe that the IRB creates unnecessary burdens and road blocks in their efforts to complete projects, says **Deana Katz**, MBe, research ethics outreach coordinator at the Center for Bioethics at the University of

### COMING IN FUTURE MONTHS

- Maintaining privacy during Internet research can be tricky
- IRBs offer advice for preparing for an FDA audit
- Dealing with consent, storing, and patient notification with regard to tissue procurement
- Will bioterrorism put stem cell research on the back burner?
- Get the community involved in informed consent

Pennsylvania in Philadelphia.

It particularly grows complicated when the student research is in the social sciences area, such as a project that involves obtaining oral histories or having a student become immersed in another culture, as in ethnography, Katz says.

"These students won't collect research in the same way, and the IRB may not understand their methods at all," Katz says. "So what the IRB will wind up doing is focusing on what they do understand, and they may pick apart things."

Safety issues are different in the social science area, and students may have a legitimate complaint that an IRB designed from a biomedical model doesn't understand their issues, Katz adds.

This is why balance should always be a consideration, Cavendish suggests.

"The role of the IRB is not to thwart research, but to protect human subjects," he says. "We don't want to set up unreasonable barriers."

For instance, at another university where Cavendish worked, there was an IRB policy to review every single funding proposal that went out, even if it was only to buy a couple of computers. All were subject to quorum review, leading to an environment in which the faculty was discouraged and research was stagnated.

## Don't get stymied by bureaucracy

Once the policy was changed so that items reviewed were those that were required by federal regulations, the research volume — in terms of funding — was increased fourfold, Cavendish says.

"My guess is that 90% or better of the research that had previously been reviewed by the IRB now was exempt from review," he explains. "So you can see in a case like that, it's not just erring on the side of caution — it's really throwing up barriers."

These are all reasons why it's important for IRBs to offer education and training about human subjects' protection to students, faculty, and others, so that they'll know when research should be submitted to the IRB for approval. **(See story on educating students and faculty about IRBs, p. 64.)**

"One thing that would be undesirable would be for IRBs to start looking at all sorts of projects that don't have anything to do with actual research," Roig says. "But that leaves us with situations where we have student assignments that ought to have some sort of ethical component and ought to be reviewed by someone."

Another issue involves faculty advisors, physician researchers and advisors, and research instructors.

## Demystify the medical myth

"Some faculty advisors, and I'm sure it's not just at this institution, say, 'I'm not sending the research through the IRB,'" Cavendish says.

In other situations, faculty advisors might not be aware of the IRB process or they are unaware that student research can require an IRB review.

"We have to change the culture of understanding of what requires an IRB review and what doesn't," Keane says. "And sometimes it's working with historic myths that only faculty research or funded research requires IRB review."

These myths can create misunderstandings, particularly in social and behavioral sciences departments where faculty may feel the IRB process has a medical bias and so their work doesn't fit into the IRB review process.

Some universities and IRBs have established a checks-and-balance system that is designed to identify university-generated research that involves human subjects and was submitted to the IRB for review.

This system could be done informally, such as IRB members hearing of an instructor who has graduate students who are involved in research that hasn't been submitted, or by having someone check faculty course offerings against IRB reviews to see whether there are some instructors who teach research or are advisors to graduate thesis projects and who haven't submitted proposals for approval.

In a more formal scenario, some universities and IRBs have collected information on published studies that generated from a particular university's staff and students and then compared this information with proposals submitted to the IRB. When cases are identified that did not use the IRB process as required, then someone is assigned to contact and educate those professors, Katz says.

"I know of a major research institution that is monitoring things this way, and I think it's a great idea," Katz adds.

When an IRB coordinator learns of a faculty member who is not instructing students to submit research for IRB review, it's best to take a diplomatic approach in dealing with the instructor, Cavendish says.

"The first step is an informal call and meeting with the chair of the IRB," Cavendish suggests. "The chair would meet with the person and explain the IRB requirements, and I think probably a majority of faculty at that point would say, 'OK, I don't like it, and I don't agree with it, but I'll at least do it.'"

A good, nonthreatening approach would be to tell the faculty member: "This is something you probably never thought about, and it's new to all of us, but things have changed generally and at this institution, and here's how it affects you," Cavendish says.

It also might not hurt to mention that if the university is sued over a student's research project, then the faculty member likely will be named in the lawsuit, as well, he adds.

"There have been lawsuits where, for example, a student took a survey in a public school that was offensive to parents and the parents had not given permission," Cavendish notes.

Some universities and IRBs might take the whole process a step further and require all faculty advisors to students conducting research to be named the principal investigator, but this is not necessary. ■

# Education is key ingredient in successful recipe

*Many IRBs are just beginning these programs*

College students and the instructors, advisors, physicians, and others who work with them on research projects should be educated about the IRB's role and the process for obtaining approval to conduct human subjects research, experts say.

"On our campus, we have a highly evolving responsible conduct of research requirement for faculty researchers, and we require graduate programs to develop coursework in ethical and responsible conduct of research," says **Moira Keane**, MA, director of the research subjects protection program at the University of Minnesota in Minneapolis.

There also are graduate seminars in ethics and clinical trials, and faculty are required to take workshops in responsible conduct in research as well as a human subjects module when applicable, Keane says.

At Shenandoah University in Winchester, VA, there's an introductory research course that discusses ethics, human subject protection, and scientific misconduct, says **John M. Cavendish**, EdD, JD, CRA, associate professor of occupational therapy.

"We're in the process of educating our faculty advisors now and revamping our policies and procedures," Cavendish says, adding that the university's top administrators have taken an interest in making certain that staff and faculty meet all regulations, policies, and procedures with regard to research.

Keane, Cavendish, and others offer these strategies for educating faculty and students about human subjects protection and the IRB's role:

**• Make forms, information accessible to all.**

As part of Shenandoah University's educational efforts, all of the IRB's processes and forms are available on the Internet at the university's web site: http://www.su.edu.

"The best thing an IRB can do, besides its job, is to make processes and forms as user-friendly as possible," Cavendish says.

These are updated when necessary and include a simple checklist that students or faculty can use to determine whether their research project is exempt for IRB review or qualifies for an expedited review. **(See Shenandoah policy form, pp. 66-67.)**

The web site also includes various forms listing questions and information pertaining to IRB review, including a Form B that is an application for the use of human subjects in research. **(See Shenandoah application for use of human subjects in research, inserted in this issue).**

**• Give faculty, students someone to contact for advice.**

Another educational strategy would be to have various IRB members, who are from different areas of the university, serve as resources to faculty and students who have questions about the IRB process. This way, the instructor or student can call the point person for his or her department when there's a dilemma or question about the need to submit research for review, Cavendish says.

Likewise, some universities may establish a committee in each department that will review all research projects that do not need a full IRB review. This way, there will be some oversight.

There's a need for an ethical supervisory review process for pedagogical and other research that falls into the gray area with regard to the IRB review, says **Miguel Roig**, PhD, associate professor of psychology at the Notre Dame Division of

St. John's College in Staten Island, NY.

**• Offer training and courses in human subjects protection and ethics.**

Research instructors could employ strategies for teaching students about IRBs that include having students read sample IRB proposal forms, the Belmont report, all federal regulations, and the IRB's own policies. Then they could have the students hold a mock IRB session discussing the mock proposal's merits and problems.

At St. John's College, there are some research courses available at the graduate levels that include information about IRBs, and there has been some discussion about making this training a requirement for all students involved with research, Roig says.

At the University of Pennsylvania, there's a post-doctoral training program and students are required to receive research ethics training through an on-line training module on human subjects research, says **Deana Katz**, MBe, research ethics outreach coordinator for the center for bioethics at the University of Pennsylvania in Philadelphia.

Even hospitals that have no direct university affiliation could benefit from having medical staff who engage in research take such courses, says **Cynthia A. Harper**, IRB coordinator for Our Lady of the Lake Regional Medical Center in Baton Rouge, LA.

"We've had a couple of situations where we've had to educate physicians that a research project couldn't be done," Harper says. "In some cases, the physicians didn't even know that what they proposed to do would be defined as research."

### The best-kept secret

"The IRB is the best-kept secret in the hospital," Harper says. "One thing we're focusing on with a task force is educating physicians and senior management so they'll know what IRBs are all about."

Now Harper gives physicians a packet of information about research and ethics, along with a videotape about human subjects protection from the Rockville, MD-based U.S. Food and Drug Administration.

Interestingly, Harper has found that medical students and residents who work at the hospital often are better educated about human subjects protection than the physicians who advise them. The students often have already received some training from their colleges. ■

# Conflict-of-interest report includes IRB guidelines

*IRBs should work closely with conflict committees*

A recent report offers universities, researchers, and IRBs guidance in navigating the tricky channels created by increased funding and collaboration in research by universities and private industry.

"One of the reasons for our taking up this issue of conflict of interest is that the number of collaborations between universities and industry and pharmaceutical companies has escalated," says **Nils Hasselmo**, president of the Association of American Universities (AAU) in Washington, DC.

The AAU formed a task force on research accountability that released in October 2001 the *Report on Individual and Institutional Financial Conflict of Interest*.

"These collaborations have escalated, and we operate on the assumption that these are beneficial relationships, but they need to be monitored so credibility of research is not undermined," Hasselmo says.

The AAU's motivation is both to offer universities guidance on how to protect themselves against having produced research where results were skewed because of an investigator's personal financial interest and also to prevent the public from perceiving this to be the case when it isn't true, Hasselmo says.

Although the AAU report recommends universities form conflict review committees, it also notes the important roles that IRBs have in this process.

### Disclose financial information

For example, one recommendation is that universities disclose financial information in the human participant review process, giving the campus IRB jurisdiction over determining whether a relevant financial interest should be disclosed to human participants in research. **(See article about AAU recommendations, p. 69.)**

"Essentially, the bottom line is that there needs to be coordination between the IRB and the other entity with the institution that

*(Continued on page 68)*

# SHENANDOAH UNIVERSITY

HUMAN SUBJECTS REVIEW BOARD

## POLICY

Shenandoah University's policy requires review and approval of all activities which involve using human subjects in research. The Human Subjects Review Board (HSRB) serves as the University's Institutional Review Board (IRB) which is responsible to the Vice President for Academic Affairs. Approval of the HSRB must be obtained prior to involvement of human subjects. Failure to have human subjects research reviewed by the HSRB, including those protocols believed to be exempt, is a violation of University policy and will be reported to the Vice President for Academic Affairs for disciplinary action.

## SELECTING YOUR REVIEW CATEGORY

IF YOUR PROJECT MEETS ALL OF THE FOLLOWING CRITERIA, YOU SHOULD SELECT EXEMPTION REQUESTED REVIEW:

- ❑ Research conducted in established or commonly accepted educational settings
- ❑ Research involving the use of educational tests if subjects cannot be identified
- ❑ Research involving surveys, interviews, or observations of public behavior that do not deal with sensitive or critical responses. All research using survey or interview procedures is exempt when the respondents are elected or appointed public officials or candidates for public office.
- ❑ The project will not involve subjects in high risk groups (See Form A, Item 11).
- ❑ Research involving the collection or study of existing data or specimens that are either publicly available, or not individually identifiable.

IF YOUR PROJECT MEETS ANY OF THE FOLLOWING CRITERIA, YOU SHOULD SELECT EXPEDITED REVIEW:

- ❑ Collection of hair, nail clippings, dental plaque and calculus, or teeth in a non-disfiguring manner, or secretions.
- ❑ Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice.
- ❑ Collection of small (≤ 450 ml per 8 weeks, and ≤ 2 samples per week) amounts of blood by venipuncture from subjects 18 years of age or older and who are in good health and not pregnant.
- ❑ Voice recordings made for research purposes such as investigations of speech defects.
- ❑ Moderate exercise by healthy volunteers.
- ❑ Study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- ❑ Research on individual or group behavior where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- ❑ Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

IF YOUR PROJECT DOES NOT MEET ALL OF THE CRITERIA FOR EXEMPTION REQUESTED REVIEW OR EXPEDITED REVIEW, YOU MUST SELECT FULL REVIEW.

## REQUIRED DOCUMENTS

IF YOU SELECTED EXEMPTION REQUESTED REVIEW, YOU MUST SUBMIT THE FOLLOWING ITEMS:

- ❑ Form A
- ❑ Form B
- ❑ Explanation of study for subjects (informed consent-optional)
- ❑ Consent for photographic or voice recording (conditional)
- ❑ Letter of approval from each cooperating organization's institutional review board or administrative representative (conditional)

IF YOU SELECTED EXPEDITED OR FULL REVIEW, YOU MUST SUBMIT THE FOLLOWING ITEMS:

- ❑ Form A
- ❑ Form B
- ❑ Informed consent form
- ❑ Consent for photographic or voice recording (conditional)
- ❑ Letter of approval from each cooperating organization's institutional review board or administrative representative (conditional)
- ❑ Electrical equipment safety check memo (conditional)

BEFORE YOU SUBMIT YOUR PROPOSAL, PLEASE CHECK THE FOLLOWING ITEMS FOR COMPLETENESS:

- ❑ All signatures are obtained on Form A
- ❑ Correct number of copies of non-electronic items are included for distribution to HSRB members
- ❑ Start date will allow sufficient time for review to be completed before involving subjects
- ❑ Current forms are being used (E-mail the compliance coordinator at su_comply@su.edu to verify current versions)
- ❑ Method of confidential storage of data is fully described

**IT IS VERY IMPORTANT THAT YOU ALWAYS PROVIDE YOUR PROTOCOL IDENTIFICATION NUMBER WHEN CORRESPONDING WITH THE COMPLIANCE COORDINATOR.**

*Source:* Shenandoah University, Winchester, VA.

(Continued from page 65)

manages conflict-of-interest disclosure as it relates to how research is implemented," says **Mark Brenner**, PhD, vice chancellor for research and graduate education at Indiana University — Purdue University Indianapolis, and associate vice president for research for Indiana University in Indianapolis. Brenner was a member of the task force that wrote the AAU conflict-of-interest report.

## Conflicts come in all sizes

Conflict of interest is not always of a financial nature. There also are conflicts of commitment, such as when an investigator is giving all of his or her attention to one project at the expense of other duties, notes **David Skorton**, MD, vice president for research at the University of Iowa in Iowa City. Skorton is a member of the AAU task force and the first president of the Association for Accreditation of Human Research Protection Programs, which is the first national accreditation program for human research programs.

"Then there is the conflict of interest of resources," Skorton says. "Is the person using resources for his or her own good rather than for the university's best interests?"

To meet National Institutes of Health requirements, most universities have a conflict-of-interest committee that focuses on financial conflicts, but the AAU report goes a step further: "What we're saying in this document is that institutions should address conflict of interest regardless of funding, and that management needs to be done by a committee ideally," Brenner says.

For several reasons, it's not a good idea to have the IRB fulfill dual duties and be the committee that looks at conflict-of-interest issues, as well as human subject protection, Skorton and Brenner say.

"The AAU position recognizes that there is a lot more to this than what the IRB normally has to deal with, and we'd like to keep the IRB focused on protecting research participants," Brenner says. "But this has to be worked out according to what's most appropriate for a research institution."

IRBs already are enormously burdened with their traditional responsibilities that will only increase, so there is no reason why they should be asked to take on the duties of a conflict-of-interest committee, which will review nonhuman research as well as research involving human subjects, Skorton says.

"It's not really fair to ask a group of people who were brought together in one area of human subject protections to review another area," he points out.

However, when the research involves human subjects then it needs to be coordinated between the conflict-of-interest review committee and the IRB, Brenner says.

## Develop a strategy

Here are two strategies for how this can work, Brenner says:

• **Model 1.**

Disclosures are sent through the general conflict review process, and when human subjects are involved, they refer it for additional review by the IRB.

"They each have a certain level of independence, and one cannot overrule the other," Brenner explains. "So they each have the capacity to say 'No,' or to say 'Modify,' but one can't speak on behalf of the other and say 'Go ahead and do it.'"

In this scenario, the disclosure would be submitted to the institution and conflict review committee, and they would make a determination of the appropriateness of the research activity by approving, disapproving, altering, or creating a management plan, Brenner says.

"What I mean by that is they will impose the right kind of oversight to ensure objectivity is occurring, and they might put certain restrictions on how the work is done," Brenner says.

Then the IRB will review the disclosure and research proposal in terms of risk vs. benefit, and they may want to further alter the management plan within the context of maximizing the protection of the human participants, Brenner says.

"And there's a further distinction: the IRB ought to seriously consider whether this financial conflict of interest should be disclosed to participants in the consent form and what the disclosure should look like," he says.

• **Model 2.**

The second way this could work would be to have the initial disclosure sent to both the conflict review group and the IRB simultaneously.

"Once they receive it, there would be coordination between the two committees," Brenner says.

"Some will argue the first model is better because the heavy lifting can be done by the conflict review committee, and the IRB should do the

reviewing afterward," Brenner says.

On the other hand, it may be more efficient to have both groups reviewing the research simultaneously, Skorton suggests.

"It's very reasonable to have both groups doing their things at the same time," Skorton says. "But it's important [that] the IRB does not complete its work until the conflict-of-interest committee has spoken."

Most institutions should have a routing procedure that begins when an investigator is applying for external funding, Skorton says.

"They have to answer questions about whether a conflict exists by university definitions, but it's also important to be concerned about conflicts that occur when research receives internal funding," Skorton adds.

### *Develop a set of questions*

Here are some sample questions, regarding conflict of interest, that the University of Iowa uses on its IRB New Project application:

• Do you or any member of your research team have a conflict of interest regarding this study? (see www.uiowa.edu/~vpr/research/coi.htm)

• If yes, has the required University of Iowa Statement of Financial Interest Form been filed?

IRBs also should decide when to require investigators to disclose financial conflicts of interest to their research participants.

"The inclination more often than not is to disclose the involvement," Brenner says.

"If it's an inconsequential relationship, but still has financial interest, and if the IRB feels there is no likelihood that the investigator is going to be influenced, then they may decide it may be more of a distraction to an already complicated consent form," he adds.

Some IRBs will require all research with financial conflict of interest to be disclosed on consent forms because they believe it's the research participant's right to know, Brenner adds.

The AAU report doesn't say which policy is better.

"I think the feeling was on the task force that we didn't want to second-guess the IRBs," Brenner says. "They understand the study and participant population and will come to an appropriate decision."

Financial conflict of interest among university-produced research was not an issue before 1980 when the Bayh-Dole Act was passed. The legislation gave intellectual property rights to universities for research conducted, resulting in the university's ability to transfer the rights to industry for commercial purposes, Hasselmo says.

"Before that, the intellectual property rights belonged to the federal government," he notes.

As a result of the legislation, industries increasingly have funded research because they want access to what could be produced, and universities have a lot of expertise that could be useful to corporations, Hasselmo says.

Although collaborations did exist prior to 1980, there was no big incentive for universities to become involved with research that could result in manufacturing a product, he adds. ■

## Two points in the AAU report pertain to IRBs

*Individual and institutional conflicts discussed*

The Association of American Universities in Washington, DC, issued in October 2001 its report and recommendations on how institutions can deal with financial conflict of interest.

Here are some of the key features of the *Report on Individual and Institutional Financial Conflict of Interest*:

**1. Individual conflict of interest**

• Conflicts of interest are considered across all academic fields, with analysis focusing only on financial conflicts of interest that involve faculty, research staff, and other officials.

• Institutions need robust campus management systems to identify potential conflicts and to determine how conflicts should be disclosed and managed.

• These should be handled on a case-by-case basis to determine whether a researcher's financial interests are related to university research and constitute a conflict of interest.

### *Take special care with financial interests*

• Special scrutiny should be paid to research involving human participants. In these cases, any related financial conflicts of interest among individual researchers and staff should not be allowed. When there are exceptions to this rule, there should be more stringent management measures, including disclosure to participants, to ensure research integrity and safety.

• Annually, researchers, faculty, staff, and administration should disclose all financial interests related to university research and provide updates when indicated.

• When research is submitted for publication, it should include a disclosure of financial interests related to the research, and it should be disclosed in oral presentations as well as to federal agencies.

• Campus IRBs have jurisdiction over determining whether and how financial interests should be disclosed to research participants. Both a conflict-of-interest committee and the IRB have important roles in examining conflicts of interest with regard to human subject research.

**2. Institutional financial conflict of interest**

• These conflicts of interest may involve university equity holdings or royalty arrangements and research programs; conflicts involving university officials who make decisions that have implications for the entire institution; and even cases in which a university official is a member of a board or corporation that is a major supplier of some goods or services to the university.

• Develop clear policies that are made public following a threefold approach: always disclose; manage the conflict in most cases; prohibit the activity when necessary to protect the public or community interest.

• Establish administrative policies and a review group on institutional conflict of interest that might consist of senior officers, faculty, and citizens, and have all potential conflicts disclosed to the review group.

• The review group will assess potential conflicts, weight risks and benefits, and take action regarding institutional conflicts, including the options of declining proposed research; reducing or modifying the financial stake involved; increasing segregation between the decision-making regarding the financial interests and research activities, and establishing a research monitoring process.

• Strictly scrutinize institutional conflicts when human participants are involved, including having the conflict review committee interact with the IRB.

• Scrutinize equity that is not liquid, looking for potential institutional conflicts. ■

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## Additional protections rule published

The U.S. Department of Health and Human Services (HHS) published a final rule that amends subpart B of 45 CFR 46. The rule was published in the Nov. 13, 2001 *Federal Register*.

The rule becomes effective on Dec. 13, 2001. The amended rule provides additional protections for pregnant women and human fetuses involved in research.

The final rule continues the protections for both pregnant women and fetuses that have existed since 1975, but makes limited changes in terminology referring to neonates.

It also clarifies provisions for paternal consent when research is conducted involving fetuses, clarifies language that applies to research on newborns of uncertain viability, and corrects technical errors. ▼

## Pharmacy group offers tips for parents

The American Association of Pharmaceutical Scientists (AAPS) issued guidelines at its 2001 annual meeting held October 2001 in Denver for parents who want to enroll their child in a clinical trial.

The guidelines are in response to the growing number of parents using the pediatric exclusivity provision enacted by the Food and Drug Administration (FDA) in 1997. The provision is in the FDA Modernization Act and encourages pharmaceutical companies to conduct clinical trials on medications often prescribed to children. Companies that participate receive a six-month patent extension on the product being tested. The law has a sunset date of Jan. 1, 2002.

AAPS developed guidelines to help parents make a more informed decision regarding enrolling their child in a clinical trial. The guidelines were developed with pharmaceutical scientists with pediatric expertise. For example:

• Share your intentions about participating in a clinical trial with your child's pediatrician. He or she knows your child's medical history and can

help evaluate the risks and benefits associated with the program.

• Ask detailed questions about the trial length and the expected time commitment. How many days of work and school will you and your child miss? Will you be compensated for your travel or time?

• Question who will be providing medical care to your child. You want a team that is specifically trained in pediatric care so they are sensitive to the special needs of sick children.

• Understand what signs and symptoms exhibited during the trial could indicate a problem.

• What criteria and / or escape clauses exist should you decide to resign your child from the trial?

AAPS is a professional society of more than 11,000 members employed in academia, industry, government and other research institutes worldwide. ■

# Excellence award to be developed

The Office of Human Research Protections (OHRP) and the Department of Health and Human Services (HHS) awarded the Bethesda, MD-based Health Improvement Institute a contract to create a national awards program to recognize excellence in protection of human research subjects.

The awards will become part of a public-private partnership encouraging continuous improvement in the nation's system for protection of human research subjects. The awards will give visibility to best practices and reward institutions, investigators, sponsors, and IRBs for their commitments to responsible conduct in human studies.

"These Awards for Excellence in Human Research Protection will encourage institutions, investigators, and sponsors to continually improve their processes. For too long, we have focused on regulatory compliance as an end in itself — what we need to emphasize is prevention of harm," says **Greg Koski**, director of OHRP.

"These awards will heighten awareness of these issues within the research community and among the general public, adding credibility to the research process and raising public confidence in research results. We believe that the research community, industry, and the American public share these goals, and these awards will recognize the best among those who achieve them," he says.

"There is excellent and ethical research being done throughout the United States and these new awards celebrate the individuals and organizations who do it best," says **Peter Goldschmidt**, MD, president of the Health Improvement Institute.

An advisory board consisting of representatives from government, industry, and scientific communities and advocacy groups will recommend awards to recognize:

• best practices;

• innovations in protecting research volunteers;

• lifetime achievement for outstanding human research protection activities.

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## Editorial Questions

Questions or comments?
Call **Kevin New** at (404) 262-5467.

*[Editor's note: For more information about the awards or to become an awards program sponsor, contact Kristin Hollingsworth at the Health Improvement Institute, 5272 River Road, Suite 650, Bethesda, MD 20816-1250. Telephone: (301) 652-1818. Fax: (301) 652-1250. E-mail: kjh@mcman.com. Web: www.hii.org.]* ■

## CE/CME objectives

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;
- 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. ■

## CME*questions*

21. Which of the following is a good strategy for educating students about IRBs and human subjects protection during research projects?
    A. Hold courses on ethics and research or offer on-line workshops.
    B. Make IRB forms and information accessible to all students through the university's web site.
    C. Assign IRB members to be resource contacts for students and faculty when research questions arise.
    D. All of the above

22. According to Deana Katz, MBe, research ethics outreach coordinator at the Center for Bioethics in the University of Pennsylvania in Philadelphia, one area where students may feel that the IRB creates unnecessary burdens is in:
    A. Education
    B. Social sciences
    C. Psychology
    D. All of the above

23. Which of the following is a good strategy for educating students about IRBs and human subjects protection during research projects?
    A. Hold courses on ethics and research or offer on-line workshops.
    B. Make IRB forms and information accessible to all students through the university's web site.
    C. Assign IRB members to be resource contacts for students and faculty when research questions arise.
    D. All of the above

24. In the Association of American University's (AAU) recently published *Report on Individual and Institutional Financial Conflict of Interest*, the AAU makes various recommendations regarding financial conflict of interest and the IRB's role, including:
    A. IRBs also should serve as conflict-of-interest committees that review all research for potential financial conflicts.
    B. IRBs should pay special scrutiny to research that involves human participants and should not allow any related financial conflicts of interest among individual researchers and staff.
    C. IRBs should instruct all faculty and staff about what constitutes a financial conflict of interest.
    D. All of the above

# FORM B
## APPLICATION FOR USE OF HUMAN SUBJECTS IN RESEARCH

Respond to each of the following items or questions. Provide enough detail so the reviewers will be able to judge how well your study protects human subjects. Your responses must be preceded by the exact question and typed in the original order. Normally, your response to FORM B will not exceed five pages.

1. Provide a brief description of the proposed study (i.e., purpose, problem to be investigated).

2. What are your qualifications for conducting the study? (i.e., what is your experience with the procedures and instrumentation to be used in this study? If a student, what is your status, and which faculty member will supervise your research and what are his/her qualifications?)

3. What are the requirements for and characteristics of the subject population? (i.e., what gender, age range, health or medical status, prisoners, institutionalized, adults, mentally handicapped, etc.)

4. How will subjects be sampled, recruited, or otherwise enlisted as participants in the study?

5. Describe, in detail, the methodology of your study. (i.e., how will the study be conducted from start to finish, as far as human subjects are concerned? Be specific about the methods, instrumentation, types of data collected, etc.)

6. Describe the personnel, materials/equipment, or other resource requirements for your study. (Identify all personnel involved in the study, their role, their qualifications, and their access to the data.)

7. How will you obtain the informed consent of the subjects? (i.e., how, where, and when will the study be explained to subjects? How will subjects indicate their consent?)

8. What are the potential risks to the subjects, and what is the likelihood and seriousness of these risks? (Risks could be physical, psychological, social, legal, etc. and may result from your experimental procedures, or your methods of obtaining, handling, or reporting data.)

9. As applicable, for each risk identified in #8, describe other methods that were considered that would reduce or eliminate these risks, and explain why they will not be used.

10. What are the potential benefits to the individual subjects and/or society as a result of the proposed research?

11. As applicable, describe how you will minimize or protect against potential risks to subjects throughout the study. (Describe emergency procedures, confidentiality safeguards, debriefing procedures, security measures for storing data, etc.)

12. As applicable, provide the names and addresses of experts in your field (*not including the investigators*) with whom the committee members could communicate to discuss the potential risks of your procedures.

13. If appropriate, provide references to any published materials that would help the committee make a judgment regarding your procedures for safeguarding the rights and safety of your subjects.

### EXPLANATORY NOTES

1. The same questions must be addressed for all types of review. Normally, however, substantially less effort would be required to justify a study in the “exemption requested” category than would be necessary for a study which involves risk to participants.

2. If any item listed above is NOT APPLICABLE for your study, type N/A beside the item number instead of leaving the item.

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