IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

November 2013: Vol. 13, No. 11
Pages 121-132

IN THIS ISSUE

Statement of Financial Disclosure:
Editor **Melinda Young**, Associate Managing Editor **Jill Drachenberg**, Executive Editor **Russ Underwood**, Nurse Planner **Kay Ball**, and Physician Reviewer **Mark Schreiner**, MD, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies related to the content in this CNE/CME activity.

AHC Media

Universities paying more attention to benefits of international research

New SOPs and guidance needed

Universities and colleges that once thought international research was beyond their reach increasingly are looking for and finding ways to conduct research overseas, some experts say.

One reason for this is that the number of international students studying in the United States has increased in recent years. According to the Open Doors report, published in late 2012 by the Institute of International Education, total international student enrollment in the U.S. increased 6% in the 2011-2012 school year, reaching a record high of 746,495 international students.

According to the Open Doors report, China, India, South Korea, Saudi Arabia, and Canada are the top five places of origin among U.S. international students.

"We have had a large influx of foreign students from all over, including students from Saudi Arabia and Nepal," says **Richard L. Sneed**, PhD, director of the office of research compliance at the University of Central Oklahoma in Edmond.

"Since these students found us, we're encouraging our researchers to do research in these countries to help bridge the divide between us and to continue to build the relationship that we've established," Sneed says.

IRB Series: Overseeing international studies

[*Editor's note: This issue of* IRB Advisor *is the first part of a series about how IRBs are handling international research studies. Included is a story about how universities are focusing more on international research, and are creating new guidelines and tools to facilitate a smoother review of such studies. There also are stories with samples of some best practices in international research guidelines and checklists. The December 2013 issue will feature additional stories about international research, including best practices in human subject protection of international study participants.*]

"The idea is to not just do research and bring it back here," Sneed adds. "It's to try to do something that will have a local benefit for the people there who are giving their time."

One of the first steps to increasing the list of international studies is to create new guidance and standard operating procedures (SOPs) for international research.

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. Telephone: (404) 262-7436. Website: www.ahcmedia.com. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

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

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m. – 6 p.m. Monday-Thursday; 8:30 a.m. – 4:30 p.m. Friday, EST.
Subscription rates: U.S.A., one year (12 issues), $399. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $65 each. (GST registration number R128870672.)
For recent permission, please contact: Stephen Vance, Telephone: (800) 688-2421, ext. 5511 • Fax: (800) 284-3291 • E-mail: stephen.vance@ahcmedia.com • Address: One Atlanta Plaza, 950 East Paces Ferry NE, Suite 2850, Atlanta, GA 30326

AHC Media, LLC is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media, LLC designates this enduring material for a maximum of *18 AMA PRA Category 1 Credits*™. Physicians should claim only credit commensurate with the extent of their participation in the activity.

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

This activity is intended for clinical trial research physicians and nurses. It is in effect for 36 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Editor: **Melinda Young**.
Associate Managing Editor: **Jill Drachenberg**, (404) 262-5508 (jill.drachenberg@ahcmedia.com).
Production Editor: **Kristen Ramsey**
Interim Editorial Director: **Lee Landenberger**

AHC Media

Editorial Questions

Questions or comments?
Call Jill Drachenberg at (404) 262-5508.

The University of Central Oklahoma has a short form and checklist for international research. Sneed created the form and checklist after working on the institution's standard operating procedures (SOPs) and discovering that there were no international forms, he says.

"I looked at what was available at universities around the country, and I was surprised at how all over the map they were: Some had no international forms at all, and some had 10-page forms," Sneed recalls. "I took certain elements that I thought should be on the form and made a new one."

Sneed created the international research checklist for investigators. The checklist differentiates between local context and consent issues. *(See sample of University of Central Oklahoma's international form and checklist, page 125.)*

"This is to raise investigators' awareness," Sneed says.

At Rutgers, the State University of New Jersey in New Brunswick, the recent heightened interest in international research is partly due to the university's push toward global affairs and global education, says **Michelle Watkinson**, IRB administrator.

The university has students and faculty from 115 countries, she notes.

"The university's theme is 'Jersey roots, global reach,'" she says. "International students take their training at Rutgers back to their local communities."

Initiated about six years ago, the global focus led the Rutgers IRB to create new international research guidelines and information, and it's helped make international research go through the IRB process much more smoothly, Watkinson says.

Having these guidelines benefits researchers and the IRB by creating a more effective and efficient way to evaluate international studies, she notes.

"Why spend months reviewing research protocols when you can tell people up front, 'If you're going to do research in another country, then here's the information we need, and here's what is expected of you,'" Watkinson says.

Most universities realize that they have faculty from other countries, and so they will harmonize the way education is provided, Watkinson says.

"They want to serve the local community and study the impact to local communities," she adds. "Some people that do research here will go back to their own countries when they earn their degrees, and they'll provide training to their local communities," Watkinson explains.

Institutions expanding their research portfolio

to include international sites need to educate researchers and IRBs about handling local requirements and standards.

"The vast majority of our work at FHI 360 is international research, and we have learned that we need to have a lot of respect to what local customs are," says **Kathleen MacQueen**, PhD, MPH, senior social scientist in social and behavioral health sciences at FHI 360 in Durham, NC. MacQueen has spoken at national conferences about international research, and FHI 360 conducts many studies in international settings.

"We defer to the local standard without disregarding the U.S. requirements," MacQueen explains. "We try to be sensitive to the local context and interpretation of how these regulations are implemented."

IRBs might view researchers as ambassadors to a foreign culture, Sneed suggests.

"They should be considerate and appropriate with people who are giving them their time and realize that many of these cultures have sensitivities that we would find bewildering," he adds.

The U.S.-based IRB might need to have a dialogue with the chair of the internationally based IRB, she adds. *(See story with tips on handling challenges with international research on this page.)*

"Building positive relationships with the international IRB is important," MacQueen says.

International research can be expensive, but with the increase in foreign students and faculty, even a small research institution might find creative ways to venture into research overseas, Sneed says.

"We might not be able to afford to send researchers overseas, but we have a faculty that is international, and they have their own connections in their own countries and can do research there," Sneed says.

For example, there was one researcher whose family owned a school in West Africa, and the researcher wanted to do a study about literacy among girls in that area, he says.

"There were issues of conflict of interest, and we had to deal with those," he adds.

But once those were resolved, it proved to be an affordable way to gain insight into female literacy in an international setting.

This type of research helps both the U.S. research institution and the local community, Sneed says.

"This gives researchers data they can work with and publish, but it could also have a benefit in the local community where it was derived," he says.

"International research gives us a way to widen our view and make the world smaller because people are people," Sneed adds. ■

IRB Series: Overseeing international studies

Experts offer strategies for international research

Be sensitive to cultural context

Reviewing studies that involve international sites and participants can pose unique challenges to American IRBs, including the basic obstacle of translation, an expert says.

"Translation is one of the big issues to deal with in the international setting," says **Kathleen MacQueen**, PhD, MPH, senior social scientist in social and behavioral health sciences at FHI 360 in Durham, NC.

"Sometimes we're dealing with languages that may not even be written languages, so we're improvising how to do translation in the field," MacQueen says. "Those that are written may not have many of the technical words we use as part of the informed consent process."

Other issues IRBs and researchers will encounter include working with local stakeholders and encountering cultural misunderstandings, she adds.

"Make sure investigators understand the local cultural niceties," says **Richard L. Sneed**, PhD, director of the office of research compliance at the University of Central Oklahoma in Edmond.

Poorly planned translation and interpretation services can cause problems for researchers and the IRB, he adds.

MacQueen and Sneed offer these suggestions for how to anticipate and deal with obstacles to successful international research:

• **Watch for translation/interpretation barriers when creating an informed consent process.** A classic example of how nuanced language can be is the story about how President Jimmy Carter visited Poland to meet with the Polish president, Sneed says.

"President Carter asked, 'What are your desires for next year?' The translation was, 'What is your carnal lust?'" Sneed says. "Many languages are heavily nuanced where a word pitched up means one thing and a word pitched down means something else."

This can be bewildering for investigators, so IRBs should make sure they are well educated in cultural issues before they engage in international research, he adds.

IRBs and researchers should think about how they will describe the study concept to non-English-speaking participants, MacQueen suggests.

"Talk about the procedures you use to make sure the informed consent process is actually informing people what research is about," she says. "It can be things that wouldn't be obvious."

For instance, an investigator whose research focuses on sexual and reproductive health of women might find that women in another country do not know what a gynecological exam is. While this is a common frame of reference for women in the United States, it could be that a research study in another setting will need to find a way to explain this concept, MacQueen explains.

One way to anticipate these types of translation challenges would be to hold focus groups among potential study participants.

Ask the focus group women how many have had a gynecological exam, and if only one person raises a hand, then researchers know that the translated informed consent information should start with a basic description of the procedure, she says.

"One of the challenges with informed consent is making sure you don't go into it with too many assumptions of what people's lives are like," MacQueen notes.

Another challenge involves language diversity within one country or even a region of a country. For instance, there are 11 official languages in South Africa, she says.

In a country that has university systems and local interpretation resources, it would be a good idea to hire interpreters who are sensitive to the various local dialects, MacQueen says.

"You can work with collaborators to identify people who are fluent in English, as well as in the local language and local dialect," she adds.

"Once you're in the field with participants, you might hear back that they do not understand what researchers are saying, and it seems your translation is not as good as you thought," MacQueen says. "So you would need to train your team to be sensitive to any potential problems, and you might have a problem with the informed consent form and need to go back to the IRB for a change to it."

• **Be sensitive to the local context.** "You can't just walk into a place and recruit people for a research study," MacQueen says. "You especially have to be sensitive with issues involving HIV or tuberculosis infection because these have a lot of stigma attached to them."

If researchers are targeting a population of people who experience discrimination and stigma, they need to be conscious of the local context that creates these problems, she says.

"A study potentially could make their lives more difficult because there are some people who will have strong feelings about the population you're recruiting from," MacQueen says.

"Most of us have learned that by talking with a broad range of stakeholders and through approaching all persons with respect, we build trust in the community and move forward from there," she adds. "It's an important lesson that those of us who work in areas like HIV really have to learn and carry with us."

In all international settings, it's important to respect confidentiality and be inclusive and respectful of local stakeholders, MacQueen adds.

• **Avoid cultural misunderstandings.** One cultural obstacle researchers and IRBs sometimes encounter involves the issue of autonomy in a setting where autonomy is not fully recognized or where a certain population, such as women, may not have autonomy in making their own informed consent decisions, MacQueen says.

"People might say a woman can't consent to be in a research study without her husband's permission, and, therefore, you need to consent the husband to get consent for the woman," MacQueen says. "I think that's an over-interpretation and incorrect."

The better approach in a setting where women have limited autonomy is to engage the husbands, demonstrating respect to them, she suggests.

"First meet with the community's leaders, and, if it's appropriate and good context for it, then meet in the community with the men," MacQueen says. "We try to make it a positive conversation about what the study is and why women might want to be a part of it."

Women who are adults may choose to participate without seeking their husband's approval, but that is their choice, she adds.

"If a woman wants to bring her husband to the study site so he can hear what's going on, then we try to support that and provide him with information," MacQueen says. "It's about respecting the relationship between men and women and husband and wife."

While a husband and wife might share the decision over whether the woman will participate

in the study, the actual informed consent is for the woman participant, she adds.

"We don't undermine their relationship, but we don't undermine the woman's decision and autonomy," MacQueen says. "If a woman wants to be in a study without discussing it with her partner, then we'll tell her about the risks of her secrecy."

Another situation where a research participant has limited or no autonomy is in the situation of studies involving brothel workers.

"That's a very difficult situation where a woman's life is controlled, and you would need permission to get into the brothel and recruit research participants," MacQueen says.

And sometimes it might be a situation where a brothel owner forces women to participate in a study. In this case, researchers would need to give women the autonomy they lack by creating a

IRB Series: Overseeing international studies

University creates international research form and checklist

Focus on culture, translation

The University of Central Oklahoma in Edmond has created an IRB form for international research involving human subjects, as well as an international IRB checklist. Investigators can use these to collect all of the information an IRB might require when they are conducting research in an international setting.

Here are some questions from each tool:

IRB international research form

- What languages are spoken at the study location?
- If working with a local collaborator, provide name (including title and position) and contact information (including email) for individual or institution.
- How will you gain access to participants?
- Will the project be reviewed by a local IRB or ethics committee?
- Describe recruitment procedures, including by whom and how potential participants will be contacted.
- Describe how you will demonstrate that the study tasks or interventions are culturally appropriate.
- Describe how you will demonstrate if risks and benefits are culturally appropriate.
- Describe how you will demonstrate/address that any instruments or interview questions are culturally appropriate.
- Will materials be translated into another language?
- Who will check the translation after it is complete?
- What documents and instruments will be translated?

International IRB checklist

- **CONTEXT:** Are any of these issues for your project?
  - ease of travel for subjects;
  - local literacy rate;
  - economic conditions;
  - local social/political structures;
  - relevance of research to local needs;
  - inclusion of local officials as researchers;
  - adequacy of data safety and monitoring;
  - legal rights of local population;
  - reporting complaints/adverse events.
- **CONSENT:** Are any of these issues for your project?
  - disclosure of research to those who may not fully trust health care professionals;
  - role of women and children;
  - status of elderly;
  - role of family in consent process;
  - oral consent;
  - awareness of local languages;
  - awareness and sensitivity to local customs;
  - local contact person(s) regarding legal rights.
- **Local issues:**
  - role of each site is clearly defined;
  - communication between sites is possible;
  - local sites compliant with safety regulations;
  - local researchers familiar with IRB policies/procedures;
  - secure storage of data is possible while at the site. ■

private space where a woman could sit and wait for the length of time that the study intervention might take place. This way the brothel owner or whoever controls her life would not know that she has chosen to not participate, MacQueen adds. ■

COMPLIANCE CORNER

Focus on essential areas to help program thrive

Communicate clearly, efficiently

IRB managers sometimes are daunted by the prospect of streamlining their program. Starting a new quality improvement initiative might seem terribly time-consuming and labor intensive. But as one expert notes, an IRB office could make considerable improvements in efficiency and compliance by just focusing on these three areas: IRB review processes, education for IRB members, staff, and researchers, and quality assurance/quality improvement.

"The first goal is to have a robust human research protection program," says **Cheryl A. Savini**, CIP, principal and chief operating officer of HRP Consulting Group Inc. of Clifton Park, NY. Savini speaks about improving IRB operations at national conferences, including the annual Advancing Ethical Research Conference, sponsored by Public Responsibility In Medicine & Research (PRIM&R), to be held Nov. 7-9, 2013, in Boston.

"Unfortunately, there are times when submitting to an IRB is considered burdensome paperwork," Savini says. "When an IRB is functioning efficiently, it can facilitate research and have the utmost concern of those participating in research."

Savini offers these suggestions for how an IRB program might focus on the three chief areas for improved compliance:

• **Supplement educational program.** IRBs can use national educational programs, such as the Collaborative Institutional Training Initiative (CITI) program, for their initial and refresher training of staff and IRB members and for researcher training requirements. But then they should follow up CITI with continuous training initiatives, Savini suggests.

Such training could include in-house lectures, webinars, provision of guidance documents, and attendance at external conferences.

"This provides a solid base for researchers, IRB members, and staff in understanding the basic protections and everyone's responsibilities for the protection of human subjects," Savini says. "It also provides researchers with the knowledge of what the IRB's roles and responsibilities are in the process."

The goal is to help researchers understand why the IRB asks for certain additional information and to help investigators learn how to more clearly describe in protocol submissions what their research is about, how it's going to be conducted, and what they are trying to accomplish, she adds.

• **Provide efficient, effective protocol reviews.** There are many tools available to assist IRBs with making the review process more timely and efficient without compromising human subject protections, Savini says.

"IRBs must be flexible and reasonable in their reviews and not impose unreasonable demands on the researcher," she says.

For example, a study might involve a benign survey, such as shopping or food preferences. In this case, IRBs that require a signed informed consent document for each participant are creating an unnecessary burden for the researcher, she explains.

"The regulations allow for waivers or alterations of informed consent or documentation of informed consent in such instances where the IRB determines that there is minimal risk to subjects and that the request satisfies the criteria for such waivers or alterations, outlined in the federal regulation," Savini says.

Instead of requiring a signed IC form, the IRB could require that the survey include a statement disclosing that the survey is for research and stating that returning the completed survey indicates consent to participate in the research, she adds.

Another strategy for streamlining the IRB review process would be to use a detailed protocol submission form, Savini suggests.

Although it will take investigators a little longer to complete the form initially, it will result in fewer questions by the IRB and a quicker turnaround time, she notes.

"A submission form that asks questions clearly rather than using broad, open-ended questions provides researchers with exactly the information the IRB is looking for and gives IRBs precisely the information they need," she says.

It's very frustrating to investigators when IRBs send them repeated requests for additional information, and it's frustrating to IRBs to have to send out these requests, she says.

"What is the IRB actually looking for? What is the researcher actually doing? They shouldn't need to guess. IRBs should have complete and detailed information in order for the IRB to make their required determinations," Savini says.

IRBs should create their own detailed submission forms that are customized to their institutions' specific needs and types of research. HRP has created its own detailed submission forms, which have been customized and successfully used by numerous organizations, including many that have become accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), she adds.

Even with the best submission forms, there might be occasions when IRBs have to ask for additional information. When this occurs, it's best to be clear and concise about which information is needed by the IRB and why it's needed, Savini says.

"You might even want to call the investigator to clarify something," she says. "It's better than sending out an email."

The phone call can be followed up with documentation, but it at least provides an opportunity for discussion and clarification, she adds.

• **Create a solid quality improvement/quality assurance program.** The QI/QA program should provide continuous oversight in how the IRB is functioning and help to ensure researchers are conducting their research as approved by the IRB, Savini says.

Solid programs might include random researcher protocol audits, observing the consent process, obtaining IRB metrics, reviewing IRB meeting minutes, review of non-compliance issues, and others, she says.

Collecting data and auditing study sites gives IRBs the information they need to determine areas of concern and which should be highlighted for additional training and education, she adds.

"For example, if you find out that the IRB is continually asking the same questions of researchers, then maybe it's time to ask that question in a more detailed and clearly written way in the submission form," she says.

Helpful metrics to collect might include the IRB's protocol turnaround time, the time it takes researchers to respond to requests for additional information, and how long it takes for the IRB to review the additional information and provide final approval.

"When HRP conducts a program evaluation, we begin by reviewing documentation, such as IRB meeting minutes, standard operating procedures, IRB rosters, submission forms, reviewer checklists, a sample of protocol determinations, and we look at turnaround time," Savini says.

"We conduct audits on a sample of protocols, and we interview all the stakeholders, such as researchers, IRB members, IRB staff, and institutional officials," she says. "It is important that interviews occur not only with those directly involved in the IRB, but also within each of the departments that play a role within the process."

IRBs can use metrics to identify problem areas and to target education and training for researchers who are having repeated problems with the submission process.

"Researchers want to do the right thing, but they need to know what it is, and they need to know how to apply the regulations, as well," Savini says.

Effective communication between the researcher and the IRB is essential, Savini says.

"There are many times the IRB is seen as a black hole where a researcher submits an application and doesn't hear anything for weeks," she explains. "That's not to say the IRB is not doing its work, but the researcher has no clue what is happening."

One way to ensure better communication between the IRB and researchers is to provide an automatic email when the submission is received, Savini suggests.

This can be done electronically or by IRB staff.

"Let researchers know when a pre-review is conducted, saying, 'We looked over your application and we see that you forgot to submit your consent form,' or that they didn't clearly describe something, or whatever the case may be," she says. "The researcher then has the opportunity to provide the information or clarifications before it goes to the IRB for review."

"The goal is to consider the IRB a partner with the researcher rather than a hindrance," Savini says. ■

Expert tips for restructuring compliance

Research councils, education are key

Across university systems and individual campuses, research programs rely on compliance programs to ensure federal regulations are followed and research is conducted ethically. A few years ago, officials with the University of Texas System saw that the systemwide compliance program needed expand to improve efficiency and effectiveness of the research programs in all its institutes.

"What I like about a systemwide compliance approach is the idea that we're working with the institutional programs to help support their processes to address compliance requirements," says **Wesley Byerly**, PharmD, assistant systemwide compliance officer for research at the University of Texas System. "Compliance is the quality control point of ongoing activities. Audits show how successful you are with compliance programs."

Early evaluations of the UT System found research compliance activities often widely distributed throughout institutions, without a clearly identified organizational structure and ultimate leadership responsibility. The need to focus on specific areas such as research led to developing a system-level research compliance program to support and assist the nine universities and six health institutions of the University of Texas System in managing and mitigating research compliance risk.

The systemwide research compliance program was developed based on the essential elements of compliance programs:

Compliance leadership: There should be someone in place, such as a compliance officer, to make sure the components of the program are there and working, Byerly says. The role should be supported by other groups.

Clear definition of roles and responsibilities: Is there any direct operational oversight? Who is supposed to do what? There should be policies in place to follow the guidelines, and the policies need to be known and understood by members of the organizations.

Training: Develop training programs to ensure there is an understanding of what it means to be compliant.

Communication: Make sure there are effective lines of communication and everyone feels free to talk about concerns.

Monitoring: This includes establishing processes to make sure compliance activities are occurring as they should, such as monitoring, quality review, and auditing.

Enforcement: Consequences that will result if regulations aren't followed need to be known, and mechanisms in place to execute those consequences if needed.

Corrective response: Respond promptly to detected problems, undertake corrective action, and report to appropriate agencies.

Institutional visits and outreach are also an important part of the program. "We used these to help the member institutions develop and maintain robust programs," Byerly says. "A lot of what we do is based on going out, visiting, and working directly with those individuals in the institutions who have boots on the ground."

The UT System compliance program is led by the chief compliance officer, and assistant compliance officers for information security, healthcare, and research.

"The idea is to have identified individuals with responsibility for our major compliance areas," he says. "These individuals bring the experience and expertise to support efforts on the campuses and to coordinate system initiatives." The assistant systemwide compliance officer works with the heads of the compliance programs and research administrative units at each of the University of Texas campuses to facilitate and coordinate communication on research-related issues; develop and implement research compliance standards, policies and procedures; assist with education and training; ensure mechanisms are in place to monitor and enforce research compliance standards; and to collaborate on investigations of noncompliance. They also advise the UT System Executive Offices on research compliance issues and act as a liaison between the institutional compliance programs and the Board of Regents to ensure that the board has sufficient information to provide effective oversight.

The UT System also developed a research compliance council, chartered by the System Executive Compliance Committee. The council is comprised of representatives appointed

by the vice presidents of research from each of the system's institutions. The council provides insight into current issues with the compliance programs at the members' various institutions. "The council evaluates issues that arise both locally and nationally and generates recommendations on how to reduce compliance risk," Byerly says. It also identifies and provides assistance for specific projects, establishes best practice solutions for compliance issues throughout the system, develops training and education modules, ensures uniformity and consistency across programs, and is collaborating on a research compliance work plan.

Another key element of the program is having a comprehensive education program to ensure everyone knows the ins and outs of compliance, understands the regulations, and to have an opportunity to share best practices. The UT System developed a compliance academy that includes webinars for various compliance issues across the university system. The compliance academy is a collaborative program with the University of California System, with both systems sharing education responsibilities. "Education is key to what makes a strong compliance program," Byerly says. "I think that is a key function that we're able to bring in from the system level." The research compliance education ranges from human subjects to animals to lab safety and fiscal compliance. "There is a full range of things for everyone to be aware of for what makes a robust program," he says.

Feedback from the program has been mostly positive, Byerly says. "Campuses don't feel like they're working in isolation — they feel the UT System is bringing them together to share best practices and engage in dialogue and pull together work groups. They have the community to fall back on," he says.

For institutions looking to improve compliance programs, "If you're thinking of dealing with systemwide compliance, the first place to start is to see what you are doing for compliance in general at a system level," Byerly says. "Associated with that is, what is the focus for providing oversight for research at that level? Define and leverage off of that to build the program." The key, he says, is to develop a council or committee and work with them to define what their needs are. "Think about compliance programs at the institutional level — what are your compliance roles from your officers to the research office? Look at that, and consider how to keep all the components of the research program and specific risks or concerns to generate synergy when revamping it," he says. ■

HRP consolidates offices to improve efficiency

Centralization also supports business areas

The process to bolster the human research protections program at Lehigh Valley Health Network began in 2006 when researcher and IRB chair **Scott Lipkin** began taking stock of the program and considering how to make it more efficient.

Lehigh Valley Health Network (LVHN) is a large academic community hospital with about 350 open protocols — a "typical large organization with a small research program," says Lipkin, DPM, CIP, chief of the LVHN Network Office of Research and Innovation. The clinical research program was not operating as a centralized, cohesive unit — there were 13 asynchronous research offices whose only common link was use of the IRB. "From the perspective of hiring, firing, opening and closing protocols, that was all done with a varying degree of accountability," Lipkin says. "As part of our evaluation, due to the size of our overall research program, what made sense for us was to centralize the program into one office."

With 13 separate research offices with their own processes, Lipkin and colleagues looked to create an infrastructure to improve efficiency, increase compliance, lessen administrative burden, and decrease turnaround times.

"Via centralization, we can not only support study design, but conduct the research and analyze the data. We can also create and deliver educational curricula with varying levels of complexity," Lipkin says.

After shoring up the program with accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in 2009, Lipkin and LVHN colleagues began to plan the

centralization of the research office in earnest. After taking a year to create the policies and procedures, the Network Office of Research Innovation (NORI) came to life in 2011. NORI now consists of these offices:

- **Office of Research Administration**, which handles the business aspects of research, including research grants, negotiating contracts, and analyzing insurance and Medicare coverage for trials. To increase compliance with federal regulations, the office has also developed its own processes for billing and coding, and for ensuring time and effort reporting. The office also conducts coverage analysis for clinical trials and knows which studies are being done for standard of care, clinical analysis, etc.
- **Office of Research Clinical Operations**, which centralizes all research nurses and coordinators.
- **Office of Research Education, Integrity, and Monitoring**, which houses research design and medical editors, and produces core education curricula.
- **Research Participant Protections Office**, which oversees the human research protection program and provides administrative support to the IRB committees.

"From a political perspective, centralization was wildly unpopular," Lipkin says. "Two years later, the research community has learned to appreciate the virtues of the services and resources provided by the NORI office. Some of the ways that helped with acceptance of centralization were open channels of communication, transparency, and continuous quality improvement."

IRB benefits

The NORI office developed processes to increase compliance with federal regulations, including creating standardized processes for billing and coding. The office has also established processes to ensure accuracy of time and effort reporting.

With the restructuring, "we've been able to increase the quality of research, and been very successful in lessening research compliance risk and enhancing the quality of human subject protections," Lipkin says. "Part of that was learning to do more with less. We've been able to provide significantly more research services to our Health Network utilizing a smaller number of full-time employees."

NORI takes on some of the administrative burden previously left to the IRB. Protocols go through departmental scientific review for resource attestation. Conflicts of interest related to research are reviewed and managed prior to IRB submission, the management plan is forwarded to the IRB as part of the research submission, and the IRB has final say with regard to the applicability of the plan. Once it passes departmental review, protocols are sent to the NORI directors for a feasibility assessment. This step looks at the significance of the research protocol, resource requirements, physical needs, enrollment potential, financial implications, vetting of principal investigators, and other issues. For example, when the IRB receives the protocol, it will know whether an investigator has the patient population to support the study, whether there are any competing studies, and if there is enough available funding to complete a study.

"With the centralization of research, we've been able to enhance the effectiveness of the IRB by allowing them to focus on research within the context of the regulatory criteria for research approval," Lipkin says. "Centralization of research services at LVHN has allowed us to support the IRB in their capacity as the ethics review committee while the research office is responsible for oversight of various institutional issues that once fell within the purview of the IRB. As a result, the quality of review and subsequent determinations by the IRB has improved significantly. From the IRB perspective, this has all been validated through successful FDA audit this year."

Compliance committee

The office provides oversight for the newly created research compliance committee. The committee is responsible for review and management of all research related compliance issues. For example, the committee reviews allegations of noncompliance and sends its findings and management plans to the IRB. "The committee is empowered to make determinations and provide management plans to the IRB for their final blessing. This way, the IRB doesn't get caught up with the politics of noncompliance," Lipkin says.

Taking much of the administrative legwork off of the IRB allows the members to focus

more on protocols and less on other issues. "IRB members really focus on meeting regulatory requirements, and we've taken mission creep out of the IRB to allow them to function as an ethics committee. It makes their life so much easier — there's much less guesswork." Lipkin says turnaround time for new protocols is usually three days from submission to feasibility review, and the IRB meets every other week. ■

CNE/CME OBJECTIVES & INSTRUCTIONS

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

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

Physicians and nurses participate in this continuing education program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
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 last test of the semester, 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. ■

COMING IN FUTURE MONTHS

■ OHRP revisits standard of care definition

■ Frustration in the board room? Help is here

■ Compliance practices for international studies

■ Interpreting and learning from OHRP determinations

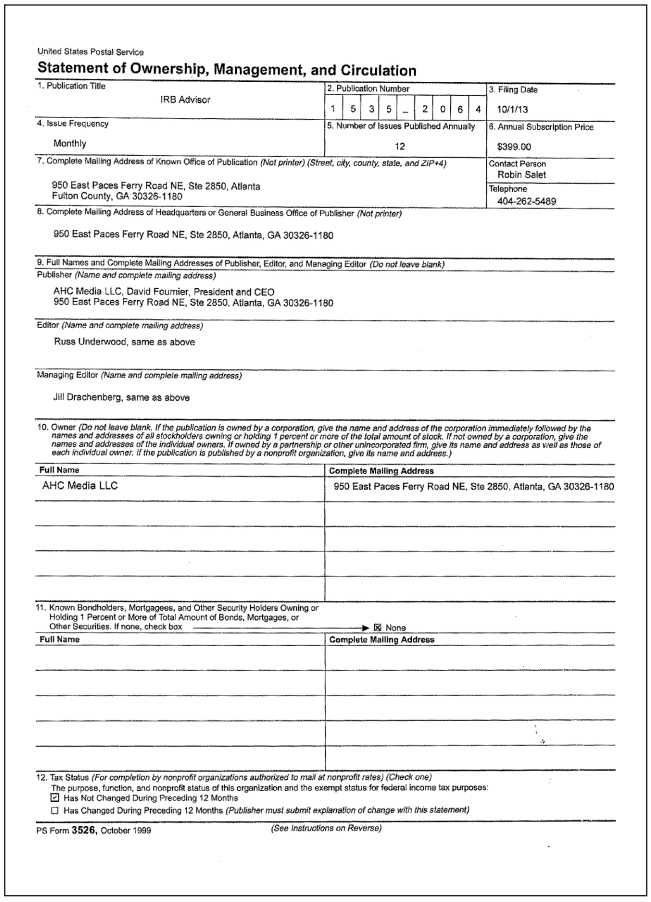
CNE/CME QUESTIONS

1. What are three areas which can be a source of conflict and misunderstandings during international research?
   A. Research ethics, self-reporting bias, Internet access
   B. Translation/interpretation, cultural differences, local context,
   C. Investigators' views toward women, investigators' religious affiliation, investigators' family connections
   D. None of the above

2. Which of the following could be an informed consent issue in an international study?
   A. Disclosure of research to those who may not fully trust health care professionals
   B. Role of women and children
   C. Status of elderly
   D. All of the above

3. Which of the following would not be a good way to provide continuous education to researchers and IRB staff and members?
   A. In-house lectures
   B. An AAHRPP survey
   C. Webinars
   D. Attendance at external conferences.

4. According to Wesley Byerly, PharmD, assistant systemwide compliance officer for research at the University of Texas System, leadership, communication, and hiring personnel are essential elements of a comprehensive compliance program.
   A. True
   B. False



United States Postal Service

Statement of Ownership, Management, and Circulation

1. Publication Title	2. Publication Number	3. Filing Date
IRB Advisor	1 5 3 5 – 2 0 6 4	10/1/13
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price
Monthly	12	$399.00

7. Complete Mailing Address of Known Office of Publication *(Not printer) (Street, city, county, state, and ZIP+4)*
950 East Paces Ferry Road NE, Ste 2850, Atlanta
Fulton County, GA 30326-1180
Contact Person: Robin Saiet
Telephone: 404-262-5489

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not printer)*
950 East Paces Ferry Road NE, Ste 2850, Atlanta, GA 30326-1180

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do not leave blank)*
Publisher *(Name and complete mailing address)*
AHC Media LLC, David Fournier, President and CEO
950 East Paces Ferry Road NE, Ste 2850, Atlanta, GA 30326-1180

Editor *(Name and complete mailing address)*
Russ Underwood, same as above

Managing Editor *(Name and complete mailing address)*
Jill Drachenberg, same as above

10. Owner *(Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual owner. If the publication is published by a nonprofit organization, give its name and address.)*

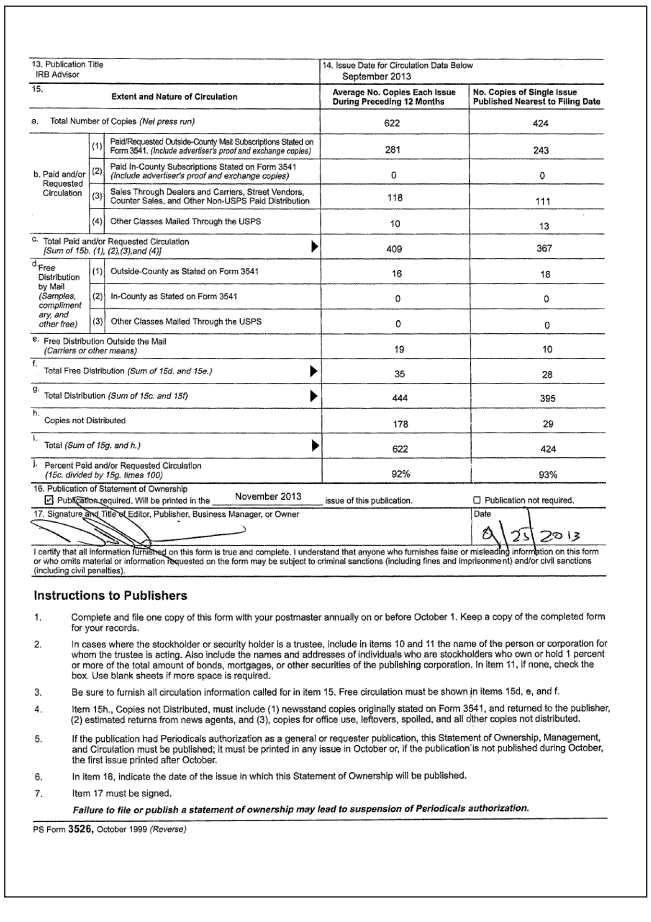
Full Name	Complete Mailing Address
AHC Media LLC	950 East Paces Ferry Road NE, Ste 2850, Atlanta, GA 30326-1180

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☒ None

Full Name	Complete Mailing Address

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates) (Check one)*
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☑ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months *(Publisher must submit explanation of change with this statement)*

PS Form **3526**, October 1999 *(See Instructions on Reverse)*



13. Publication Title: IRB Advisor	14. Issue Date for Circulation Data Below: September 2013	
15. Extent and Nature of Circulation	Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Total Number of Copies *(Net press run)*	622	424
b. Paid and/or Requested Circulation (1) Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. *(Include advertiser's proof and exchange copies)*	281	243
(2) Paid In-County Subscriptions Stated on Form 3541 *(Include advertiser's proof and exchange copies)*	0	0
(3) Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Non-USPS Paid Distribution	118	111
(4) Other Classes Mailed Through the USPS	10	13
c. Total Paid and/or Requested Circulation *(Sum of 15b. (1), (2),(3),and (4))*	409	367
d. Free Distribution by Mail *(Samples, complimentary, and other free)* (1) Outside-County as Stated on Form 3541	16	18
(2) In-County as Stated on Form 3541	0	0
(3) Other Classes Mailed Through the USPS	0	0
e. Free Distribution Outside the Mail *(Carriers or other means)*	19	10
f. Total Free Distribution *(Sum of 15d. and 15e.)*	35	28
g. Total Distribution *(Sum of 15c. and 15f)*	444	395
h. Copies not Distributed	178	29
i. Total *(Sum of 15g. and h.)*	622	424
j. Percent Paid and/or Requested Circulation *(15c. divided by 15g. times 100)*	92%	93%

16. Publication of Statement of Ownership
☑ Publication required. Will be printed in the November 2013 issue of this publication. ☐ Publication not required.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner — Date: 9/25/2013

I certify that all information furnished on this form is true and complete. I understand that anyone who furnishes false or misleading information on this form or who omits material or information requested on the form may be subject to criminal sanctions (including fines and imprisonment) and/or civil sanctions (including civil penalties).

Instructions to Publishers

1. Complete and file one copy of this form with your postmaster annually on or before October 1. Keep a copy of the completed form for your records.
2. In cases where the stockholder or security holder is a trustee, include in items 10 and 11 the name of the person or corporation for whom the trustee is acting. Also include the names and addresses of individuals who are stockholders who own or hold 1 percent or more of the total amount of bonds, mortgages, or other securities of the publishing corporation. In item 11, if none, check the box. Use blank sheets if more space is required.
3. Be sure to furnish all circulation information called for in item 15. Free circulation must be shown in items 15d, e, and f.
4. Item 15h., Copies not Distributed, must include (1) newsstand copies originally stated on Form 3541, and returned to the publisher, (2) estimated returns from news agents, and (3), copies for office use, leftovers, spoiled, and all other copies not distributed.
5. If the publication had Periodicals authorization as a general or requester publication, this Statement of Ownership, Management, and Circulation must be published; it must be printed in any issue in October or, if the publication is not published during October, the first issue printed after October.
6. In item 16, indicate the date of the issue in which this Statement of Ownership will be published.
7. Item 17 must be signed.

Failure to file or publish a statement of ownership may lead to suspension of Periodicals authorization.

PS Form **3526**, October 1999 *(Reverse)*