IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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To return or not to return? The debate over incidental findings

Planning ahead is essential for IRBs

As technology in genetic and genomic research expands, most if not all IRBs will face the issue of incidental findings, including how to manage them, and whether researchers have a duty to report them to study participants, experts say.

"Given the fact that these new technologies — some new and some standard — are now in widespread use in clinical and research settings, sometimes researchers will be looking for one thing and find others," says **Lisa M. Lee**, PhD, MS, executive director of the Presidential Commission for the Study of Bioethical Issues in Washington, DC. "What to do with the findings is the key question."

Incidental findings (IFs) are findings that arise secondary to the stated goals of the research protocols. In addition to fulfilling regulatory requirements to protect human subjects, many IRBs are faced with creating plans to manage and disclose IFs to research subjects. There is no regulatory guidance for managing IFs, leading to IRB judgment calls on the issue — and debate among researchers and ethicists.

One of the biggest areas of IFs is in whether to return results to subjects in genomic and genetic research. Whole genome sequencing, for example, has opened the door to new discoveries in genetics research — and a new host of IFs. "In thinking about genomics sequencing, there's a huge debate going on in the genetics field about how to handle IFs," says **Michelle Huckaby Lewis**, MD, JD, research scholar at the Johns Hopkins Berman Institute of Bioethics and the Genetics and Public Policy Center in Washington, DC. "If you sequence the whole genome, you may get information you weren't looking for. There is an ongoing debate in the field about whether to return those findings."

A major issue of IFs in genetics research, Lewis says, is whether the researcher has a duty to "look at everything." In whole genome sequencing, she says, the machine can be set to look only at the information a researcher needs, and not necessarily at anything else. "Is that

any different from reading an X-ray?" Lewis asks. "Even if they [technicians] are only looking for a broken bone, the way a chest X-ray is read is methodical. If they notice a suspicious spot that could be indicative of lung cancer, that would be reported. There's a question of whether incidental findings are the same kind of thing in other studies."

So far there is no consensus in the research field about reporting IFs, Lewis says. There is not a standard of care as far as what is returned. "Actionability is the key factor," Lewis says. "Think about actionability of return — is there something that can be done about it [the finding]? Can we prevent the disease from developing, or lessen the symptoms?"

IRBs must consider many different ethical issues when deciding how to manage IFs within a specific protocol. There is no regulation or law that addresses the return of IFs to subjects. Every research protocol has different goals, and disclosure of IFs to research subjects may not work in the context. Subjects in imaging studies may believe that a diagnostics expert will be reviewing the scans in a timely fashion, even if informed consent states otherwise. The IF may not have any clinical relevance, and disclosure could lead to great anxiety and emotional harm for patients.

IRB responses to IFs

Two years ago, **Janet K. Williams** and colleagues at the University of Iowa conducted a study to gather IRB chair and researcher perspectives on IFs.

"The idea of the study came when newer forms of testing could yield results you weren't anticipating and not necessarily answer your research question," says Williams, PhD, RN, FAAN, professor of nursing and chair of the Behavioral and Social Science Research IRB at the University of Iowa in Iowa City. "Testing was changing, and newer forms for testing could yield answers not anticipated."

For example, she says, a researcher may be investigating what gene variants occur in children with autism and discover a variant for inherited cancer. "Several ethical questions come up as to how you would handle that," she says.

The 2012 study involved structured interviews with 53 participants that included IRB chairs and genomic researchers. The participants were asked questions about what comes to mind when they hear the term "incidental finding;" whether and how they have encountered IFs; if the topic of genetic or genomic IFs had been discussed at IRB meetings; how researchers feel about giving subjects a way to opt out of receiving findings; and what information chairs think should be included in informed consent documents. At the time, Williams says, neither group had much experience with IFs.

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Editorial Questions

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"The IRB chairs looked at the matter from an ethical perspective, but had very little experience with it; either they hadn't encountered it at all, or there was very little guidance for when they did encounter it. Others wanted to be prepared for it." Overall, the IRB chairs followed ethical principles when considering genetic IFs: They endorsed the need to develop a management plan prior to protocol approval, for returning the IFs to subjects for clinically significant, actionable issues, and informing subjects of the possibility at the informed consent stage. Others did not have a policy due to a lack of literature and guidance on the issue.[1]

Researchers also had little experience with IFs but gave general reasons for not disclosing them: the belief that research is for general knowledge and not individual results; risks associated with disclosure or over-disclosure; and labs not being CLIA (Clinical Laboratory Improvement Amendments)-approved. But some researchers who did encounter IFs felt compelled to disclose and went to the IRBs for guidance.[1]

"The changes since this study are that the research community is more engaged in trying to determine how to proceed and inform research participants of possible incidental findings," Williams says. "It is now a very common topic."

Although it has been two years since the study was released, many of the issues involved are the same, Williams says. "There are practical issues that come up with informed consent: What kind of information should be disclosed or returned? There are issues with variants that may have uncertain implications for health risks. There are also issues with how the information should be returned; some researchers say they are not qualified to discuss this, as they are not genetic counselors. The types of situations have changed, but the basic questions and issues are still very relevant — it's just a bigger field," she says.

When IRBs are reviewing protocols, it is important for them to identify studies that could result in IFs and create adequate plans for managing and reporting them, Lewis says. "The researchers and IRBs should be doing this in the right way to protect patients," she says. "It's important to make sure there is a plan in the protocols to handle the findings. It may be that the researcher goes back to the IRB or goes before a committee, but there must be some sort of plan. Research participants must also know the plan upfront in the informed consent documents."

When to report?

Some experts have proposed the idea of determining IF disclosure by dividing IFs into three groups. The categories were proposed in a report by Susan M. Wolf and colleagues[2]:

- **Findings that offer strong net benefit.** These findings reveal conditions that are potentially grave or life-threatening, and can be treated. One example is the discovery of an operable brain tumor in an unrelated MRI imaging study.[2]
- **Findings that offer possible net benefit.** Researchers may wish to disclose these findings that a research subject may deem important, even if the potential condition cannot be avoided.[2] One example is the discovery in a woman of the BRCA gene mutation that could lead to breast or ovarian cancer. While developing either condition cannot be avoided, the subject could then choose to have annual cancer screenings based on the findings. The finding could also have reproductive significance, as the gene may be passed down to children. An indication of susceptibility to Alzheimer's disease also falls in this category. Researchers can consult with IRBs when determining whether to reveal these findings.
- **Findings that have unlikely net benefit.** The report recommends that these findings generally not be returned to subjects, as they could offer greater burden than benefit. These could reveal conditions that have no clinical significance and would not lead to a life-threatening condition or reproductive significance. Some of these IFs may have undetermined clinical actionability and reproductive significance, and would only cause distress for the subject. Examples of this include misattributed paternity, or the discovery of a very small nodule in the lung of a nonsmoker.[2]

There is also debate as to whether IFs should be reported to research subjects at all. "When you get sequenced in a clinical context, a physician ordered it and is there to help you interpret the results," says **Robert Green**, MD, MPH, associate professor of medicine in the Division of Genetics at Brigham and Women's Hospital and Harvard Medical School, Associate Director for Research at the Partners HealthCare Center for Personalized Genetic Medicine, Boston. "Who is the intermediary if you get sequenced in a biobank? In the clinical context, the chain of custody for the sample and analysis is in a CLIA-approved, standard pipeline. The patient says, 'Please perform this test to help me with my health.' Biobank donations in a research context don't have the same fiduciary

contract with the researcher." The amount of time elapsed between the collection of the sample and the discovery of the incidental finding, and whose responsibility it is to contact the individual with the result, can complicate disclosure. This creates a "parallel clinical system" with the research study just to deliver the care, Green says. "Some find that acceptable and some don't," he continues. "I think this is a great issue, and I certainly don't have the answer."

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Report gives IRBs guidance on IFs

IRBs must "anticipate and communicate"

There are no industry standards for handling incidental findings (IFs) in research. To help give IRBs and researchers guidance for IFs, the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) released its report, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, in December 2013. The comprehensive report looks at the ways in which IFs are encountered and managed in the clinical, research, and direct-to-consumer settings, and can be read at http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf.

"This report came to light because incidental findings are something that are likely to be faced by most of us, and eventually all of us," says **Lisa M. Lee**, PhD, MS, executive director of the Bioethics Commission in Washington, DC. "Many different scholars have looked at them [IFs] in one modality or one setting. This report did two things by looking over different modalities and settings: The commission came up with some overarching recommendations that apply in any setting, and some recommendations for each specific setting."

The main recommendation, she says, is to "anticipate and communicate" any IFs that could occur. "It is important for IRBs to know that the commission recommended that researchers anticipate what incidental or secondary findings might arise, and plan what to do with those," Lee says. "Once they anticipate, they must communicate that to the potential recipient. Those two things — anticipating and communicating the potential findings — are the key pieces for any researcher or practitioner."

The overarching recommendations apply to all situations that involve discovery of IFs. These recommendations include the following:

- Clinicians, researchers, and direct-to-consumer providers should describe to participants the types of IFs that could occur, and discuss the plan for disclosure and what may or may not be returned.
- Professional groups and institutional leadership should develop guidelines to categorize findings, best practices for managing findings, and train practitioners on these guidelines.
- Federal agencies and other parties should continue to fund research to examine issues with incidental and secondary findings, including the ethics, costs, benefits, and harms of disclosure, and ways in which practitioners divulge these findings to participants.
- Public and private entities should prepare educational materials to inform all stakeholders — including practitioners, institutional review boards, and potential recipients — about the ethical, practical, and legal considerations raised by incidental and secondary findings.
- The principle of justice and fairness requires that all participants have adequate knowledge, guidance, and support for making informed decisions about what tests to undergo, information to seek, and what to do with the information.

These guidelines can be used by all who encounter incidental findings across the clinical, research, and direct-to-consumer contexts. The commission also offered recommendations specific to researchers — recommendations about which IRBs should be aware.

The commission's recommendations for researchers include the following:

- **Explain IFs to subjects during the informed consent process.** This key piece, Lee says, is whether the IF plan is adequately communicated to the research participant. "Is it clear what the incidental finding might be? Is it clearly communicated? Whatever the plan is, they must communicate it," she says. "Subjects can consent to participate or not based on that."

• **Communicate to subjects what incidental findings are, what might be found, whether they will be disclosed, and how the subject can opt out of receiving the findings if he or she chooses.** The informed consent document should thoroughly detail this process, along with an expected timeframe of results to be returned. If the researchers have an ethical objection to a subject opting out of receiving results, that subject does not have to be enrolled, the report states.

• **Create a plan to manage the anticipatable incidental findings.** Researchers should determine what IFs can reasonably be expected to be found during the course of the research study. The plan should also include who will be responsible for returning the results and discussing them with subjects. "An IRB will really need to be thinking whether incidental or secondary findings are possible given the protocol, and whether the research team has adequately planned to manage them," Lee says.

• **Researchers should also decide on a process for evaluating unanticipatable findings.** Despite best efforts to anticipate every IF that could arise, there may also be those that no one expected. "What is the plan for the things they can't anticipate? You can't know everything, but there must be a plan," Lee says. "There must be a way to handle the unexpected. Have a plan, resources, and support in place to deal with the unanticipated."

• **Carefully consider whether to actively seek IFs.** A secondary finding is a finding that is actively sought by a practitioner that is not the primary target. Practitioners might actively seek secondary findings when doing so is recommended by an expert body, or by a consensus of practitioners. However, researchers do not have an obligation to seek out secondary findings, the report says. A research study may not have adequate funds to put toward the time and resources it would take to search for the findings, or it could be decided that seeking them would not advance the goals of the study. But even if researchers decide not to seek those findings, it is still important to develop a plan to manage IFs that do come up, the report says.

"It could be that they [researchers] will not look for secondary findings — they don't have an ethical obligation to seek them, so they might decide not to," Lee says. "If they happen to seek secondary findings, they must have a plan about how they will be managed and, based on that plan, informed participants can decide if it is research to which they want to consent."

Training all involved personnel in the handling of IFs is also a key piece of the puzzle for IRBs, Lee says. The commission is currently working on a primer for IRBs to address and offer guidance on all issues pertaining to IFs. The primer will include how and when incidental findings arise, how to deal and cope when they are found, and how to develop and execute a plan. The release date for the primer is set for late April 2014 and will be available at Bioethics.gov/education, says Lee.

"We're really excited about the possibility of helping researchers and the IRBs who review their protocols deal with incidental findings," Lee says. "We hope that this report and accompanying primer can really help move IRB members along and help them gain a greater understanding of what the ethics are of the growing issue of incidental findings."

[Editor's note: This is the first in a series of articles on IRBs and incidental findings. Watch for more articles in coming months, including IRB plans for handling IFs, and considerations for biobanks.] ■

IRB reins in complicated, unwieldy IC forms

New form uses tables, diagrams for simplicity

An IRB member and human research protection expert learned firsthand how complicated informed consent (IC) forms could be when her granddaughter was seriously ill.

Both of the girl's parents are professionals, and the mother is a physician. Yet they could not comprehend the consent document during this stressful period, says **Elizabeth Senft**, MDiv, MLS, research community liaison at Cincinnati Children's Hospital Medical Center.

"IRBs need to take that into account," Senft says, referring to how difficult it is to read complicated forms when one is under extreme stress.

Senft chaired a task force to improve informed consent (IC) forms and assent forms. The group consisted of IRB staff, faculty, research professionals, and research nurses.

"When we started the whole simplification, we started with the assent forms because this was something we could have across the board," says **Mina Busch**, MS, CCRP, CIP, ORCRA education consultant at Cincinnati Children's Hospital Medical Center.

Older children sign the assent forms, which were written with a sixth-grade readability level, Busch notes.

"We allowed for more white space, bigger fonts," she says.

The IRB encourages the use of tables and diagrams to show patients and their parents what will happen next in a study, Busch adds.

The IC template guidance offers an example of a table to demonstrate risks of a procedure or intervention. The example includes rows for common, uncommon, and rare risks and columns for life-threatening, serious but reversible, and mild and reversible risks. Another example shows a table that could be used to explain which activities would occur on each of five visits: informed consent, physical exam, urine sample, blood draw, and EKG. An IC form would simply have a checkmark next to the activity on the visits at which it would take place. *(See sample items in the IC template guidance on this page.)*

"Having that information in a table is much more easily digested," she says.

One of their goals was to create an IC template that could be read by someone with a sixth-to-eighth-grade reading level and to reduce the size of IC forms, she says.

"We have some consents that are 52 pages, and that's ridiculous," Senft says. "Our template with all of its guidance is eight pages, and that includes suggestions for wording."

The IC form still contains all necessary information, but it makes good use of appendices and puts information in digestible units, Busch explains.

The consent template is a table with the guidance and directives on the left and the text on the right. It is completed electronically, and it walks users through an IC form's creation. When researchers use it they can delete the left column.

"It's actually simpler to use than the old one," Senft says. "While it's eight pages long, it doesn't have to be eight pages; it can be shorter, and our goal is to have the informed consent forms shorter."

Busch also has heard positive reports of the new forms.

"When I ask people about the new consent form, they respond very favorably," Busch says. "People understand the new form better; they like it better, and it's a lot cleaner."

This isn't always practical because some areas have long standard of care sections included in their IC forms, she notes.

"We've been shortening those, too, and we're trying to get people to separate the research part from the standard of care," Senft says.

The IRB also has been working with sponsors to encourage them to use simpler language in consent documents, she notes.

"Usually, they say 'No, we can't take anything out of the form,' if it's the investigator who asks," Senft says. "But if the IRB from a nationally-ranked hospital sends the forms back, saying the sponsor's consent form is too complicated and has too much information, then sponsors are more willing to negotiate."

There are many ways IRBs can change standard IC wording to make it easier to understand, but it requires thinking differently about even the most common of terms, such as the word "risk," Senft says.

"We have found anecdotally that people respond toward risk as if it's something they take upon themselves," she explains. "Risky behavior is doing drugs or jaywalking or something like that."

Informed consent documents would be able to align research participants' expectations and understanding of risk more precisely if they did not use the word "risk" and instead explained with this kind of wording: "What are the bad things that could happen to you because you're on this study?" Senft says.

Developing the IC template was a fairly quick process. The task force began in December 2011 and finished in May 2012. Then it was rolled out in the fall of 2012, Senft notes.

Like all changes, it took a while for stakeholders to accept the new template, but once they began to use it they found it to be easier than their previous template, she adds.

"What I've heard from IRB staff is they like it better because it's easier to use," she says. ■

Suggestions from IC template guidance

Eliminate the technical jargon

The Cincinnati Children's Hospital Medical Center IRB and a special task force developed guidance and a template for improving and simplifying informed consent forms. Among the guidance's suggestions are these tips for making an IC form more readable:

• Write the consent document to a sixth-to-eighth-grade reading level.
• Use Arial, Calibri, or other plain font in 11 point or larger size.
• Use underline, bold, or boxes to emphasize important points. Do not use italics or all caps.
• Have a clear page layout with a lot of white space.
• Use page numbers, bullets, graphics, tables, and flow charts.
• Avoid technical, medical, legal jargon.
• Spell out acronyms and abbreviations the first time they are used.
• Be consistent with words and terminology throughout the document.
• Keep words to three syllables or fewer and write short, simple, direct sentences.
• Limit paragraphs to one idea and keep them short.
• Use an active voice and use second person with the pronouns "you," "we," and "I."

The template also offers examples of preferred language. Here is a sample:

• Instead of saying "trial" or "experiment," use "research study" or "project."
• Instead of using the word "randomization," say, "like flip of a coin or like drawing numbers from a hat." ■

Case studies clarify social, behavioral risks

These examples build experience

IRBs often struggle with determining risks of social and behavioral research studies. It's easy to be both too cautious and too complacent.

So a subcommittee formed by Harvard Catalyst, The Harvard Clinical and Translational Science Center, has developed a variety of case studies with examples of how to assess risk in social and behavioral research.

The social, behavioral, and educational research (SBER) subcommittee includes IRB directors, managers, staff, regulatory officers, quality assurance/improvement experts, and other stakeholders in the human research protection program, says **Matt Stafford**, IRB manager, Boston Children's Hospital and co-chair of the SBER subcommittee.

Risks in social-behavioral studies are a little less concrete and defined, Stafford says.

"Most people emanating from an accredited medical school will come to a common understanding of a certain kind of immediate risk to health and the long-term consequences of things that impact their body," he says. "But everything else is a little more subjective and experience-based."

The idea to create case studies developed organically as members of the subcommittee shared ideas, he notes.

"We had witnessed issues in our own institutions and thought there was a need for broader understanding of these issues," Stafford says.

For instance, Boston Children's Hospital handles a lot of behavioral research, including behavioral interventions and preventive measures such as reinforcing positive health behaviors and discouraging negative behaviors, he says.

"We thought case studies would be an effective teaching tool," he adds. "We made the case studies versatile and worked to get a standard format for them with the goal of making them available as a resource to the research community and the public."

The case study library is available online at http://catalyst.harvard.edu/programs/regulatory/sber.html and is about half finished, he says.

So far there are case study PDFs available in these areas:

• behavioral economics;
• business research;
• end of life issues;
• gang violence;
• prisoner research;
• social anthropology;
• students in research.

Future topics will include crisis research, deception in research, illegal behaviors, edges of research, recruitment of employees, terrorism research, and the use of focus groups.

Each case study follows a format of providing a fact pattern, regulatory, cultural, and ethical issues, and a risk-benefit analysis and risk management options. While the case studies were inspired by some researchers' and IRB members' recollection of actual studies, the studies presented are fictional.

Once all of the case studies are complete, the subcommittee will pilot test them and present them in discussions with faculty and the research community, Stafford says.

The subcommittee, which meets for an hour each month, held some two-hour meetings to create the case studies. Each case study has an author, and the group reviewed draft copies.

"Every topic was assigned a primary author and first reviewer," he says. The first reviewer's comments were discussed at the meetings, he adds.

"We reviewed the text of the cases, putting them on a projector and going through them," Stafford explains. "We saw some original comments on the side, and everyone contributed comments and constructive criticism until we agreed on the final details."

The new case studies could be used as part of a for-credit program for human research protection programs, Stafford says.

"We might encourage people to hear them by convincing local institutions to qualify these as continuing education," he says. "We could put the audience in the roles of IRB members and think through some of these things."

Feedback will make the case studies richer. They're fluid and could be improved, he says.

The point is not a template, but a basis for understanding.

"In the absence of experience, the case studies provide exposure to the possibilities," Stafford explains. "It's a 'Here are some things to think about,' which I think is all it takes for an earnest researcher or ethics panel." ■

Accreditation expert offers assessment tips

It's about more than the IRB

One chief hurdle in human research protection program (HRPP) accreditation is the mindset that it's all about the IRB, an expert says.

"When you want to accredit the organization, there is more to it than just the IRB," says **Russ Price**, MArch, federal compliance manager, Utah State University in Logan. Price has served as a reviewer and site visitor for the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Price also was scheduled to speak about the accreditation process at the AAHRPP conference, held April 22-25, 2014, in Salt Lake City.

"There are other units involved, including the sponsored program office, compliance, legal counsel, and academic administration," Price says.

"For example, there is a standard that talks about making sure all of the facilities doing research are trained in human research protection," he adds. "So the first thing you have to do is have them start to think about where that might happen."

The principal investigator's research site typically is compliant with all HRPP training requirements, but what about the laboratory that only occasionally is involved in research, or a site that does behavioral research that has limited oversight?

"If [AAHRPP] site visitors see that you work with outside groups that are not accredited, then they want to know how you do quality assurance within the organization that's not accredited," Price says.

There are other nuances to seeking accreditation and research protection compliance that organizations should know. Price offers these suggestions and observations based on best practices and mistakes in self-assessment:

• **Policies and procedures (P&Ps).** It's a mistake to adopt another organization's policies and procedures, Price says.

Developing policies and procedures is time-consuming and challenging, so some organizations might seek best practice examples of P&Ps at other institutions and adopt one of those, he explains.

"The reality is a little different from that," Price says.

No two organizations are exactly alike, and so if one institution tries to adopt the P&Ps of another, it likely will not be a good fit, he adds.

AAHRPP recommends organizations start with their IRB when writing or revising P&Ps because IRBs know their own procedures and policies, he says.

Starting with the IRB also can help build commitment and trust in the process of revising P&Ps, and this serves as an example for the rest of the organization, he adds.

• **Focus on the organizational domain.** The goal is to build teams and achieve buy-in for the work necessary to conduct a self-assessment and become accredited, Price says.

"By buy-in, I mean I'm going to participate as this affiliated unit in helping to make sure we're doing what needs to be done," he says.

"In my own institution, I have a lot of educational clinics, and we have to reach those," Price adds. "They might work with special education rehabilitation, early childhood education; all clinics have outreach capacity and also are doing research."

Every unit involved in research will need

P&Ps, and these need to be crafted with flexibility to account for differences in how they're providing service.

• **Follow AAHRPP standards.** Accreditation standards contain a lot of information about regulations, and they list the outcomes AAHRPP is trying to achieve by having the standard, Price says.

It's not necessary to create a checklist, he says.

"What we're really after is: 'What does your university do that is unique and that makes it possible for you to meet this standard in a way that other people could learn from?'" Price explains.

"One of the great things about doing site visits is I get to see so many great things people are doing out there," he says.

"We tend to call them best practices, but that makes it sound like everyone has to do it," he adds. "To me, best practices have to do with how you are applying them in your circumstances, given the way you've set up your program, affecting the type of research your organization is capable of doing."

• **Practice effectively.** Just as highly skilled musicians become professionals in their craft through years of practice, so might research organizations become experts in HRPP through practiced self-assessment.

"Look at what you're doing in your organization with a goal in mind," Price advises. "Make sure you are using your talent base to get to that end product."

There's a long period of time when a young musician practices piano on the bench beside a teacher because he hasn't learned how to practice on his own, Price notes.

Likewise, an organization will need some assistance with self-assessment in the beginning, but eventually should find this to be a routine exercise.

"Self-assessment is seeing your talent base and using it to make your organization better," he adds. "Waiting for someone else to tell you what to do is a mistake people make."

• **Hold focus groups.** Having a focus group can show an organization whether goals are being met, and it is another method for giving information and holding an IRB accountable.

Through a focus group consisting of stakeholders, an IRB will discover its weaknesses, where it is less effective, and where it should direct new focus, Price says.

For instance, Price learned from a focus group that people found privacy and confidentiality issues confusing.

"We had not been adequately clear on how to differentiate between them," Price says. "So we strengthened both our training materials and online materials and online application."

This is an opportunity for improvement that would not have occurred without the input of a focus group, he notes.

"Focus groups strengthen that process with the people in the field," he says.

• **Develop shortcuts that enhance the mission.** "Four years ago, when our organization initially was accredited, we took our policies and procedures and standard operating procedures and created an investigator handbook," Price recalls.

The goal was to create something simpler and more useful for investigators to use, so they wouldn't have to read through all of the SOP material that was intended to drive how the IRB operated, he explains.

The SOPs still contained all of the necessary information, but the investigator handbook was shortened and set up in a procedure-by-procedure basis, telling investigators what they needed to know. The SOPs have 400 to 500 pages, and the handbook is a more manageable 60-80 pages, Price says.

"We found the investigator handbook to be a powerful tool to help new faculty, especially, to know how to respond to our IRB," he says. ■

Study: Registration data still incomplete

While the informational quality of internationally registered trials has increased, there's still room for improvement, according to a recent study.

The study, published in the Jan. 10, 2014, issue of *PLOS One* and a repeat of 2009 study from the same authors, looked at a random sample of 400 trials listed on the World Health Organization's International Clinical Trials Registry Platform (ICTRP) between Jan. 1, 2012, and Jan. 1, 2013. The study assessed information on contact details, interventions, and primary outcomes. Evaluation of registered intervention data was limited to studies on drugs, biologics, or vaccines.[1]

The study described the following improvements from the 2009 analysis:

• The number of registrations that included a phone number or email address is 74.9%, up from 68.7% in 2009.

• 51.9% were complete in registering intervention specifics, up from 44.2%

• 57.6% has primary outcomes that were specific measures with a meaningful timeframe, a significant increase from the previous 38.2%.

• A contact name appeared on 85.5% of studies, up slightly from 81%.

• Half of all trials continue to be retrospectively registered, the authors wrote.[1]

Despite these improvements, "important problems with quality remain and continue to constitute an impediment to the meaningful utilization of registered trial information," according to the authors. While 85.5% of studies listed a contact name, there were still many that did not. Contact information is also absent, in many cases removed after completion of the trial. "Explicit mentioning of the name of the principal investigator is important to increase the accountability of trialists," the authors wrote. "To allow patients, healthcare workers and other researchers to inform themselves of clinical trials, it is important that trialists can be contacted at any stage of a trial. Such information should remain available after a trial is completed or stopped."[1]

Retrospective registration is also a continued problem, according to the authors. "Without prospective registration, before enrollment of the first participant, we cannot be certain that trial outcomes are not retrospectively registered in such a way that favors a particular result," they wrote.[1]

Quality of registered trial data likely varies due to differences in requirements and quality control among the different clinical trial registries, the authors suggested. "For example, some registries specifically ask trialists for the methods of measurement for each outcome. Others have only free text fields for outcomes. Some registries ask for specific details on interventions, others, again, have only free text fields," they wrote. "More effort needs to be made to improve data recording formats, enhance quality control measures and scale up enforcement of trial registration."[1]

REFERENCE

1. Viergever RF, Karam G, Reis A, Ghersi D (2014) The Quality of Registration of Clinical Trials: Still a Problem. *PLoS ONE* 9(1): e84727. doi: 10.1371/journal.pone.0084727. ■

Smartphones pose new ethical challenges

Unscrupulous use is growing concern

The exponential increase in smartphones and social networking sites has led to concerns from some patients regarding the possible unlawful distribution of images outside the realms of their care.[1]

"This creates a unique ethical concern," says **Rhys Van der Rijt**, MBBS, of St. Vincent's Hospital in Sydney, Australia. "As technology and social media become an integral component of modern life, it inevitably creates a potential interface between the clinical environment and non-private domains such as social media sites."

The unscrupulous use of clinical photography can affect the doctor-patient relationship, breech ethical codes of conduct, and have legal ramifications for the clinician, warns Van der Rijt.

"As everyone now walks around with a fully functional recording device, it becomes harder to prevent unauthorized recordings," says **Jessica Wilen Berg**, JD, MPH, a professor of law and bioethics at Case Western Reserve University in Cleveland.

Consent and confidentiality concerns

Patient consent and confidentiality are two fundamental ethical codes that may be breeched if the right approach is not taken in regard to clinical photography.[1]

However, over-enforcing rigid hospital policies and disallowing clinicians to take photographs disrupts an efficient tool for communication and compromises patient care, argues Van der Rijt.

"The clinician's obligations to respect the patient's rights of autonomy and confidentiality must be balanced against the benefits of clinical photography in each case," Van der Rijt says. Here are some of the primary ethical concerns involving smartphone photography:

• **Informed consent.** The expectation is that one will get the patient's informed consent before any kind of recording, says Berg. If recordings are designed to be used solely for internal educational purposes, an "opt-out" model of consent might be used. In this model, patients are informed about the photography in general institutional

documents and allowed to opt-out if they choose, but specific informed consent isn't obtained for each use. Photographs used for non-clinical purposes, or for research, will need a specific, detailed informed consent, however, says Berg.

"The key, for either a specific consent or for an opt-out system, is a description of how the recording or picture will be used," she says.

• **Security concerns**. Smartphones raise significant security concerns because the devices are rarely used for purely professional purposes. "It seems inappropriate to take photographs on a personal device unless the consent specifically allowed for this and, thus, allowed for the personal use by the photographer," says Berg.

Partners HealthCare recently rolled out applications that allow clinicians to take pictures that are directly uploaded to the patient's medical record, and are not stored locally on the phone.

"This is obviously a big advantage with respect to security, when you want to take a picture that's going to be used for clinical care," says **Thomas Cochrane**, MD, MBA, senior ethics consultant at Brigham and Women's Center for Bioethics and assistant professor of neurology at Harvard Medical School, both in Boston. "We still need to use caution and get consent when we want to take those images and use them for teaching or publication purposes," adds Cochrane.

Photos from personal devices should have strict electronic security and should be deleted as soon as possible if they are not used for patient records, advises Van der Rijt.

"Some hospitals are providing specific clinicians with work mobile phones to aid in the security of photographs and to ensure correct storage and disposal," Van der Rijt reports.

• **Privacy.** "Photography and videography in the clinic is becoming extremely common because we all have these great cameras in our pockets, built into our phones," says Cochrane. Photographs, especially when they're personally identifiable, are a particularly sensitive type of health information, however.

"Once they are beyond the control of the photographer, these can be distributed to a large number of people or posted publicly," says Berg. "Of course, this concern exists with all digital images."

REFERENCE

1. Van der Rijt R, Hoffman S. Ethical considerations of clinical photography in an area of emerging technology and smartphones. *J Med Ethics* doi:10.1136/medethics-2013-101479 ■

Hospital Report blog

For further analysis and discussion of topics important to hospital professionals, check out **Hospital Report**, AHC Media's free blog at http://hospitalreport.blogs.ahcmedia.com/. *IRB Advisor*'s executive editor Russ Underwood and associate managing editor Jill Drachenberg both contribute. ■

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. Scan the QR code below or 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

■ Finding flexibility in documenting consent

■ OHRP tips for quality assessment

■ How the Internet can enhance clinical trial performance

■ Tips for IRBs for handling emergency use agreements

CNE/CME QUESTIONS

1. According to a report by Susan M. Wolf and colleagues, which findings generally should not be returned to research subjects?
A. Findings that may have reproductive significance
B. Findings that may cause subjects great burden with little or no clinical benefit
C. Findings for which there is undetermined clinical actionability
D. Both B and C

2. In the study conducted by Janet K. Williams, PhD, RN, FAAN, and colleagues, which of the following is not a reason researchers gave for not returning incidental findings to subjects?
A. Labs used were not CLIA-approved
B. The belief that research is for general, and not individual, knowledge
C. Researchers did not have enough experience
D. Risks associated with disclosure and over-disclosure

3. Which of the following does the Cincinnati Children's Hospital Medical Center IRB say is not a good suggestion for making informed consent documents easier to understand?
A. Use Arial, Calibri, or other plain font in 11 point or larger size
B. Use underline, bold, or boxes to emphasize important points. Do not use italics or all caps
C. Reduce the amount of white space on each page
D. Use an active voice and use second person with the pronouns "you," "we," and "I"

4. According to Russ Price of Utah State University IRB, the best practice for revising or creating new policies and procedures is to find another institution's successful P&Ps and adopt that model.
A. True
B. False

IRB Advisor

2014 Reader Survey

In an effort to learn more about the professionals who read *IRB Advisor*, we are conducting this reader survey. The results will be used to enhance the content and format of this publication.

Instructions: Mark your answers by filling in the appropriate bubbles. Please write your answers to the open-ended questions in the space provided. Either fax the completed questionnaire to 404-492-5933, or return it in the enclosed postage-paid envelope. The deadline is **July 1, 2014**.

1. How would you describe your satisfaction with your subscription to *IRB Advisor* newsletter?

O A. very satisfied O B. somewhat satisfied O C. somewhat dissatisfied O D. very dissatisfied

2. Are the articles in *IRB Advisor* newsletter written about issues of importance and concern to you?

O A. always O B. most of the time O C. some of the time O D. rarely O E. never

Questions 3-10 ask about the importance of various topics in *IRB Advisor* newsletter. Please fill in your answer using the key below.

	A. very important	**B. fairly important**	**C. not very important**	**D. not at all important**
3. informed consent	O A	O B	O C	O D
4. Common Rule compliance	O A	O B	O C	O D
5. subject recruitment	O A	O B	O C	O D
6. ethical conflicts	O A	O B	O C	O D
7. financial conflicts of interest	O A	O B	O C	O D
8. subject compensation	O A	O B	O C	O D
9. education programs	O A	O B	O C	O D
10. HIPAA	O A	O B	O C	O D

Please rate your level of satisfaction with the following. Please fill in your answer using the key below.

	A. excellent	**B. good**	**C. fair**	**D. poor**
11. quality of newsletter	O A	O B	O C	O D
12. article selections	O A	O B	O C	O D
13. timeliness	O A	O B	O C	O D
14. length of newsletter	O A	O B	O C	O D
15. overall value	O A	O B	O C	O D
16. customer service	O A	O B	O C	O D

17. Do you plan to renew your subscription to *IRB Advisor*?

O A. yes O A. no

If no, why not?_____

_____

18. What can *IRB Advisor* do to improve?_____

_____

19. What issues or topics would you like to see covered in *IRB Advisor*?_____

_____

_____

20. How many IRBs does your institution sponsor?

O A. 1 O B. 2 O C. 3 O D. 4 O E. 5-10 O F. 11 or more

21. How many studies does your IRB oversee each year?

O A. 1-5 O B. 6-10 O C. 11-15 O D. 16-25 O E. more than 25 per year

22. How would you categorize your IRB?

O A. affiliated with a university
O B. independent consultants
O C. affiliated with a Department of Health
O D. Other_____

23. In what capacity do you serve on the board?

O A. coordinator O B. chair O C. co-chair
O D. scientist O E. community member (non scientist) O F. other_____

24. To what other publications or information sources do you subscribe?_____

_____

_____

25. Which publications or information source do you find most useful?_____

_____

26. What did you like most about that publication or information source?_____

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Optional

Name: _____

E-mail address: _____