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IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

INSIDE

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Determining subjects' mental capacity is essential for true informed consent

Evaluation should be ongoing

Whether a mentally ill or mentally impaired adult research subject is capable of giving informed consent has been a much-debated topic in recent years. Ultimately it's up to IRBs to decide policies for handling research that potentially involves these populations.

"If consent is not informed, it can't be voluntary, and there's a big tension with that and the principle of beneficence and the principle of social justice," says **Paul B. Gold**, PhD, assistant professor of psychiatry in the department of psychiatry and behavioral sciences at the Medical University of South Carolina (MUSC). Gold also is the primary reviewer for the MUSC IRB.

"If we were to make the assumption that people with severe mental illness have no decisional capacity, which has been done in the last couple of decades by some people, this population doesn't get to participate in research studies that ultimately could be of benefit to them," Gold explains. "Decisional capacity needs to be weighed against other principles."

On the other side of the equation, it has been a fairly common problem for IRBs and researchers to overlook the need to assess whether subjects actually have the capacity to consent to a particular research project, notes **Paul Appelbaum**, MD, professor and chair of the department of psychiatry at the University of Massachusetts Medical School in Worcester, MA.

The most common mistake IRBs and researchers make with regard to decisional capacity is to not recognize it as an issue, Appelbaum says.

Also, IRBs and researchers who do realize this can be a problem often fail to create procedures and policies for assessing decisional capacity, he adds.

However, this doesn't mean assuming that once a subject is determined to lack decisional capacity that the subject always will lack it.

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"This last issue is very important because we have a small but growing body of data suggesting that patients with impaired capacity may be able to ultimately understand what a study is about and reach a good decision as to whether or not to participate," Appelbaum says.

Appelbaum and colleague **Thomas Grisso**, PhD, with funding from the MacArthur Foundation, conducted a large-scale study of clinical competence in people with mental illnesses, and from that work they developed a tool, the MacArthur Competence Assessment Tools (MacCAT) for assessing decisional capacities. The latest version of MacCAT was published last year and can be used for clinical research (MacCAT-CR). A previous version was the MacCAT-CA for criminal adjudication. **(See information on MacCAT-CR, p. 51.)**

All-or-nothing approach is the easiest

The problem is that the easiest approach to determining mental capacity of mentally unstable subjects is to make an all-or-nothing policy, and some people in the research industry have advocated for permitting no informed consents among these populations after decades of the opposite stand, Appelbaum says.

"In some cases, IRBs will swing 180° in the opposite direction and issue blanket rules regarding the necessity for wholesale screening of research subjects based on their diagnosis," Appelbaum says. "Often, for example, they'll require that anyone with a mental disorder or, sometimes, a particular mental disorder undergo screening by an independent evaluator prior to being allowed to consent to participation."

The National Bioethics Advisory Commission (NBAC) has even recommended this policy, Appelbaum says.

"But I think that's a mistaken way to approach the issue — even though capacity is a very important issue for IRBs and principal investigators to pay attention to — because it misdirects resources," Appelbaum says. "Screening for capacity takes time and money and therefore should be done when high-risk populations at risk for incapacity are being involved in research and the research itself is of a sufficient degree of risk to warrant the investment of additional resources for the screening process."

Mental disorders encompass a wide spectrum of conditions and some are extremely unlikely to be associated with decisional capacity problems, Appelbaum says.

"Even in a single diagnostic category, such as depression, [patients] with moderate or mild depression are extremely unlikely to have decisional incapacity, and those with extreme depression are more likely to have decisional incapacity," Appelbaum explains. "So to treat the two groups the same doesn't make sense."

In a paper written by **Rebecca Dresser**, JD, a John Deaver Drinko-Baker & Hostetler Professor at Case Western Reserve University School of Law in Cleveland, there is a discussion of policy issues regarding people with mental disabilities.

Titled *Research Involving Persons With Mental Disabilities: A Review of Policy Issues and Proposals,* the paper was published in March 1999 by the NBAC and is available at this web site: http://bioethics.georgetown.edu/nbac/pubs.html.

Dresser's paper proposes that 13 basic questions be addressed in the deliberation of creating an appropriate federal policy on research involving adults with mental disabilities. These questions include these three key areas of consideration:

1. "What capacity standard(s) should apply to persons deciding about research participation? (Should a lower standard be applied to persons designating a research proxy decision maker?)"

2. "What procedures, if any, should be required to ensure that an individual's decision to enter (and remain in) research is capable, informed, and voluntary? Should special procedures be required only in certain cases, such as research presenting no prospect of direct benefit? When, if ever, should an independent monitor be involved in such an evaluation?"

3. "Should limits be placed on the degree of

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Tool provides easy method to assess competency

Studies point to instrument's necessity

The MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) is the latest in the MacArthur capacity instrument series of tools that assess competency among mentally ill and mentally disabled populations.

Created by **Paul S. Appelbaum**, MD, and **Thomas Grisso**, PhD, with funding from the MacArthur Foundation, the tools have been used for legal and medical purposes and now will provide guidance for assessing capacity among research subjects.

Here's where you can obtain more information about MacCAT-CR:

- **Professional Resource Press**, P.O. Box 15560, Sarasota, FL 34277-1560, sells the MacCAT-CR for $22. Contact the company at (800) 443-3364; web site: www.prpress.com/mactcrfr.html.
- A paper, *Competency to Decide on Treatment and Research; The MacArthur Capacity Instruments,* by Elyn R. Saks, discusses MacCAT-CR and its use, benefits, and drawbacks in an evaluation that considers goals of the National Bioethics Advisory Commission (NBAC). The paper is part of the NBAC's March 1999 report, *Research Involving Persons with Mental Disorders That May Affect Decision-Making Capacity, Commissioned Papers.* The report is available on-line at the web site: http://bioethics.georgetown.edu/nbac/pubs.html. ■

risk permissibly presented in research involving incapable subjects? What prospect of direct benefits to subjects or benefits to society is sufficient to justify various degrees of research risks? Should a national review process be adopted to consider the justification for certain categories of research with risk-expected benefit ratios unfavorable to incapable or questionably capable subjects?"

Appelbaum notes that the NBAC's focus on mental disorders and decisional capacity obscures the reality that many patients with other types of disorders, such as pain, disorientation, poor oxygen-carrying capacity, medications, etc., are likely to be unable to give competent consent.

"What we need is a much more carefully refined and targeted approach to this issue, rather than simply saying in a blanket fashion that everyone who falls in this category should be treated similarly," he says. "Moreover, the risk that subjects run should be calculated into it."

Low-risk studies require little scrutiny

Studies involving very low risk of harm to subjects may not require as careful assessment of subjects' decisional capacity as do studies with high risk, Appelbaum says.

"In low-risk studies, the consequences of involvement are negligible, and the participants' wishes at the moment should prevail," he says. "On the other hand, subjects entering into research with significant risk, we care very much whether they are making competent decisions."

While the debate continues over informed consent among mentally disabled populations, the MacCAT-CR tool offers IRBs and investigators a simple way to assess competence, Gold suggests.

"We use it in our studies," he says. "We work on rehabilitation interventions for people with severe mental illness and severe substance use disorders because we have to be careful about whom we enroll if their decisional capacity is compromised."

Subjects who may not have decisional capacity problems include the obvious populations, such as those who are severely mentally ill or have dementia, but they also can include people who abuse controlled substances, patients who are seriously injured and under the influence of pain killers, and people who have life-threatening illnesses that are so anxiety-provoking that their reasoning ability is diminished, Gold notes.

"Any one of us can be rendered in a heartbeat unable to give voluntary consent," Gold says.

However, investigators who follow normal practices of screening potential subjects for inclusion/exclusion criteria typically can adequately assess decisional capacity without relying on an independent monitor or the MacCAT-CR tool, Gold says. **(See story on how one institution's informed consent process works, p. 52.)**

"Unless you're dealing with people who are in acute stages of mental illness or acute mania or acute and severe depression, not everybody needs to be screened with MacCAT tools," Gold adds. "In talking with someone in an ordinary interview, you can get a sense of where they are

and if it's necessary to do a formal assessment."

Appelbaum suggests that investigators try different approaches to educating potential subjects about informed consent when it appears that there may be a problem with their comprehension.

"They may need an opportunity to talk with people who've been in the study or watch a video or computer program about it, or learn about it in different ways," Appelbaum says. "You may think of these people as having something more of a learning disability than incapacity, and we'll have to work harder to teach them about a particular project." ■

Obtaining consent can be multistep process

Here is how it works for one institution

Investigators who spend 15-30 minutes discussing a study and then hand participants an informed-consent paper to sign may be missing the point.

Depending on a study's level of risk and its study population, there probably should be a more thorough and educational approach to obtaining informed-consent, and this is especially true of studies where research subjects have mental health issues.

Research participants need to understand the purpose of procedures, the risks and benefits, have an appreciation of how the study might affect them personally, and how they might reasonably make a choice, says **Paul B. Gold**, PhD, assistant professor of psychiatry in the department of psychiatry and behavioral sciences for the Medical University of South Carolina (MUSC) in Charleston, SC. **(See Informed Consent Checklist, p. 53.)**

Gold, who is a primary reviewer for the MUSC IRB, under the Office of Research Integrity, provides this example and these guidelines to obtaining informed consent through a comprehensive and multistep process:

1. Know the study's target population.

Gold offers an example of a study involving a population with potential decisional capacity problems. It's a randomized clinical trial at the Institute of Community Living (ICL) in Charleston that involves vocational rehabilitation interventions used on persons with co-occurring severe substance-use disorders and mental illnesses, including DSM-IV-defined schizophrenia and mood-spectrum illnesses.

2. Set inclusion/exclusion and other enrollment criteria.

Subjects are excluded from the ICL study if they have an acute and severe episode of substance use/withdrawal and/or mental illness. Subjects having an acute and severe episode may later be included in the study with the resolution of their acute illness episode.

Subjects who meet the enrollment criteria will be considered for study enrollment only upon completion of 60 days of treatment after initial intake, focused on initial stabilization of their illnesses.

The research study coordinator, who has a doctorate in psychology, will inform potential subjects of the study's purpose, procedures, risk, and magnitude of harms and benefits, alternatives, and other matters.

3. Interview potential subjects.

The research study coordinator of the ICL study will informally assess each client's capacity to consent along four dimensions: understanding, appreciation, reasoning about risks and benefits of participation, and expressing a clear and unmistakably voluntary choice.

Then the research study coordinator will ask clients to summarize the study's aims and procedures and to articulate their own assessment of the risk/benefit balance of the study as it applies to them personally. They also are asked to indicate if they feel any pressure to volunteer.

"The only way I can get a grip on it is by asking them questions," Gold says of how he typically handles that role. "I have to ask them to summarize for me what I just talked about or, in their own words, tell me what are the potential harms of the study and what we are doing to try to protect them against those harms."

Once Gold has completed the consent discussion, he asks the person what he or she thinks and what are the pros and cons of participating in the study.

"I have to rely on my clinical intuition because someone can comprehend and understand and reason quite well, but not be able to give a real personal decision," Gold explains. "People who are catastrophically depressed and who have their wits about them but who don't care what happens to them should never be enrolled in a study even though they can tell you exactly what's going on."

(Continued on page 54)

Informed Consent Checklist

	COMMENTS
Introduction ☐ Statement that the study involves research ☐ Description of study goals and purposes ☐ Name of principal researcher(s) ☐ Name of sponsor(s)	
Procedures and Subject Involvement ☐ Expected duration of subject's participation ☐ Approximate number of subjects involved ☐ Description of procedures (where applicable: description of research vs. clinical procedures)	
Possible Risks and Benefits ☐ List of reasonably foreseeable risks and discomforts ☐ Statement that some risks may be unforeseeable ☐ List of reasonably foreseeable benefits ☐ Alternative procedures or treatments	
Costs and Compensation ☐ Description of all costs to the subject that may result from participation in the study ☐ Description of any recruitment incentives, medical treatments, or compensation available to subjects	
Confidentiality ☐ Statement that confidentiality will be maintained to the extent possible by law ☐ Description of procedures for maintaining confidentiality and protecting subject privacy	
Contact Information ☐ Name and telephone number of contact person for questions about the research study ☐ Name and telephone number of contact person for questions about subject rights as a research subject ☐ Where applicable: name and phone number of contact person in case of medical complications	
Subject Rights as a Research Participant ☐ Statement of voluntary participation ☐ Statement of right to withdraw at any right without penalty or loss of benefit ☐ Where applicable: policy on termination of subject participation without subject approval ☐ Where applicable: policy on disclosure of research findings and clinically relevant information	
General Issues ☐ Is the language used in the informed-consent materials understandable to subjects? ☐ Will subjects have the opportunity to ask questions about the study and their participation in the study? ☐ Are the informed-consent materials culturally appropriate for the study population? ☐ Where applicable: Are there plans to obtain the assent of participating children? ☐ Where applicable: Are there plans to recruit individuals with questionable capacity for consent?	

Source: National Institute of Environmental Health Sciences, Research Triangle Park, NC.

4. Decide whether the subject has decisional capacity.

If the research study coordinator doubts that a potential subject's consent is both informed and voluntary, the coordinator will defer enrollment and ask that the client take extra time to consider.

If the research study coordinator believes capacity to consent may be compromised, the coordinator will request an independent clinician to undertake a formal assessment of capacity to consent, using the MacCAT-CR, which typically takes about 20 minutes.

"I'd have the MacCAT administered on a different day, because at this point, the person has sat through an hour to 90 minutes of discussion, and that's fatiguing," Gold notes.

The MacCAT-CR has various questions that the clinician will ask the participant, and the answers are recorded and scored. If the participant's score is above a certain threshold, then the study coordinator can be more confident that the person has decisional capacity, Gold says.

5. Document the process and findings.

The entire informed consent process will be described in detail by the research study coordinator in an addendum that is attached to the consent document and is stored in each subject's consent file.

The MacCAT-CR assessment would be included with the documentation.

6. Follow up and monitor subjects' decisional capacity.

After the baseline informed consent process is completed, clients of the ICL study will be encouraged to attend a research induction group meeting held twice a week. These meetings will feature the research study coordinator discussing the informed consent again and encouraging participants to ask questions and to carefully judge the merits of study participation.

Also, it's important for investigators to monitor these subjects' decisional capacity over time, especially when studies last more than a year, Gold says.

"Interviewers continue to monitor for capacity anyone we thought at baseline might be at risk of fluctuating into a place where they don't have capacity; and then if we see trouble, we'll reevaluate," Gold says.

Over a course of two years, investigators may meet with subjects every six months and assess their decisional capacity at these meetings. Another strategy for monitoring decisional capacity is to ask the providers to notify investigators if they believe any of the subjects may be having problems with their mental illness or substance abuse.

"We need a lot of thought and consultation with other professionals about these decisions," Gold says. "It's hard to keep someone in a study if the person has lost decisional capacity, and it's difficult to take someone out if they want to stay in because that's also a violation of their autonomy. These are not cut-and-dried issues."

Finally, if investigators and the IRB are in doubt, the subject will be given the MacCAT-CR test.

6. Audit informed consent discussions.

With the ICL study, Gold will evaluate a random sample of 5% of the consent discussions through a combination of in-person observation and a review of audiotaped consent discussions.

Research subjects will be given a separate consent form for the audiotaping of the consent discussion, and they will be clearly informed that they may decline the audiotaping and that this refusal will not affect their eligibility for study participation. ■

It's not enough to follow rules. Get a new attitude

OHRP moving from compliance to quality

In 1998, the Health and Human Services' (HHS) Office of Inspector General (OIG) released a report that warned of weaknesses in the IRB system. Titled *Institutional Review Boards: A Time for Reform,* the report listed a number of weaknesses auditors pinpointed in the system. Among them were:

- IRBs review too much, too quickly, with too little expertise;
- IRBs conduct minimal continuing review of approved research;
- IRBs face conflicts that threaten their independence;
- IRBs provide little training for investigators and board members; and
- IRBs do not devote much attention to evaluating their effectiveness.

A follow-up released in April 2000, reports that few of the original recommendations had been enacted. For example, few IRBs engage in ongoing monitoring of research projects, no educational requirements have been mandated for investigators or IRB members, and conflicts of interest still are problematic.

"If we aren't more proactive in strengthening the system, the public trust may be threatened," says **George Gasparis**, director of the division of assurances and quality improvement in the Office for Human Research Protections (OHRP).

"In consideration of OIG and GAO [General Accounting Office] reports suggesting that the IRB infrastructure is weak or crumbling," he continues, "we felt there was a need to help try to improve understanding of the regulations."

In an open letter to the human research community, **Greg Koski**, PhD, MD, OHRP director, challenged researchers and oversight committees alike to move from mere compliance with federal guidelines regarding protecting human research participants to a program of quality improvement and assurance.

"A key element of the remodeling process in human research protections is the move from a system focused on regulatory compliance to a system focused on the prevention of harm," wrote Koski.

"Our primary goal is to improve quality, performance and efficiency," says Gasparis. "An IRB that deals with a larger volume of research — academic, community, or large teaching hospitals — tends to have systems in place to deal with the volume that they review. They have submission forms, a database to keep track of information, and processes and forms. They have been thinking through how to best operate. What we want to do is share the best ideas, serve as a networking outfit, and broker relationships with IRBs in need of improvement with those who are stronger."

QI program helps improve oversight methods

To that end, OHRP last December launched a quality initiative. The primary purpose of the quality improvement (QI) program is to help those involved in human research improve their oversight methods.

The QI program will be conducted in three phases: quality assurance, quality improvement, and continuous quality improvement. Phase I comprises evaluation of the level of compliance with federal regulations. The OHRP division of assurances and quality improvement (DAQI) will take a look at forms, processes and records to determine the level of compliance.

Phase II involves sharing of best practices. This will be achieved through networking as well as posting best-practice procedures and tools on OHRP's web site. Gasparis stresses that this sharing will be done with the permission of participating IRBs.

Phase III will consist of assistance with and evaluation of institution-initiated quality improvement programs.

Step one of Phase I, which is now under way, is self-assessment. DAQI developed an assessment tool designed to gauge an institution's compliance with federal regulations. It takes about two hours to complete, and DAQI staff, after review of the submitted tool, will be able determine the strengths and weaknesses of the human subjects protection program, says Gasparis.

Participating institutions must be willing not only to complete the self-assessment, but also be open to interaction with DAQI staff through any number of methods including on-site consultation visits. DAQI also may ask to review written operating procedures to determine how effective they are in promoting human subject protection.

"Then we would make a decision as to what follow-up method would be most productive — on-site consultation, videoconference, or telephone conference with or without written correspondence."

The QA Self-Assessment Tool should be available later in the summer. In the meantime, the tool will be posted on OHRP's web site (http://ohrp.osophs.dhhs.gov/irbasur.htm) for public comment. Until Office of Management and Budget approval of the tool is obtained, DAQI reviewers are conducting the first stage of the QI program by evaluating written operating procedures and minutes to determine the level of compliance and then conducting interviews with key staff members of a human subjects protection program.

The program's pilot study, launched July 2001, involved six institutions. Since January's official open-enrollment date, six more have signed on, and another 15-20 are expected to be scheduled soon, says Gasparis.

Participation is voluntary, and information provided will be kept confidential "to the extent allowable by law," he says. Should weaknesses be found, DAQI will offer consultation and education to improve the institution's existing program.

"At first, we were going to require reporting to the division of compliance oversight," says Gasparis. "Now we will notify the institution about deficiencies and work with them. We will consider our discovery of noncompliance situations as satisfying the reporting requirements to OHRP."

"Should a serious problem or serious systemic

noncompliance that has or may cause harm to subjects be found, DAQI would expect the institution to submit a corrective action plan promptly to address such deficiencies and will provide necessary consultation to facilitate this process," he continues. "DAQI would also report this situation to the director of OHRP, who will contact the institutional official about the matter."

Gasparis points out the information obtained during the OHRP QI program from participating institutions and independent IRBs may be considered exempt from being released to the public under the Freedom of Information Act.

"We had to structure the program in a way that would make institutions and independent IRBs want to invite us in. On the other hand, if we find a serious problem or serious systemic noncompliance that has or may result in harm to subjects, we have an obligation to do something about it," he assures.

There are no plans to make the QI program mandatory. "It's contradictory to the notion of quality improvement," he says. "You want to motivate people to want to do this as opposed to forcing people to do this."

For more information, visit the OHRP web site at: http://ohrp.osophs.dhhs.gov. Institutions interested in volunteering should write: Office for Human Research Protections, Division of Assurances and Quality Improvement, Attn: George Gasparis, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. ■

Public opinion counts when it comes to human subjects

Community board members speak for the people

Local research review boards have been around since the mid-1960s when the federal government issued its first policy designed to protect human subjects. The policy mandated that local communities create committees to review grant applications for projects requesting federal funds.

These committees were to be made up of members who were capable of assessing the project and determining the risks to and assure the safety of the human subjects participating.

Two years later when the National Institutes of Health took a look at these local review boards, they noted that 73% had members who were exclusively from the scientific community.[1] In May 1969, federal guidelines were revised to require that institutions gain input from not only the scientific community, but also from the community at large.

Local review boards became IRBs in 1974, and at that time, federal regulations stated IRBs should have a minimum of five members. These members are to come from a variety of fields — science, law, and any other area related to the study or the study population.

Additionally, IRBs are to have at least one nonaffiliated member, someone who is not from the scientific community and who comes from the community at large. They can include ministers, teachers, attorneys, businesspersons, or homemakers, as long as the community member is able to represent the views and mores of the population from which the study participants will be drawn.

There are various ways to recruit community board members. "Usually, people who are already on the IRB help us with the recruitment," says **Charlotte L. Shupert**, PhD, manager of research compliance and assurance at Oregon Health and Science University (OHSU) in Portland. "Other people they know become interested in their activities on the board and are often interested in serving."

OHSU has three IRBs. Each has at least one nonaffiliated member — among them are a history professor, a minister, and a family counselor.

The city of Philadelphia Department of Public Health (PDPH) uses similar recruiting methods, says **Judith Samans-Dunn**, MSIA, executive secretary of the PDPH IRB. "We use various methods depending on current needs, including asking for interest among users of our services, asking members and associates for recommendations, and occasionally responding to unsolicited referrals from various sources."

The PDPH IRB is made up of 13 members, among them three medical doctors, three nurses, two psychology professionals, four public health professionals, and one layperson. All have voting rights, as do the members of OHSU's IRBs.

"All members' input is considered with the same weight," reports Samans-Dunn.

"The nonresearchers review protocols in exactly the same manner as all other members of the IRB, and their opinions are respected and acted upon in exactly the same way," echoes Shupert.

Samans-Dunn says that community members have helped the IRB with issues involving expanding explanations on the consent form, accommodating non-English-speaking patients, adjusting the language level used to communicate

with subjects, and recruiting.

"Each of the community members bring the perspective of the subject and the nonmedical community into the room," says Shupert. "They are very good at pointing out when protocols are burdensome or inconvenient for subjects. Researchers can easily become excited about the possibility of learning something and lose sight of exactly what a researcher may be asking a subject to do. Our community members rarely lose sight of what the subjects duties and burdens are, and help us see studies from that perspective."

Reference

1. Stewart WH. Clinical Research and Investigation Involving Human Beings. *Experimentation with Human Beings.* New York City: Russell Sage Foundation; 1972. ■

SPOTLIGHT ON COMPLIANCE

Whistle-blowers: They can sue, and they could win

Be careful how you handle concerns

By **J. Mark Waxman**, JD
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Boston

The Federal False Claims Act (FCA) prohibits entities from making false statements that result in the government being defrauded. That act also covers federally funded research programs. An important section concerns the protection of employee whistle-blowers who expose false statements made by companies or institutions applying for federal funds and as a result are subject to retaliation by their employer.

This section states that: "Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done the by employee on behalf of the employee or others in furtherance of action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole [FCA, 31 U.S.C. § 3730 (h)]." Simply put, this section of the act is designed to protect employees who are dismissed because they reported misdeeds.

A recent case, *Dookeran v. Mercy Hospital of Pittsburgh* [281 F. 3d 105 (3rd Cir. 2002)], involved a physician and a research hospital. Keith Dookeran, MD, was director of clinical oncology trials and research for Mercy Cancer Institute. Dookeran was asked to prepare a grant application to serve as a clinical center for a National Surgical Adjuvant Breast and Bowel Project (known as the Star P-2 Study), a study on the effectiveness of two drugs used to reduce breast cancer in post-menopausal women.

Dookeran prepared the application and turned it over to a colleague to submit, but the colleague refused, stating he believed that inadequate resources for protecting the human subjects were being provided. Dookeran was then instructed to submit the same application and refused for the same reason. Mercy Hospital representatives replaced Dookeran and submitted the application. He cited that retaliatory actions were taken by the hospital and sued.

The first question the court considered was whether the FCA was applicable in this case. An FCA claim is "any request or demand, whether under a contract or otherwise, for *money* or *property* that is made by a contractor, grantee, or other recipient if the United States government provides any portion of the money or property that is requested or demanded, or if the government will reimburse such contractor, grantee, or other recipient for any portion of the money or property that is requested or demanded." Because the application to be a clinical center for the study was not itself an application for funds, the Appellate Court held that even if the charges were true, Dookeran could not sue under the FCA.

That determination in effect stripped Dookeran of protected whistle-blower status and protections provided to those so designated. Federal law states whistle-blowers may not be subject to retaliatory conduct if they are engaged in "protected conduct [31 U.S.C. § 3730(h)]." To be engaged in protected conduct requires conduct leading to the distinct possibility that a viable FCA could be filed and knowledge by management of the protected conduct. Here, because no viable FCA claim was even

at issue, no viable whistle-blower claim could be filed and, as a result, the court dismissed the claim.

While in this case, the judgment went to Mercy Hospital, the case provides a cautionary tale. The whistle-blower was a current employee who felt the hospital's conduct was inappropriate. Had a viable FCA claim existed, whistle-blower protection would have applied.

So note, if you receive federal funds, employees not only can report misconduct but also have federal protection from attempts to quiet or dismiss. Had Dookeran been successful, he would have been entitled to damages that could have included compensation for emotional distress.[1]

On the bright side, however, is the apparent holding that it is only an actual request for money or property that could result in an authorization of the payment of federal funds for the provider that will meet the claim requirements of the FCA. Further, it has also been held that the protection only covers employees and not independent contractors.[2]

References

1. *Hammond v. DPS Associates,* 148 F. 3d 407 (4th Cir.,1998).
2. *Vessell v. Northland Counseling Center,* 218 F. 3d 886 (8th Cir., 2000). ■

Special series: IRB Software for the Millennium

(Editor's note: In this issue of IRB Advisor *is the second installment of a special series on IRB software and how it is being used to improve quality and make the jobs of IRBs easier and better organized. This month, we are profiling Pro IRB by ProIRB Plus Inc. of St. Petersburg, FL. Look in future issues for profiles of iMedRIS by iMedRIS Data Corp. of Yucaipa, CA, and IRB Navigator sold by West Beach Software of Santa Barbara, CA.)*

Pro IRB may be convenient system for mid-sized IRBs

IRB coordinators discuss pros and cons

Pro IRB is a Microsoft Access-based IRB software application that some mid-sized and smaller IRBs have found convenient and efficient in assisting with day-to-day operations.

One of its timesaving features is its ability to automatically generate letters to investigators, says **Kay Beauvois**, CIM, IRB coordinator for Bayfront Medical Center IRB in St. Petersburg, FL.

"It keeps a tickler of all of your letters; you can pull up a program, and it will pull out your renewals every month so you don't have to search for them," she reports.

Beauvois began to learn the software program in August 2000, when she was hired as a coordinator, and it took her about three months to become proficient.

ProIRB Plus Inc. of St. Petersburg, FL, installed the software for the IRB, and an administrative assistant manually loaded all of the protocols.

"But they don't do it that way anymore," Beauvois says. "They wrote a program to convert all the data into the software program, and that's much easier."

Likewise, ProIRB regularly sends software updates through e-mail links to a web site where the improvements can be downloaded.

Another advantage to Pro IRB is that it's affordable for small and mid-sized IRBs, notes **Paula A. Bistak**, RN, MS, IRB coordinator for Newark (NJ) Beth Israel Medical Center of Newark.

As a part of the Saint Barnabus Health Care System in Livingston, NJ, the Newark Beth Israel IRB is separate from IRBs at the system's three other hospitals. However, the health system was able to obtain a discount by having all four IRBs purchase the Pro IRB system, Bistak says.

"We saw the need for better tracking the history of our protocols," she explains. "And because we are a health care system and our offices are one person per IRB office, we thought it'd be nice to have a backup person who knew how to go into our database."

Since all four IRBs use the same software system, any of the four IRB coordinators could fill in for one another in the case of an emergency, Bistak says.

Beauvois and Bistak outline the pros and cons of the Pro IRB software system:

- **Benefits.**

ProIRB Plus provides hands-on training for staff. The four IRB coordinators with the Saint Barnabus Health Care System met with a company representative for half a day to learn how to use the software, Bistak says.

"We downloaded the software through e-mail, and that's how we get all of our updates," she reports. "It's very easy."

Beauvois finds that the software is a great time-saver, although she jokes that an IRB coordinator shouldn't tell the boss that since they'd assign more work.

"What makes the software more efficient is that you load protocol information one time, and when you do your minutes, agenda, and correspondence letters, it loads all that data for you," she says.

"We have 80-100 studies a month that are open, and the software is cost-effective," Beauvois adds. "It saves you so much time in typing, and it keeps things so much more organized than a Word document."

Once the protocol information is loaded into the software program, the IRB coordinator simply has to pull up the information, click on the desired category, and the letter or document desired would appear on the screen with all of the protocol information already included, she explains.

"You're able to run any type of string search on one word, such as a search by the investigator's name, the drug's name, the serious adverse events (SAE) of an event, and you can run any kind of report," Beauvois says. The software makes auditing and checking for trends a breeze, she adds.

Reports can be pulled on all studies that are open for a specific period of time as well as using other criteria.

Bistak says she likes the way the study information only has to be typed in once and then every time a scheduled meeting or documentation deadline comes up, the software will make it easy to update and print out a report, using the information already in the system.

For example, if Bistak wants to review all of the SAEs studies up for renewal have had in the past year, the software system will easily pull up this information and list it chronologically.

The software program offers some flexibility for a particular IRB coordinator's preferred style, Beauvois says. "You have the ability to set up your letters however you want to, to any type of template if you're not comfortable with the standard format."

• Drawbacks.

However, learning how to use the program's flexibility takes time.

One of Bistak's concerns is that she hasn't been

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. ■

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able to manipulate the program's letter-writing format according to the style she likes, so she exported it to a Microsoft Word file to adjust the letter style.

"I can't change fonts or the style unless I save it to a Word file," she explains, adding that she has had the same difficulty in manipulating the IRB meeting minutes on the Pro IRB software.

"If we do something during our meeting that is not centered around a study, but I'd like to include it in our minutes — that's not always easy to do," Bistak says. "I'm having trouble getting used to its style."

Another concern Bistak, who has been using the software since late 2001, has about Pro IRB is that she has not been able to pull up lists of studies that are grouped in a way that is preferable to her. "I can't manipulate it to what our system is used to."

However, ProIRB Plus has been very responsive to her concerns and has makes constant adjustments, including several updates in the past four months, Bistak says. "They do listen to you and have changed some things around in response to people who are using their software, but it is not a perfect item."

ProIRB Plus asks for feedback from its customers and often will make improvements and changes according to what they say, Beauvois says.

If Beauvois had a wish list for improving the software, she would like it to enable more formatting features, such as permitting bold type and underlining words.

"It doesn't have that capability right now, but it is formatted for the future to do that," she says.

(Editor's note: For more information about Pro IRB software, contact ProIRB Plus Inc., 6020 44th Ave. N., St. Petersburg, FL 33709; e-mail: info@proirb.com; web site: www.proirb.com.) ■

CME questions

17. Study participants who may have trouble with decisional capacity include people who have which of the following medical problems?
A. Mental disorders and substance abuse
B. Pain disorientation and dementia
C. Poor oxygen-carrying capacity and medication problems
D. All of the above

18. Which of the following is the best strategy for determining a study subject's decisional capacity?
A. Use the MacCAT-CR tool to assess decisional capacity.
B. Have the research study coordinator discuss the study in detail with the subject, ask the subject questions that demonstrate the subject's comprehension, and the use the MacCAT-CR tool only when the subject has mental/physical problems that make render it difficult for the study coordinator to decide based on subjective evaluation.
C. Present the study coordinator's information about the informed consent process to IRB members and have them vote on whether the subject has decisional capacity.
D. None of the above.

19. According to federal regulations, IRBs must have at least how many community members?
A. 0
B. 1
C. 2
D. 5

20. The federal False Claims Act:
A. does not protect whistle-blowers from retaliation by employers.
B. prohibits entities from making false claims that result in the government being defrauded.
C. is applicable for research studies funded by the federal government or the private sector.
D. none of the above