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Electronic informed consent a growing force in HRPPs

Electronic forms track how subjects use the data

For decades, IRBs and ethics panels have lamented the sorry state of informed consent documents. The complaints have included too much legal and medical jargon; too long and cumbersome; too visually unappealing; too much focus on minutia and too little focus on risks; and unlikely to be read and understood by potential research subjects.

What if an IRB were told of an informed consent document that has resolved all of these problems? There is only one catch: It's not on paper.

Electronic informed consent is a growing force for human research protection, and to at least one medical ethics director, this change has been needed for a long time.

Paper consent forms have become antiquated and are not up to the job of 21st century informed consent, says **Arthur L. Caplan**, PhD, director of the division of medical ethics at New York University Langone Medical Center in New York, NY.

Informed consent presented in non-paper formats is better suited for young people, people with impairments, and low-literacy populations, he notes.

"We definitely need to be moving toward an electronic and visual consent form, and these would have many advantages," Caplan explains. "These allow people to move at their own level of literacy: You can set it hard, moderate, easy, and you can let people spend as much time as they like with the electronic form, asking it questions or reading up more on concepts that are hard to understand if they want to."

For example, there is a mobile app for research informed consent that can track how long a person spends looking at a particular section and whether the person flagged a certain word to learn its definition. This provides valuable data for where to make readability improvements to the IC, says **Anthony Costello**, chief executive officer of Mytrus in Davis, CA. Mytrus is a clinical technology firm that specializes in patient-

centric technology and in technology for clinical trials.

Electronic consent has enormous advantages for use in international and low-literacy settings, Caplan says.

"You can document their informed consent by recording it, which is useful overseas when faced with populations that don't write or have a written culture," Caplan says. "You can use your iPhone video camera or an app on a portable device to record the response, which stands up much better because it's harder to forge that than to forge a signature."

"Also, electronic IC is easier to update when new information is available," he adds. "I think the only reason we haven't moved in that direction sooner is because local IRBs didn't have the resources to invest in these kinds of technology."

Federal regulators have approved electronic consent processes, and IRBs increasingly are on board. The biggest obstacle today is the cost, Costello says.

"There's a perception that the current paper consent system might not work well, but it's cheap," he explains. "When you build an iPad app and distribute iPads, you have built-in, associated costs."

Plus, any new technology has to go through an adoption curve: "It takes a while to get comfortable with new technology, and we're going through the start-up curve," Costello says.

Now that the research industry is moving more to sponsored research and there are increasing numbers of central IRBs, these organizations have more resources for driving a change to electronic consent, Caplan says.

"They want to improve efficiency and reliability of informed consent," he says. "It's all good, and it's overdue."

Potential uses for electronic IC include the following:

• **IC on a tablet.** Informed consent on a tablet computer is an educational tool as well as a documentation tool. Companies have begun to put an IC form on the tablet to make it easy to manage hundreds of signed IC documents on one device, Costello notes.

But IC on a tablet can be useful in many more ways. For instance, a tablet IC can show potential research participants a video that explains some key information about the clinical trial, he says.

"Patients can watch an animated video we produce about the study," he says. "We use cartoon characters to keep them engaged about the main aspects of clinical trials."

As people read the written consent on the tablet, they can change font size for readability and flag words they don't understand, and some terms and sections can be hyperlinked to dictionaries or any other additional information.

Electronic consent can include graphics, video, and photos to illustrate procedures and other points in the IC, Caplan says.

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Editorial Questions

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"We know that's how people understand better, and we can use illustrations and film clips to demonstrate techniques," he says.

• **Data on what potential subjects read and what they understand.** "We capture metrics," Costello says. "We see how long they spent reading the form, which things they flagged, and whether they seemed to be understanding certain things better."

Electronic IC can track participants' eye movements across a screen and collect data on which words they linger on, Caplan says.

"I've used one where it asked me a question if I was lingering on a word," he adds.

• **Test participants on retained knowledge.** Electronic forms can include a knowledge assessment section where participants are asked questions about the study.

"They can focus on the main aspects of the trial, and it's usually seven or eight questions in a multiple choice questionnaire," Costello says. "If they get one wrong, we circle them back to that section of the informed consent to read the correct information and then take the quiz question again; we reiterate this until they pass the entire quiz."

Participants also have the option to stop reviewing the IC form, he adds.

"Most patients do read the document and may read it quickly, but they don't just ignore it the way we thought they may have with paper," Costello says. "The other important learning we've had so far is that patients learn a lot from video, and it's helpful to have a knowledge assessment at the end."

• **Electronic signature capability.** "Electronic signatures are being used all over for clinical trials now," Costello says. "Everyone who collects data signs in with a username and password, and 21 CFR11(c) clearly specify that a user name and password is equivalent to a handwritten signature."

Electronic IC forms also can collect a participant's signature on the tablet, and the actual signature will appear on any printout copies of the form, he adds.

Whether participants sign on a tablet or sign in and use a password, the electronic IC copy will record the time and date of the consent.

• **Feedback loop.** One of the chief advantages of using electronic consent is that it continually provides metrics that can be used to improve the IC document.

For instance, if an IC form has words or phrases that a majority of participants find difficult, electronic feedback data lets investigators and sponsors know about this problem.

"The big advantage is if patients are flagging words as they go through the app, the site and sponsor can see all of the words that are being flagged," Costello says. "If one word is disproportionately flagged by patients, then they can amend the document by putting in a new sentence or description; they can write the consent so there's less confusion."

This feedback loop isn't possible — or at least isn't as data-driven — with paper informed consent forms, he adds.

"In the paper consent you'd never collapse any of those metrics across multiple patients and learn from them," Costello says. "The big advantage of this in the long run is it will bring radical improvements in how patients understand consent." ■

How to find non-affiliated IRB members

Try volunteer, retiree organizations

IRBs continually struggle to find nonaffiliated and nonscientist volunteers to fill the challenging role of IRB member.

While many IRBs ask attorneys, clergy, and community organization leaders to fill this role, there are some ways to recruit nonaffiliated members who represent more diverse demographics.

For instance, one research compliance official recruited mothers of young children by asking for help from a local Junior League.

"I thought of places that might otherwise have people who volunteer for them, and the Junior League came to mind," says **Kara Brocious**, MPH, CIP, research compliance consultant, human subjects office, Indiana University in Indianapolis.

"The Junior League does philanthropic and other activities, so I thought if we reached out to their membership there might be people who were interested," she says. "It worked. We had three or four responses from people who were interested, and we still have one of them as a board member several years later."

Organizations for retired people also are good resources for recruits, says **Laura Noll**, MS-candidate, LAT, ILAM, research compliance manager at

Radford University in Radford, VA.

Noll recruits members for both an IRB and an institutional animal care and use committee (IACUC), and she recalls the time when an IACUC was in danger of being closed because of the loss of two community members.

"We sent out a Hail Mary, asking for help in trying to find us someone, and one member asked a minister, who came on board," she says. "Another person found a retired computer executive and he came on board, too."

After that experience, Noll learned of the national Retired and Senior Volunteer Program (RSVP). She contacted the RSVP director, who helped find volunteers for the ethics boards.

Finding ethics board non-affiliated members in Radford is particularly challenging because the university is near Virginia Tech, and the two universities are the area's biggest employers.

"Most people who live here work at the university or have a spouse who works there or have kids who graduated from there," she says.

Brocious found that recruiting women volunteers through Junior League provided additional benefits to the IRB because of the new members' ability to offer a different perspective on informed consent and research proposals.

"They're younger people with young children," she says. "One woman we recruited had a pharmacist background, but she wasn't working as a pharmacist anymore."

The community volunteers worked out well for the Indiana University IRB, providing at least one nonaffiliated member who stayed on the board for about three years, Brocious says.

"I would go back to the Junior League or an arts organization for non-affiliated members," she says. "And I would look for volunteers from a local professional organization that has younger, educated members who offer their expertise to nonprofit groups."

Brocious and Noll offer these tips on how to recruit non-affiliated members:

• **Stress the community altruism aspect.** Noll tells new board members that their participation on the board is a service to the university and their community.

"It helps us fulfil federal regulations," she adds. "But I also explain the spirit of the regulations and how we want the community involved so there is a non-scientist, non-affiliated perspective on the research."

• **Talk about how interesting it can be to discuss research.** The Junior League recruits found IRB work very interesting, and they were enthusiastic about attending board meetings and looking at research proposal materials, Brocious says.

"These all were educated people and could follow along well with scientific concerns," she says.

• **Promote their role in representing research participants.** The Indiana University board's members include a physician, a pharmacist, a biostatistician, and others with research backgrounds, Brocious says.

So when she recruited young women volunteers who were not actively working in their professions while staying at home with their children, she found that they helped to diversify the IRB. The young mothers on the IRB liked having a sense that they were representative of research participants, Brocious says.

"In IRB discussions they look at it from the point of view of someone being asked to enroll in the study, wondering how they would receive information about the study and whether it would make sense," she says.

• **Be upfront about the time commitment.** Noll describes the board's time commitment and meeting schedule, but also describes how interesting the studies can be.

In recruiting new board members, some of the regulations and confidentiality issues should be emphasized, as well.

"I explain that a lot of what we review is proprietary, so it needs to be kept confidential," Noll says. ■

Grad assistants help with one-person office

Grad student went on to be 'rock star'

Laura Noll, MS-candidate, LAT, ILAM, research compliance manager at Radford University in Radford, VA, has had to learn ways to get a lot of research compliance work accomplished on a shoestring budget. She is a

one-person office that handles IRB work, IACUC work, and other aspects of research compliance. She has found that it's very useful to have graduate student assistants help her with the workload. *IRB Advisor* asked Noll how she trains graduate students to become productive IRB office workers, especially since they work in this role only temporarily.

***IRB Advisor*:** Would you please explain how you are able to use graduate student assistants in the research compliance office?

Noll: When I came here four years ago, the office was set up to use graduate student assistants. A lot of times they would change every semester. I felt this was a very bad idea, and everyone understood.

Out of desperation, we've set down some ground rules for my GAs: My 20-hour student stays with me for two years, and no one else can use this student; my 10-hour student is not reallocated, either, but the 10-hour students don't necessarily stay with me for all two years of their graduate program. The 10-hour student generally only performs protocol intake and approval processing, plus general filing, so the training isn't as in-depth. But the longer I can keep them, the more efficiently the office will run.

I train them, and they learn office skills and how to interpret the regulations. I use my graduate students at a higher level than most other graduate students on campus. They receive a lot of mentoring and a good internship. They review protocols for completeness and somewhat for content, make basic comments on protocols, shuttle submissions back and forth between the reviewer and principal investigator, and they are doing it all pretty quickly. This is intense training, and some have been overwhelmed, but they catch up and we get it done. My IRB has helped me to streamline some things and make it a somewhat distributed review process rather than to expect too much out of students. By the time the students leave here, though, they are ready to take a job in an IRB office or other compliance-type of office.

***IRB Advisor*:** Where do you find students and how long do they work for you?

Noll: To date, all of my students have come from the psychology department. We have found that it works well to have students from the Department of Psychology, either from the Experimental or Industrial/Organizational concentrations. I try to find students who are about to start the first semester of their master's program and have them start work in the summer. I try to train them before the start of the fall semester, which is our busiest semester. I don't need them to be panic-stricken when all of the protocols start to roll in. The students read all kinds of protocols throughout the year, so they get to learn a lot about research, and then by the time they take their research methods course, they already know a fair amount about it because they've been reading submissions for so long.

One of my first graduate students took a job in a major university's IRB office. There were six schools across the country competing for him. He started interviewing for jobs during winter break of his senior year. He'd worked here 1.5 years. He's a rock star and earned his CIP quickly after starting his new job. Now he's on a full-board pre-review committee. Before he took the IRB graduate assistantship with me, he was considering going on to a doctorate in psychology after his master's was complete, but then he fell in love with compliance. I think he'll find a doctorate program that meshes well with compliance shortly, though. ■

Switching to Web entry can result in challenges

Here's how to overcome obstacles

The transition from a paper IRB submission process to an electronic one can be a long and, at times, frustrating journey. The key is to break goals into phases and deal with obstacles as they arise, an expert says.

"We have a brand-new system and are rolling it out in phases," says **Kara Brocious**, MPH, CIP, research compliance consultant, human subjects office, at Indiana University in Indianapolis.

"Several years ago, everything was submitted to the IRB by paper, and now everything is by email," Brocious says.

Email submissions require some behind-the-scenes work, with IRB staff putting information in electronic folders. Soon that will change, says Brocious.

"We're transitioning into a Kuali Coeus IRB program where the system will do everything," she says. "Investigators will go into it and create their own submissions, like a new study or amendment or renewal, and they will revise documents directly

in the system."

The new system will allow electronic reviews. "It's all self-contained," Brocious says. "IRB reviewers will go into the system and do everything internally."

Phase one

The first phase was implemented in August 2013 with a focus on new studies. Investigators were required to submit all new studies via the KC IRB system, and email submissions were stopped. Several IRB forms were discontinued as well, as all necessary documents were uploaded to the KC IRB system.

One of the obstacles as the transition unfolded was that some of the investigators and other people who needed to be trained to use the new system found it difficult to schedule time for training, Brocious says.

IRB staff addressed that problem through individualized training when investigators called in with questions, and with proactive outreach, Brocious explains.

Training was offered in July 2013, first only for information. "Here's the new system, what it looks like," Brocious says. "We also had training guides, screen shots, and videos posted on our website."

Then more individualized training was offered.

"We go out into the departments and do mini-training sessions to help people get used to the system and to answer their questions and show them how it works," she says. "We have a feature in our system where we can share computer screens with someone who has a question about KC IRB."

Brocious or other IRB staff can see what investigators' issues are and help them resolve them by sharing their computer screen images.

Another obstacle was that some people were resistant to the change to an electronic system, Brocious says.

The solution?

"You have to ease them into the change," Brocious says. "We understand it's complicated and much more challenging on their side than just filling out a form and sending it in to us, but pretty much everything on campus is computerized, and medical records are electronic, and internal document storage systems are electronic."

So while Brocious encourages staff to be gentle with those who are resistant to change and taking them by the hand to walk them through the system, she also makes sure investigators know that this system is what they will have to use.

A third obstacle involved the system itself.

As the system's phases were implemented, some problems emerged: "Out of the box, it didn't do everything we needed it to do," Brocious says.

"We have had IT [information technology] rewrite code," she says.

One of the drawbacks is that the system is not intuitive, she says. It works well once a user learns the step-by-step process, but that process needs to be repeated and memorized, she adds.

Some hurdles were anticipated and prevented through the pre-implementation phase. The research institution had training working groups, testing working groups, and communication working groups.

"It took a lot of work by a lot of people to implement this system," Brocious notes.

"Before we started rolling it out, there were maybe four to six weeks of prep work, and, since then, ongoing work to get the next piece ready and rolling out," she says.

Phase two

In November 2013, the second phase began with ongoing study actions. Researchers were permitted to submit all study actions including renewals, amendments, and general information via the KC IRB system. They also began to have on-demand access to all study documentation.

The third phase began in April 2014 with implementation of the exempt questionnaire. The electronic system made the exempt research checklist unnecessary, and the information within the checklist was integrated directly into the KC IRB system. The amendment form was also unnecessary, helping to streamline the submission of exempt submissions.

Starting this summer, the fourth phase will mean the discontinuation of most IRB forms. All of the forms' information will be entered directly into KC IRB. This will reduce duplication and streamline the submission process.

"Amendments and renewal forms are going away in phase four," Brocious says. "The close-out reports will continue beyond phase four to be something they submit as a form by email to us."

But most other forms will be discontinued, she adds.

"Phase four is our last roll-out for the research community to get them using the system," she says. ■

Certificates can protect subject identities

Extend to 'sensitive' research topics

Protecting the identities and sensitive information of study subjects is one of the top priorities in research, particularly if a study involves topics that could be damaging to a subject's reputation. Investigators can seek an extra layer of protection known as Certificates of Confidentiality for such studies.

The National Institutes of Health (NIH) issues Certificates of Confidentiality (CoC) to protect the privacy of research subjects by shielding investigators from being compelled to release subjects' identifying information. The certificates can allow an investigator to refuse to submit identifying records if compelled by civil or criminal trials, or other proceedings.

Because the statutory authority that established the CoC protection is specific to the Department of Health and Human Services (HHS), to be eligible for a CoC, a research study must be health-related and must also be collecting sensitive, identifiable information. "'Sensitive' is very broadly defined as any information that, if released, could potentially harm the subject," says **Ann Hardy**, DrPH, Extramural Human Research Protections Officer and Certificates of Confidentiality Coordinator at the NIH Office of Extramural Research (OER). "'Identifiable' is also broadly defined as information that could lead to the identification of a subject; this includes more than just a subject's name."

Examples of sensitive research include:

- research on the psychological well-being and mental health of subjects;
- studies on sexual attitudes, preferences, or practices;
- studies collecting information on substance abuse or other illegal risk behaviors;
- health-related studies that gather information that, if released, could be damaging to a participant's financial standing, employability, or reputation within the community.

The definition of "sensitive research" has expanded in recent times to include genetic research. The increase of sensitive genetic research in the last decade has led the NIH to consider genetics studies as containing potentially identifiable data, Hardy says. "We have issued certificates to genetic studies and for research repositories that contain genetic data, in part to encourage researchers to be more willing to submit findings to repositories such as NIH's dbGaP [database of Genotypes and Phenotypes]," she says.

Eligibility

Certificates are limited to research that is health-related, Hardy says. "One of the misunderstandings IRBs might have is that they [certificates] are for any type of research," she says. "There are a lot of research topics that can be considered sensitive, but are not eligible for a certificate because they are not health-related." Federal funding is not a requirement for a certificate, although the research must be allowable by HHS policy.

The study must also collect identifying information. The CoCs don't necessarily protect all research data — just the data that can ID subjects. "It may not be widely appreciated that [the regulations] were written specifically to protect identifiable research data," Hardy says.

HHS also requires IRB approval or conditional approval before issuing a certificate. "This way, we can make sure there are no changes to the study, and what we're describing is what will happen," Hardy says.

"Subjects have to be informed of the certificate and what it does and doesn't do, and we have suggested informed consent language on the website," Hardy continues. "NIH is happy to work with researchers on the consent language."

It is vital to note that the certificates don't protect against voluntary disclosure of data by investigators or study subjects, Hardy says. For example, an investigator can disclose identifying data if he or she thinks it's necessary in order to prevent harm to the subject or someone else, such as cases of abuse or suicidal ideation. "If investigators want to disclose something like suicidal ideation, they need to be clear in the consent form that they intend to do that," she says. "If it's a study where voluntary disclosure won't be an issue, then investigators don't need to worry about this."

The application for a CoC has a study start date and end date for subject recruitment, collection of data, and analysis, Hardy says. If the certificate expires while the data analysis is being performed, the subjects are still protected under

the certificate. "What you don't want is a study that continues to enroll subjects after the expiration date, because those subjects would not be protected by the CoC; in such cases, an extension would be needed," she says. "If there is a change in the study, we may need to issue an amended CoC because we want to make sure if someone uses the CoC to refuse a legal demand that it is clear that the CoC applies to that particular study. Once a study is completed, the CoC protection of the subjects is permanent."

When to use

Some IRBs may not be clear on when and how to require a certificate for research protocols. A study published in 2012 in the journal *PLoS ONE* examined IRB chairs' knowledge of certificates, how they work, and when to use them. "We found when we did the survey of the IRBs that there was a lot of uncertainty or incorrect answers about the certificates," says **Leslie E. Wolf**, JD, MPH, professor of law at Georgia State University College of Law in Atlanta, and co-author of the study. "We were a little surprised, but I think there's confusion out there and the study confirmed it."

The study involved surveys with 453 IRB chairs nationwide, and follow-up interviews with 21 of these. Forty-five percent responded that they were familiar or very familiar with CoCs. Those with more familiarity had more years of experience as IRB chairs. Fifty-five percent answered three or more of the six true/false knowledge statements correctly.[1] The statements included:

- The HIPAA Privacy Rule provides the same protections as does a certificate. [False]
- A certificate is granted to the research institution for a particular project, not to the principal investigator of that project. [True]
- With a certificate, a researcher may voluntarily comply with state reporting laws, but only when such disclosures are specified in the informed consent document. [True]
- Research participants are only protected until the expiration date of the certificate. [False]
- Even with a certificate, researchers must release identifiable data to the federal government as required for program evaluation or audits of research records. [True]
- With a certificate, a researcher may withhold identifiable data, even if the participant consents in writing to disclosure. [False][1]

The only question a majority of the respondents answered correctly was the question about HIPAA privacy, the study says.[1]

The study interviews showed that some chairs believed that CoCs only protect information on subjects' illegal activity. Others responded that they would not require a certificate if there is no risk of a subpoena. Some chairs also stated that they did not consider genetic research sensitive enough to require a certificate.[1]

Much of the uncertainty surrounding certificates was consistent with individual experience, Wolf says. "I think some IRBs are more experienced in a positive or negative way, or they have a lot of a particular type of research that deals with certificates. Some institutions that don't do a lot of that type of research may be less informed."

If IRBs or investigators are unsure of how and when to obtain a certificate, the NIH has a Certificates of Confidentiality Kiosk at http://grants.nih.gov/grants/policy/coc/index.htm, which includes frequently asked questions, application instructions for intramural and extramural studies, contact lists, and flow charts. "The flow chart helps guide those who are new to the process," Hardy says.

Legal challenges

In the study, 86% of IRB chairs said that CoCs were currently used at their institutions, and 10% stated that they have received legal demands to disclose identifiable data. It also showed mixed opinions on the level of protection chairs thought the certificates afford, and the extent to which the certificates have been tried in court.[1]

"We also spoke to legal counsel about the effectiveness of certificates in practice — it was reassuring, though not fully clear, in that the demands for research data were relatively rare," Wolf says. "Often, the certificate was successful, but not through a legal case that would say definitively that this [data] was absolutely protected. Rather, counsel would raise the fact that there was a certificate, and the demand would go away. That's good as a deterrent."

"Anecdotal information suggests that oftentimes when there is a request for data and certificate is mentioned, it just goes away and doesn't get to subpoena stage," Hardy adds.

However, there are still concerns about whether certificates would be upheld in some criminal

proceedings, Wolf says. "The concern would be if a criminal defendant were to raise the question of guilt or innocence based on the data, and whether those constitutional issues would trump the statutory protections of the certificate," she says.

The closest the issue has come to being tested is in the case of the State of North Carolina v. Bradley. A criminal defendant believed a witness to be part of a Duke University Health System study on psychiatric disorders, and requested a court order for all study records on the witness. The motion was granted, but reversed when Duke researchers moved for a protective order and cited the certificate. The defendant was convicted and later appealed, requesting that Duke turn over the sealed witness records as possible exculpatory evidence. The judge agreed to let attorneys look over the documents and decide the relevance to the case, allowing them only to be viewed by the defense and prosecuting attorneys. The appeals court found the records to be immaterial to the case and vacated the court order. The court declined to consider whether the Certificate of Confidentiality would have protected the records if they were found to be material to the case.[2]

"The Bradley case was a criminal case, but it was not as directly exculpatory and the court ultimately decided the information wasn't relevant to the case," Wolf says. "We haven't seen a case that would decide if it [the certificate] would be upheld if it were something more squarely exculpatory."

The Bradley case wasn't necessarily a failure for CoCs, Hardy says. "Unfortunately, I think people interpret that case as a failure of the certificate," she says. "[The certificate] was clearly considered and the review of research data allowed was very limited. The court ultimately decided that the information wasn't relevant, and no further examination of the data was allowed. I view it as the court being very careful about the information because of the certificate. However, someone's constitutional rights may trump the CoC regulations," she says.

Hardy cites another case in which researchers uncovered evidence of child abuse, and child protective services requested research data. "The courts decided that since the researchers already reported the abuse that they had to disclose the additional data," she says.

If an investigator thinks there is a likelihood that his or her study will draw a legal demand, he or she should consult institutional legal counsel, Hardy says. "It's unfortunate that a lot of researchers don't consider this," she says. "I strongly advise talking to legal counsel before designing the study. A certificate isn't the only means by which counsel could refuse a demand for data."

"Data can be given with certain identifiers removed and only used for particular litigation and not re-identified," Wolf adds. "I think sometimes we think the data is totally protected and it's not — only the identifiable data."

REFERENCES

1. Beskow LM, Check DK, Namey EE, Dame LA, Lin L, et al. (2012) Institutional Review Boards' Use and Understanding of Certificates of Confidentiality. *PLoS ONE* 7(9): e44050. doi:10.1371/journal.pone.0044050.
2. Beskow LM, Dame L, Costello EJ. Certificates of Confidentiality and the Compelled Disclosure of Research Data. *Science*. Nov 14, 2008; 322(5904): 1054–1055. ■

One IRB's lessons in biorepository development

Consent timing studied

Biorepositories of tissue and blood samples are valuable resources for disease research. When developing the framework for a biorepository, IRBs and researchers must find the right balance of policies and procedures to fit the needs of the institution, ensure patient confidentiality, and fulfill regulatory requirements.

"Every biobank and every IRB have the same questions; it's consistent across the board," says **Yasmin Isler**, PhD, Biorepository Research Specialist at ProMedica in Toledo, OH. ProMedica, a health system headquartered in Ohio that includes 12 hospitals, operates the Academic Health Center BioRepository (AHCBR), which began collecting samples in June 2012. Patients diagnosed with pre-cancer or cancer can choose to donate excess tissue samples from surgical procedures to the biorepository for use in biomarker research.

The idea of a biorepository was first floated in 2009, and development of the biorepository began in 2011. "They brought me in in January 2012 to get things moving forward with documents and procedures and get everything situated with the IRB," Isler says. "Once we got things rolling and got IRB approval, we collected our first specimen in June 2012." The focus is on samples from patients diagnosed with breast,

colon, gynecological, kidney, prostate, liver, skin, lung, or pancreatic cancer or pre-cancer.

When developing the biorepository, the ProMedica IRB found that some of the biggest challenges surrounded informed consent. "You don't want to do anything harmful or disrespectful to others," says **Lee Booze-Battle**, MPA, CIP, director of the ProMedica IRB and IBC. "We want to deal with an honest broker — how will the bank be set up? Will they release the samples with or without identification? What identifications can be used per federal regulations while still maintaining the confidentiality of subjects? Since there has been an influx of biobanks over the last 10 or 12 years, you can reach out and communicate with those who are already doing this work."

The willingness of other institutions to share information and best practices helped shape the policies of this biorepository, Isler says. "Other biorepositories are very helpful and want to help everyone else. We conferred with a lot of other ones to see what they did and whether it would work in our institution," she says.

The AHCBR is based at ProMedica Toledo Hospital and works directly with the pathology department for collecting samples. Pathology lets the biorepository team know when there is excess tissue available for banking. Samples are stored on site, de-identified, and largely consist of "highly sought" breast and gynecological tissue, Isler says.

"Everyone has to tailor their processes to their institution," Isler says. "We were seeing what others were doing and we would pick the best parts and piece together what would work for us."

Deciding what would work for the institution also included getting input from the health system's surgeons. "Any of the samples that we collect, we have to work with every surgeon to see what would best suit them and work with how they work," Isler says. "There's no real cut-and-dry method — we tailor it to their liking."

Informed consent study

One of ProMedica's challenges in developing the biorepository was determining how and when to give patients informed consent. Some biobanks consent patients after their procedures, while others consent patients before. "Informed consent has been and always will be an ethical dilemma," Booze-Battle says. "The IRB office, the biorepository, and other areas want to learn from the unfortunate mishaps others encountered while doing what we wanted to do. We wanted to learn as much as we could while still protecting subjects. The way we found to do that was to just ask people."

The IRB conducted a pilot study in 2013 to determine whether patients would prefer pre-procedure or post-procedure consent. Fifty patients were enrolled and given a survey to determine consent preference. Questions included how well informed they felt on the subject of consent, if they had sufficient time to decide whether to participate, which approach — pre-op or post-op — was right for them, if they had participated in a biobank before, and whether they would feel inclined to participate again in the future. The consent process began for the patients in the weeks leading up to their procedure, during pre-operative testing. In all, 92% reported feeling very informed by the consent process, 6% felt somewhat informed, and 2% did not feel informed. Ninety-six percent said they preferred to be consented pre-procedure. All 50 participants felt they had sufficient time to consider the consent form, and all decided to participate in the biorepository.

Patients preferred the pre-procedure consent so they could have more time to think about it, Isler says. "Any time during a procedure is stressful," she says. "They preferred having time to sit in a room with you while they're not in a hospital gown. It's a more comfortable setting to ask questions. Those are some of the reasons they gave for it being the best time; [pre-procedure] is probably one of the least stressful times for them."

Lynnea Lau, MPH, CIP, ProMedica IRB coordinator, adds, "If the responses would have been in favor of being consented after the procedure, we would have considered revising our protocol to allow for consent both pre- and post-procedure."

To date, 267 people have been consented for the biorepository and there is a 92.6% success rate, Isler says. Consent takes place at the patient's advance admissions appointment a week or two before the procedure, when blood work is done and the nurses explain the patient's procedure. The consent process takes about 10 to 15 minutes of discussion, Isler says. "So far, there haven't been any issues with the informed consent procedure. Before we collected our first specimen, we made sure the process we decided

to go with would be the best one for us," she says. "We've tweaked it and made changes here and there, but haven't had any hiccups. We're continuously revising it to stay on top of things and make sure we adhere to all the standards and regulations."

The consent study and pre-procedure consent process also has support from surgeons at the center. "With such challenging ethical issues, our study attempted to evaluate the effectiveness of our consent process," says **Fedor Lurie**, MD, PhD, associate director of research, education, and vascular laboratory, at Jobst Vascular Institute of ProMedica. "The only person who can tell you whether the consent is appropriate is the research subject. We usually don't ask them for their feedback. There are two important questions: Is sufficient information provided to the study participant, and — important to me — is sufficient time given to the subject in order to truly understand all the aspects of the consent? Our study demonstrated that most patients felt they had sufficient information and time to consider what they were asked to do. It is very important in the surgical settings. It often looks like you have enough time to consent before surgery, but the psychological pressure is so high that patients might not be capable to digest the issue. Our study showed that this did not happen. The consent process we have in place is quite effective." ■

Hospital Report blog wins first-place award

AHC Media's Hospital Report blog won first place for best blog or commentary at SIPA 2014: Strategies for Growth, the annual conference for specialized information publishers, held June 4-6 in Washington, DC.

IRB Advisor's executive editor Russ Underwood and associate managing editor Jill Drachenberg both contribute to the blog, which features commentary on a variety of issues relevant to hospital professionals, including quality improvement, informed consent, patient safety and satisfaction, research, and regulatory issues. Joy Dickinson, executive editor of *Healthcare Risk Management*, and Leslie Hamlin, managing editor of *Medical Ethics Advisor*, also contribute.

You can find Hospital Report on the Web at http://hospitalreport.blogs.ahcmedia.com/. ■

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.

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COMING IN FUTURE MONTHS

- Simple steps to developing a risk matrix
- Confidentiality and informed consent post-Belfast
- IRB creates doable workaround for teaching PIs
- Ways in which IRBs are using flexibility in the regulations

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CNE/CME QUESTIONS

1. Which of the following is a benefit to using technology for informed consent documentation, according to Mytrus CEO Anthony Costello?
   A. Electronic data collected and metrics can help improve informed consent
   B. The iPad or electronic tablet can provide links to definitions, videos, other information
   C. An electronic signature can be time and date-stamped
   D. All of the above

2. When an IRB is looking for non-affiliated members, which of the following do Kara Brocious and Laura Noll say are alternative sources that might provide good candidates?
   A. Junior League or similar volunteer-oriented organization
   B. Running ads on message boards
   C. Posting fliers throughout the community
   D. Both A and B

3. Which of the following is not one of the common complaints from IRBs and ethics panels about informed consent documents?
   A. Too much legal and medical jargon
   B. Too long, too wordy
   C. Written at too low of a reading level
   D. Visually cumbersome and unappealing

4. According to Leslie Wolf, JD, MPH, Certificates of Confidentiality have been upheld in criminal cases when the study records have been found to be directly exculpatory to the case.
   A. True
   B. False

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