IRB ADVISOR

YOUR PRACTICAL GUIDE TO INSTITUTIONAL REVIEW BOARD MANAGEMENT

DECEMBER 2015 Vol. 15, No. 12; p. 133-144

INSIDE

AHC Media

IRB solutions for the age of health system growth

Videoconferences for IRB meetings

Since the Affordable Care Act was signed in 2010, health systems have merged and grown, and with their geographic sprawl, so have IRBs grown and spread out. This raises the challenge of convening an IRB meeting in a central location when IRB members live and work within a wide radius.

"Our health system was founded in 1997 with the merger of North Shore and LIJ," says **Jon Newlin**, CIP, assistant director of the Office of the Human Research Protection Program, Feinstein Institute for Medical Research at North Shore–LIJ Health System in New Hyde Park, NY.

The health system has grown from a small group of hospitals to 21 hospitals. Five of those hospitals were added within the past five years, notes **Hallie Kassan**, MS, CIP, director of the office of the human research protection program, North Shore-LIJ Health System IRB.

"We have geographically separate committees," Kassan says. "We have 21 hospitals in the New York metro area."

> THE IRB'S TURNAROUND TIME WAS AROUND 98 DAYS, AND THE GOAL WAS TO CUT THAT DOWN. NOW THE TURNAROUND TIME IS 45 DAYS FOR FULL BOARD REVIEWS OF NEW STUDIES.

As the health system grew, it became clear that the traditional IRB model was too inefficient. The institution decided in July 2014 to restructure the local IRB into a flexible IRB model, and use videoconferencing instead of the typical board meetings in person, Newlin says.

The IRB's turnaround time was around 98 days, and the goal was to cut that down. Now the turnaround time is 45 days for full board reviews of new studies, Newlin says.

Financial Disclosure: Editor **Melinda Young**, Senior Staff Writer **Gary Evans**, Managing Editor **Jill Drachenberg**, Associate Managing Editor **Dana Spector**, Physician Reviewer **Mark Schreiner**, MD, and Nurse Planner **Kay Ball**, RN, PhD, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

IRB ADVISOR

IRB Advisor,
ISSN 1535-2064, is published monthly by
AHC Media, LLC
One Atlanta Plaza
950 East Paces Ferry Road NE, Suite 2850
Atlanta, GA 30326.

Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.
GST Registration Number: R128870672.

POSTMASTER: Send address changes to:
IRB Advisor
P.O. Box 550669
Atlanta, GA 30355.

SUBSCRIBER INFORMATION:
Customer Service: (800) 688-2421.
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Hours of operation: 8:30 a.m.- 6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST.

SUBSCRIPTION PRICES:
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"It has made a big difference for us in full board turnaround time," he adds.

The flexible IRB model also was designed to solve some major issues that arose as the health system grew, including the following:

- Many of the acquired hospitals had IRBs and their committee members were not enthusiastic about driving a long distance to regular IRB meetings, and
- the overall IRB membership grew to be large and cumbersome.

With the flexible model, the human research protection program (HRPP) had all IRB members listed on one roster for regulatory purposes. But in practice, the 60-plus IRB members were divided into four small IRB committees, each with seven to 15 members who would meet on a bi-weekly basis. The second big change was that meetings were conducted by videoconference instead of in a board room.

New IRB member orientations are held in a separate videoconference, followed up with the new members' attendance at the bi-weekly videoconference board meetings.

The videoconference meetings are not recorded, although the technology makes this possible. Each person engaged in the meeting uses his or her own computer or electronic device to sign on via the Internet. The IRB provided inexpensive video cameras to each member for use during the conferences. The technology also makes it possible to block a particular member if the person is recused from a portion of the meeting's discussion, Newlin says.

"For most people, it's a hands-free experience where they use the computer speakers and Web camera," he says. "It allows everyone to be on the screen at the same time, which gives it a group feel."

The convenience of videoconferencing has made it possible to convene boards on short notice, he adds.

"One unique experience we had with videoconferencing was we were designated by the state of New York to be an Ebola treatment center, and they — health system administration and clinicians — wanted to open a compassionate use treatment center for people who came into the hospital with Ebola," Newlin says.

This was part of a protocol that needed a quick IRB review. So the IRB held an ad hoc meeting, sending out an email to all members, and 25 members joined in the videoconference, which lasted about an hour, he recalls.

"This system was functioning at a very high level, while with an in-person system we would have had to exclude most members from attending," Newlin says.

"Each committee meets every other Tuesday or Thursday, and the meetings are limited to five to seven items," Newlin says. "Meetings never go over an hour."

Previously, meetings would have 20-30 attendees and last much longer, he adds.

Each group is designed to be a generalist group, with expertise in various areas of research: "Each group has one or two oncologists, surgeons, and each group should be able to review most types of studies that come in," Newlin explains. "We use consultants if we really have to."

But most of the time, any needed expertise can be found within the larger IRB member

group, he says.

"For instance, if we didn't have someone on Group A with scientific expertise, we can ask Group B to send someone over to Group A," Newlin says. "Everyone is on the same roster, so it's not like that person would be prohibited from attending the meeting."

Each IRB group's meeting minutes show the names of all of the IRB members and who was present at that particular group's meeting, he adds.

Also, there are never more than nine voting members at any meeting. "We want diverse expertise present, so we limit the number of voting members from each particular expertise," Newlin says. "So, for instance, we generally don't have meetings with eight doctors and one community member, although that is theoretically possible."

Instead, each board includes a nonscientist/community member and a variety of other members, including a statistical member.

Each of the four groups has two or three of these nine people present. Then for the remaining voting spots, IRB members on the group are designated as alternate voting members, so there always are nine voting members at each meeting, Newlin explains.

Each group has an IRB chair, but there also is a super-chair for the entire IRB, and the IRB has 60-plus alternates, Kassan says.

"That's the beauty of the flex model," Newlin says. "It's always been allowable under the regulations."

The flexible model passes regulatory muster and has been presented at national conferences, so it's a well-established model, he adds.

Minutes from each of the group meetings are sent to every person on the IRB roster, regardless of whether they were present, Kassan says.

After 90 days of using the flexible model, the IRB conducted a survey to assess what stakeholders thought of the change. Most appeared to be happy, Newlin says.

"We retained three-quarters of our IRB members, and 95% said on the survey that it was easy to use the videoconferencing," he says. "Even members who are not that technically advanced find it easy to use and most say the picture and audio quality are good."

MOST IRB MEMBERS SAID THE NEW SYSTEM WAS AS EFFICIENT OR MORE SO THAN THE OLD SYSTEM AND THEY APPRECIATED THE SMALLER AGENDAS.

One interesting finding with the flexible model change was that IRB staff, who also was surveyed at 90 days, mostly found that the new model resulted in the same workload, Newlin notes.

"We had three people who said there was a minor increase in work, one said minor increase, and three said the same workload," Newlin says.

For IRB staff, the workload under the flexible model includes having people attend more IRB meetings, but no one has complained that they should go back to the old model, he adds.

Most IRB members said the new system was as efficient or more so than the old system and they appreciated the smaller agendas, he adds.

"Before the change, they'd have to drive an hour to an IRB meeting and then settle in for a 2.5 hour meeting," Newlin says.

One of the reasons why the videoconferences are shorter and more efficient is because there are fewer side conversations at meetings, he notes.

Some IRBs previously had centered their meetings around dinner, but those dinner sessions were ended before the IRB moved to videoconferencing, Newlin says.

Acknowledging that some IRB members might miss face-to-face interactions, the IRB asked members if they would like to occasionally get together in person, and there was a mixed response, Newlin says.

"Some people didn't want to get together ever, and some wanted to get together four times a year," he says. "We settled on having an in-person meeting twice a year, and they can do this if they want."

The chief disadvantage to videoconferences is that it reduces social interaction, he notes.

While the amount of time spent discussing progress reports, modifications, and new studies is roughly the same as before, with the in-person meetings, the camaraderie of a Web meeting is different, Newlin says.

"So we definitely lose something in the social sphere, but I don't think — and the IRB member surveys agree — that it has any effect on how well the IRB is doing its central job of applying regulations and protecting subjects," Newlin adds. ■

People with lower incomes less likely to participate in cancer clinical trials

Only 11% of those with income below $20k join trials

In cancer research findings that could have implications for other diseases and human subjects, investigators found that patients with annual household income below $50,000 were 32% less likely to participate in a clinical trial.[1]

Indeed, there was a direct relationship, with trial participation decreasing as annual household income fell.

"Historically, it has not been considered necessarily something that would predict outcomes or is a crucial variable to collect," says lead study author **Joseph Unger,** PhD, MS, assistant member in the public health sciences division at the Fred Hutchinson Cancer Research Center in Seattle. "At this point, I would say it is a crucial variable to collect and is probably a similar issue in other disease settings. I do think this is something for IRBs to consider."

Unger and colleagues examined the association between annual income (<$50k vs. ≥$50k) and trial participation in a multivariable logistic regression model stratified by cancer type. They adjusted for the following factors that could potentially influence participation rates: age, sex, race (self-reported by participants), education, travel distance, and disease stage (initial diagnosis vs. recurrent disease). They also examined whether there was evidence of an income level and trial participation association in other annual levels below $50,000. The 1,262 patients with annual income were predominantly younger than 65 years (71%), female (84%), and not African American (93%). In multivariable regression, patients with annual household income below $50,000 had 32% lower odds of trial participation than higher income patients (12% vs 17%). Trial participation decreased as annual household income fell to between $20,000-$49,999 (13%); and to less than $20,000 (11%).

Incentives, not coercion

The reasons for this finding — which was first determined in an earlier study[2] by some of the same researchers — are not completely understood. "Lower-income patients are likely more sensitive to marginal financial expenditures than higher-income patients," the authors concluded. "Incentives or reimbursements may be appropriate, though they should not be coercive to patients."

Thus, IRBs may face the dilemma of having research skewed by income or risk providing incentives to lower-income people that cannot pass ethical muster.

"We want to level the playing field in terms of access to trials on the one hand, but you don't want to unduly influence patients with some kind of outsize [incentive]," Unger says. "That may overwhelm other considerations that are important for them. It is a tricky issue and an area where I think some research needs to be done to figure out what would be an appropriate way of compensating [lower income] patients without being overly influential."

One approach to alleviate the financial risk associated with clinical trial participation would be to cover the "excess costs" of participation, including copayments and coinsurance. Strategies could also address issues like time off from work, childcare, and transportation, Unger and colleagues note.

The confirmation of patient income level as an independent predictor of clinical trial participation leads to an obvious moral observation about the current situation: Access to cutting edge treatment is primarily the purview of those of means.

"From the patients' perspective, clinical trials can give them access to the most recent innovative treatments," he says. "We want to be sure there is a level playing field as far as getting access to those treatments and that shouldn't be dictated by someone's income level."

Moreover, if income is associated with health status — much as outright poverty has been clearly linked to poor outcomes — then improving representation of lower-income patients in trials would make the findings more generalizable to the population as a whole.

"If patient level income is related to cancer outcomes like survival, for example — and let's say lower income patients have worse survival [rates] — if they are not adequately represented in trials of a new drug, that is going to end up influencing your results," Unger says. "The overall

results are not going to be quite as representative of what's going on in the population."

Also, greater participation of lower-income patients would allow trials to be conducted more quickly, speeding the development of new treatments, he says.

"If there's a certain segment of the population that is unwilling or unable to participate, you are not going to enroll patients and complete trials as quickly," he says. "You can't formally [determine] the efficacy of new treatments as quickly, so the research slows down."

Unger is hesitant to go beyond data gathered solely on cancer research, but concedes a similar trend could be found in other areas of study. The problem is income level is not a question that is typically asked in setting up a research protocol.

"It's quite possible — perhaps even probable — that the same issue exists in other diseases as with cancer, which is that the cancer patients are not usually asked what their income is," he says. "So that really limits our ability to examine this question."

The information is typically not sought from research subjects in part because it may be seen as intrusive and become a disincentive to participate, Unger notes. In the study, Unger and colleagues used data from a prospective cooperative group survey study of barriers to participation in clinical trials conducted in eight geographically diverse cancer clinics.[3] In that study, patient-level baseline characteristics, including income, were collected.

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■

Draft guidance for IRB meeting minutes calls for documenting a broad array of actions

Draft open for comment through Jan. 4, 2016

When in doubt, document. That may be the best default position for IRBs based on draft federal guidelines created in part because some boards were being cited or warned about having inadequate meeting minutes.

The draft was issued jointly on Nov. 5 by the Office of Human Research Protections and the Food and Drug Administration under the title "Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards." The draft is open for comment through January 4, 2016.

"Because IRBs have been cited in OHRP determination letters and FDA warning letters as having inadequate minutes, OHRP and FDA are providing recommendations on the type and amount of information to include in minutes in order to help IRBs meet the regulatory requirements for minutes," according to the guidance.

Examples of noncompliance related to minutes include:

- minutes are missing,
- minutes lack sufficient detail to show the vote on actions taken by the IRB, including the number of members voting for, against, and abstaining,
- minutes are incomplete and only describe voting actions as "passed unanimously,"
- minutes do not clearly indicate, or contain discrepancies about, what the IRB approved,
- the IRB maintains multiple sets of minutes with different information for the same meeting, and
- minutes fail to include a summary of the discussion of controverted issues.

Recommendations unless regs cited

The draft guidance is a product of the two agencies' ongoing effort to "harmonize" their regulatory expectations and requirements for human subject research.

"The draft guidance, when

finalized, will represent the current thinking of OHRP and FDA on minutes of IRB meetings," the agencies stated. "You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations."

In that regard, the guidance describes OHRP's and FDA's "current thinking on a topic" and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

That said, IRBs that review research subject to HHS and FDA regulations (45 CFR part 46 and 21 CFR parts 50 and 56, respectively) must comply with the requirements in those regulations. Both the HHS regulations at 45 CFR 46.115(a)(2) and the FDA regulations at 21 CFR 56.115(a)(2) specifically require that institutions, or where appropriate, an IRB, prepare and maintain adequate documentation of IRB activities, including minutes in sufficient detail to show:

- attendance at the meetings,
- actions taken by the IRB,
- the vote on these actions, including the number of members voting for, against, and abstaining,
- the basis for requiring changes in or disapproving research, and
- a written summary of the discussion of controverted issues and their resolution.

Designate person responsible

The agencies recommend that institutions and IRBs decide who is responsible for preparing and maintaining minutes at their institutions and outline the process in the IRB's written procedures. If the institution and IRB have a process for review and either acceptance or approval of minutes, this process should be covered in the IRB's written procedures. Institutions and IRBs may consider creating a standard template to assist in the preparation of their minutes.

OHRP and FDA recognize that in addition to documenting the IRB's findings and determinations in the minutes, or elsewhere in the IRB records, IRBs may also choose to document other activities that occur during the meeting. For example, some IRBs provide continuing education and training to the IRB members at a convened meeting and document such training in the minutes. IRBs may also communicate announcements or other information to the IRB members and attendees at the meeting and document this in the minutes (e.g., upcoming meeting schedule, staff or membership changes). This practice is acceptable to OHRP and FDA.

IRBs may choose to record IRB meetings (e.g., video, audio tape) and use the recording as a tool to assist in the preparation of written minutes. This process, if used, should be described in the IRB's written procedures. However, retention of complete recordings of meetings does not relieve an IRB of its obligation to keep written minutes in accordance with the requirements of 45 CFR 46.115(a)(2) and 21 CFR 56.115(a)(2).

"We do not expect the minutes to include a verbatim transcription of what each member said during the course of the meeting," the draft states.

Records required by the regulations, including meeting minutes, must be retained for at least 3 years after completion of the research subject of the review and must be accessible for inspection and copying by authorized representatives from OHRP and FDA at reasonable times and in a reasonable manner.

Key provisions

IRB members should review the full draft guidance for specific details, recommendations, and requirements. Some of the key areas outlined include the following:

- **Actions taken by the IRB.** The minutes of IRB meetings must be in sufficient detail to show the actions taken by the IRB at the convened meeting. OHRP and FDA interpret "actions taken by the IRB" to refer to any vote taken by the IRB related to a proposed research activity. The minutes must summarize all research activities being reviewed by the IRB at that meeting, and must document actions taken by the IRB. The minutes should serve as a central repository for IRB decisions on proposed research activities.
- **Criteria for IRB approval of research.** The minutes, or other IRB record, should summarize the IRB's consideration of the approval criteria and should include a determination as to whether the criteria were met, as applicable.
- **Informed consent.** The minutes should indicate that, as part of its review and approval of a study, the IRB reviewed the informed consent form(s) and determined that the form(s) meet the applicable regulatory requirements. The minutes, or other IRB record, must also summarize any changes to the informed consent form(s) required by the IRB. Both OHRP and FDA regulations permit an IRB to waive the requirement that the subject or the subject's LAR sign a written consent if the IRB determines that certain criteria are met. The agencies recommend that any such waiver of documentation of

informed consent be documented in the minutes with protocol-specific information justifying the IRB's decision(s).

• **Unanticipated problems, serious or continuing noncompliance, suspension or termination of IRB approval.** If at a convened meeting, the IRB reviews an issue that requires prompt reporting to the IRB, the minutes should summarize the report and must document the IRB's action, if any, resulting from that review. Any review of such information and any decisions made outside of a convened meeting (e.g., as determined by the IRB chair or institutional official for subject safety reasons) should be reported to the convened IRB and documented.

Editor's note: The full draft guidance on IRB minutes is available at http://1.usa.gov/1iOdsnU. Comments on the draft document should include the docket number FR Doc No: 2015-27986 and be submitted by Jan 4, 2016. Submit electronic comments to http://www.regulations.gov. ■

Columbia researchers observing students in social situations to detect signs, clues to sexual violence

Waiver of informed consent in certain situations raises questions

Students at Columbia University in New York City have expressed curiosity and concern about an ongoing ethnographic study wherein researchers observe their behavior in public settings that have included bars and parties in campus housing. One student termed it "pretty weird and uncomfortable," while others said the researchers were friendly and forthcoming.[1]

For their part, Columbia researchers say they are on solid ethical ground and the Sexual Health Initiative to Foster Transformation (SHIFT) study has been approved by the university's IRB. As described on the website of Columbia's Mailman School of Public Health, SHIFT is examining a variety of factors that shape sexual health and sexual violence for undergraduates at Columbia.

SHIFT includes a year-long ethnographic study of undergraduate student life that will examine and analyze the range of student experiences related to socialization, sex, and sexual health, describing the range of practices and experiences that may be categorized as sexual misconduct. The ethnography will include in-depth student interviews, focus groups, interviews with key community and university stakeholders, and participant observations. It is these observations, some of which are being done under a waived requirement for signed informed consent, that raise questions about this important line of research.

The Columbia institutional review board declined interview requests by *IRB Advisor*, but issued this statement regarding the informed consent issue: "The Columbia University IRB reviewed and approved the SHIFT study after weighing the scientific importance of the research and ensuring that the confidentiality of individuals about whom data would be collected was safeguarded. The approved protocol does not permit collection of identifiable data in situations where informed consent could not be obtained."

It is this concept of "identifiable data" that is key, as the researchers have noted that having all observed students sign consent forms could paradoxically make the preservation of their privacy less likely. The study also includes a quantitative component, which includes a "daily diary" that will examine the occurrence and fluctuations of mood, stress, substance use, and sexual behavior among undergraduate students over 60 days. In addition, a large one-time survey will be used to identify the individual and social risks and protective factors associated with sexual health and sexual misconduct at Columbia. The findings will be used to develop recommendations and strategies to reduce sexual violence and other forms of gender-based misconduct.

Q&A with lead researcher

SHIFT certainly addresses a current compelling topic, and the researchers say it will add important new data. The existing research to this point has been largely focused on individual factors, rather than on the social and institutional factors that can play a significant role, the researchers emphasize in explaining the SHIFT study. **Jennifer Hirsch**, PhD, Columbia professor of sociomedical sciences and a SHIFT principal investigator, agreed to an interview with *IRB Advisor* via email.

IRB Advisor: In the student newspaper coverage, some students expressed concerns about being observed at bars and other settings. How are you responding to these concerns?

Hirsch: It is of paramount

importance to SHIFT to protect the rights of the undergraduate student body as research subjects, as well as to maintain their trust. As part of our project, we meet weekly with a group of 18 undergraduates to discuss our work and its relationship to student life. We also communicate with the students through giving interviews, sending emails, and writing pieces in their newspapers and blogs so that students are aware of what we are doing. Transparency is of the utmost importance for our project. With observations in public spaces, we do not collect identifying information, and our unit of observation is the social context, rather than individual.

IRB Advisor: Were traditional informed consent requirements waived to protect the identity of the students?

Hirsch: In order to reduce risk to participants' privacy — as is typical in community-based participant observation — the only element of informed consent that was waived was the requirement to obtain written documentation from each student or individual with whom a researcher comes in contact. We obtain written documentation of informed consent for the individual interviews, key informant interviews, and focus groups. We will also obtain written documentation of informed consent from students who invite an individual member of the research team to accompany them to a social or extracurricular activity.

IRB Advisor: I understand researchers introduce themselves and explain the study. Is that done as some formal announcement or only if students question why they are there?

Hirsch: The research team members introduce themselves immediately as researchers to the individuals with whom they come in contact. This involves sharing [the following] points:

- what the study is about (sexual health, sexual violence, and socializing among undergraduates at Columbia)
- that the students may decline to interact with the researcher,
- that the data collection we do in the participant observation is anonymous, in that we are not collecting the names of the people with whom we interact,
- contacts for those desiring more information about the study.

IRB Advisor: As a practical matter, given the group dynamics of a social setting as people come and go, it doesn't seem feasible that everyone is going to be able to give consent to being observed. Is this another reason informed consent was waived?

Hirsch: As noted above, the primary reason that we requested a waiver of written documentation was that it would reduce risk to participants. Documentation would also present feasibility challenges in situations with large numbers of people. When two members of the team attended the homecoming football game, it would have been impossible to collect written consent from the thousands of people in the stadium. We were scrupulous, however, in following the above procedure for each person with whom we came in contact. We would also note that in almost every case where informed consent is waived, we are observing public spaces like football games, restaurants, libraries, where subjects don't have a reasonable expectation of privacy, and we are collecting information on patterns of social behavior, not the actions of identifiable individuals.

IRB Advisor: When students are told they are being observed, doesn't that create the potential for a Hawthorne effect — the observation could change the behavior of the study subjects?

Hirsch: Ethnographic researchers typically deal with the Hawthorne effect in two ways. First, through the creation of "rapport" based on extended interaction in naturalistic settings, research subjects sometimes become comfortable enough to act in ways that approximate the ways that they would act were the researcher not present. Second, ethnographers explicitly analyze the ways in which their particular social characteristics shape what they do and do not learn from research participants. Known as "reflexivity," this is a hallmark of rigorous ethnographic research.

IRB Advisor: Is the ultimate goal of SHIFT to establish risk factors for sexual violence in these student social interactions?

Hirsch: SHIFT's overall goal is to examine the individual, interpersonal, and structural (cultural, community, and institutional) level factors that create vulnerability to sexual violence or that promote sexual health, both so that we can advance scientific understanding in those areas and so that we can make recommendations to the university for how to enhance campus climate. The ethnographic research involves participant observation, individual interviews, and focus groups. There will be 120 individual interviews with students, as well as follow-up interviews with a smaller sample of students. The survey research includes a daily diary study, which is currently underway, and a population-based survey, which will take place in the spring.

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■

Small IRBs can demonstrate value to research institutions

Education is the answer

Among the anticipated changes with the Common Rule's recent Notice of Proposed Rulemaking (NPRM) is a shift from having IRBs make exempt determinations to researchers using an exempt status tool to make their own determination.

This raises questions about what will happen to small IRBs at social-behavioral research institutions where many of their submissions are for studies that qualify for exempt status. The changes also might mean they'll have fewer reviews of multisite studies as these could be reviewed by larger, central IRBs.

As one comment to the NPRM noted, allowing investigators to determine their own research's exempt status could be problematic for IRBs. "This would unnecessarily complicate matters in terms of increasing the burden of trying to determine what categories of exempt research would be suitable for use of the decision tool and not require further administrative review versus those that do require further administrative review," Deb Elek wrote.

Others have wondered if the small IRB might be made obsolete with the proposed Common Rule changes.

But there's another way to look at the small IRB's role, says **Shannon L. Harr**, EdD, CRA, CIM, director of research integrity and compliance at Morehead State University in Morehead, KY.

"I don't think outsourcing reviews strips away the need for a human research protection program [HRPP]," Harr says. "You can still have a clearly defined HRPP for your own institution and also have an IRB of record."

The Morehead State University IRB has a reciprocal agreement with the local health system so that if any of the university's researchers have a biomedical study, the health system's IRB will review it. Likewise, if hospital employees have a social-behavioral study, the university's IRB will review that, Harr explains.

"It's not absolute; we can review any study, but if we feel the expertise lies at the other institution, then we'll reciprocate," he adds.

The IRB mostly sees submissions of social-behavioral research that is determined to be exempt from review, Harr says.

"What would change under the NPRM is that some researchers would not have to submit a protocol in the formal sense as they do now," he says. "And there would be no need to grant exemption formally by the IRB."

Plus, some of the protocols that now receive expedited review might be exempt under the Common Rule changes, he adds.

"The majority of the work we do is exempt and expedited," Harr says. "But I'm not concerned about the changes putting me out of business."

Although the NPRM could change significantly how the IRB operates, regulators are moving in the right direction, Harr notes.

"In my personal opinion, we may have been over-regulating some of these research projects in the past," he says. "There are aspects where we can relax some of the regulatory burden on researchers."

So how do institutions maintain their autonomy in human research protection programs in light of the changes? The answer is in putting resources into education, monitoring, and customer service, Harr suggests.

"Education is the key," Harr says. "The NPRM would make the process of becoming approved to do research a bit more streamlined, but it doesn't change the fact that we have to — throughout the life of research — maintain research participants' protection."

The IRB requires research teams to be trained in human research protection through CITI. "We hold workshops on how to do CITI training, getting people into the computer lab," Harr says.

"The chair of the IRB goes with us to the training and is always available," he adds.

"We invite people who are experts in human subject protection to hold seminars," Harr says. "It's important that we hold seminars and go over review processes with researchers so they better understand regulations, including newly proposed changes to the Common Rule."

Education becomes even more important when IRBs have less contact with investigators, as might occur under the proposed Common Rule changes, Harr suggests.

"We need to rely more heavily on making sure folks do the required training and take refresher courses when necessary," he says.

Also, IRBs could continue to require researchers to submit some notification of exempt studies.

"We might require exempt studies to notify our office and give us a brief explanation of the research they're doing — even if they're not required to do so within regulatory guidelines," Harr says. "We want to know what's going on."

A proposed study might appear to have minimal or no potential harm to participants, but the risks could change over the course of the study, he notes.

"If someone makes a significant change to the study, it might not stay exempt," Harr adds. "We can't say, 'You're good to go and don't tell us anything;' we need to keep our finger on the pulse of what's going on to make sure that we — as an institution — know what's going on."

Customer service is another area where an IRB and IRB office can offer value, Harr notes.

"We take great pride in our customer service in the office of research," he says. "We provide pre-review services in the office."

The IRB office typically can give feedback to researchers within 48 hours of a protocol's submission, Harr says.

Everyone considering a research project can meet with a member of the IRB to talk about their study ideas. "We also meet with them when they have a protocol draft to make sure all the I's are dotted and T's crossed, so there will be a smooth submission process," Harr says.

If exempt determinations change, the IRB will be available to investigators who need advice on using the exempt tool, he adds.

Other ways the IRB office enhances customer service is by attending departmental and faculty meetings and meeting people who might initiate research studies or mentor students with studies.

"We want people to know what we're about, know our faces, and know they can contact us at any time," Harr says.

The outreach has produced positive results, he notes.

"We've had faculty who asked for us on a regular basis," Harr says. "There's a newly created doctorate in educational leadership here, and they do an orientation for students in the summer; we're always part of that orientation, talking with students about research and the specific steps that they have to go through to do research at Morehead State University."

Other customer service strategies are to keep an open-door policy and to answer researchers' questions via email, he adds.

Small research institutions sometimes combine IRB and research compliance efforts, with the IRB office handling monitoring.

"Most of our research is exempt," Harr says. "We still ask investigators to submit a completion report and we ask them for their exempt protocols, and we do our best to keep up with those."

As a small IRB's mission and workload evolve, it's important for IRB chairs and directors to keep their finger on the pulse of what's going on, Harr suggests.

"These Common Rule changes will make it easier for researchers to be able to engage in research," Harr adds. "But we still want to know what's going on, and we want to engage our IRB committee more as a resource to the university community to talk about research and educate them about human research protection." ■

Is it a study or not? Decision tree helps

Researchers requested help

When researchers told the Cornell University IRB in a survey how difficult it was to determine whether a study should be submitted for IRB review, the IRB office created a tool that would make it easier for researchers to make the correct choice.

The tool, an interactive decision tree, was created before the Notice of Proposed Rulemaking (NPRM) on the Common Rule was published in September.

When studies involve minimal risk, the decision on whether a study can be exempt from IRB review or needs expedited review can be unclear, notes **Amita Verma**, MS, MBA, director of the Office of Research Integrity and Assurance at Cornell University in Ithaca, NY.

"The criterion of no more than minimal risk is somewhat subjective," Verma says. "So if you're doing an interview or questionnaire, depending on the nature of the questions or the population or the context, the study could be expedited or exempt, or even need full IRB review."

The turning point came in 2013 when an IRB satisfaction survey found that researchers were not happy with how minimal risk research was handled, Verma says.

"They expressed frustration that they did not always know which form to fill out and what to expect in terms of the review procedures or timelines," she explains.

"Often, they did not realize that

their research that involved human data or projects was not considered research under the IRB rules," Verma adds. "So we decided to create two tools that they could use themselves rather than talking to us every time they had questions about their project."

One of the decision trees helps researchers determine if their project is considered research. The goal is to make it easier for investigators to decide whether their study should be submitted for exempt, expedited, or full IRB review — particularly for types of research that are in a gray area.

For example, oral history often falls into gray areas of human subjects research: "Certain portions of that work does not need IRB review," Verma says. "If I'm doing oral history and I'm not making generalizable conclusions, then I don't need an application to the IRB."

The same can be true with classroom projects, she adds.

"Students are interested in learning statistical techniques and not really figuring out a research question," Verma explains. "We tell people if the intent is not to publish the data as generalizable knowledge, then you don't need an IRB application, and we've made that clear in the decision tree."

For instance, one question asks, "Is the project an oral history, ethnographic, or journalistic piece?"

The "yes" answer states, "Does the project involve stories that will or may draw broad conclusions about the population, cultures, and practices — even if no research hypothesis is being tested or validated?"

Also, investigators routinely might turn in an exemption request for studies using secondary data even when this might not be necessary, she adds.

"There are certain types of secondary data that can be exempted, and certain types cannot be," Verma says. "Those differences are described in the regulations, but they are not always clear to researchers."

The IRB created a second decision tree specifically to address secondary or existing data, documents, or biological specimens.

The first question on this decision tree is "Are the data/specimens about or from individuals who are or may be still living?"

A "yes" answer takes the researcher down a path requiring an application to the IRB office and written notice of approval or notice of exemption before research can begin.

For convenience, the decision tree is available in a PDF format as a chart and also in an online version in which each answer can lead to a different question. "We wanted to make sure people had multiple ways to make use of the tools and arrive at the right initial determination," Verma says.

Part of the decision tree's creation included getting extensive feedback from researchers and IRB members. The feedback period lasted a couple of months and led to many changes to simplify the language, introduce more logical branches, and develop an interactive format, Verma says.

Once the decision tree was reviewed, it stayed in a beta mode for a while.

"We continued to get feedback and to tweak it," Verma says. "It's now up on our website, and several of our peer institutions have told us that they intend to borrow it, modify it for their IRB, and publish it."

The Cornell IRB office is beginning to advertise the tolls and track usage.

The NPRM has also suggested that investigators will be able to use a tool to determine whether a study is exempt from IRB review.

If NPRM is finalized as it was published in September, then the decision trees will need to be revised because some categories of exemptions will change, she says.

"With the NPRM, a lot of research that is currently exempt will be excused from the definition of research, and the exemption criteria will be different than it currently is because certain types of experiments will be exempt from review," Verma says. "But at least we have a framework, and if all we have to change are some questions, we can do that." ■

COMING IN FUTURE MONTHS

- Lean thinking in IRB operations
- Facilitating collaborative review processes
- Best practices in QI efforts
- IRB review innovations for vulnerable populations

IRB ADVISOR

CNE/CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions:

1. Read and study the activity, using the provided references for further research.
2. Scan the QR code to the right or log on to AHCMedia.com, then select "MyAHC" to take a post-test.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the test, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

CNE/CME QUESTIONS

1. What is a clear benefit of a flexible IRB model using videoconferences?

A. It reduces IRB members' driving time to meetings
B. Videoconferencing produces measurably better results
C. It gives IRB members a better sense of community
D. All of the above

2. In cancer research documenting the lack of clinical trial participation among those of low income, which of the following was considered a possible result of this finding?

A. Lower-income patients lack access to cutting edge treatments
B. Study data is less generalizable
C. Research trials are slowed down
D. All of the above

3. According to federal draft guidance on IRB meeting minutes, boards may record meetings via video or audio tape instead of using written documents as long as they archive the recordings for at least three years.

A. True
B. False

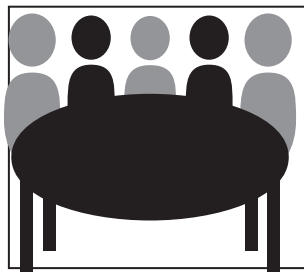
4. What are some ways a small IRB can show value to its institution in addition to conducting human subjects reviews?

A. Education
B. Monitoring
C. Customer service
D. All of the above

CNE/CME OBJECTIVES

The CNE/CME objectives for IRB Advisor are to help physicians and nurses be able to:

1. establish clinical trial programs using accepted ethical principles for human subject protection;
2. apply the mandated regulatory safeguards for patient recruitment, follow-up and reporting of findings for human subject research;
3. comply with the necessary educational requirements regarding informed consent and human subject research.



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