IRB ADVISOR

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RELIAS MEDIA

IRBs Can Expect Increase in Gun Violence Studies

Gag order at CDC is lifted

By Melinda Young

In 2018, a spending bill allowed for research by the CDC into the causes of gun violence, paving the way for new studies to explore the issue. IRBs will need to anticipate these protocols and better understand risks and ethical issues involved in gun research.

A confluence of factors is contributing to an increase in research addressing the problem of preventing gun violence, says **Patrick M. Carter**, MD, assistant professor of emergency medicine at the University of Michigan Medical School. Carter also is assistant professor of health behavior and health education, School of Public Health, and assistant director for the University of Michigan Injury Prevention Center.

> A CONFLUENCE OF FACTORS IS CONTRIBUTING TO AN INCREASE IN RESEARCH ADDRESSING THE PROBLEM OF PREVENTING GUN VIOLENCE.

The rise in gun violence research partly is due to more media and public attention on this issue because of mass shootings, Carter says.

"There is a greater number of requests for applications for federal grants and a small increase in federal funding availability," he adds. "There also has been some increased interest in the private sphere to help conduct research on this topic."

The CDC gag rule, called the Dickey Amendment, had prevented the CDC from studying gun violence since 1997. The amendment stated that CDC-sponsored research could not be used to advocate for gun control, but it had a broader chilling effect on all federally funded gun research — something Jay Dickey, the Arkansas Republican who

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introduced the amendment, later said he regretted. In 2018, President Donald Trump signed an omnibus spending bill clarifying that the Dickey Amendment does not ban research into the causes of gun violence. *(More information on the amendment can be found at: https://n.pr/2JjSEUP.)*

The Dickey Amendment was a serious suppression of gun violence research, says **David C. Clark**, PhD, director of the human research protections program at the Medical College of Wisconsin in Milwaukee.

"We hope it has been lifted, although we never know," Clark says, referring to researchers' skepticism that the CDC begin to fund gun violence studies. *(More information is available at: https://n.pr/2JjSEUP.)*

A PubMed.gov search for "gun violence" shows a 25% increase in U.S. studies on this topic between 2017 and 2018.

The authors of one recent study investigated how seeing gun violence and hearing gunshots affects children. Investigators surveyed children, ages 10 to 17 years, and caregivers of children, ages two to nine years. The study found that women and younger children were at risk of experiencing high fear as a result of the violence.[1]

The Crimes Against Children Research Center at the University of New Hampshire, where the study was conducted, is accustomed to handling studies with sensitive data and vulnerable participants, says **Kimberly J. Mitchell**, PhD, research associate professor of psychology and senior research scientist at the center.

"Our IRB is wonderful to work with, and they're great in overseeing research participants and finding a balance," Mitchell says. "We do national surveys, asking about child treatment and victimization, but this study was on a smaller scale."

For the gun violence study, investigators wanted to survey children anonymously. Research staff brought tablets to several housing authorities or youth community centers, asking children or their caregivers to complete the survey anonymously in a private room.

"We were clear about what the survey was about," Mitchell says. "Participants were warned that the questions might be upsetting or sensitive, and they could stop at any time or skip questions."

After completing the survey, participants received a debriefing paper with mental health resources and locations they might need in the event they were upset or distressed, she adds.

Some studies are designed to test interventions to decrease violence involvement among youths who are recruited from the ED after firearm injuries. The young people report on a screening survey that they possess a firearm and use substances, Carter says.

"We designed an intervention around decreasing their substance use and violence behaviors. They are randomized into two groups: one that gets the intervention, and one that has enhanced usual care," he explains.

For the enhancement part of the usual care, researchers give each participant, including those in the control group, a gun lock to ensure the weapon can be safely stored, Carter says.

One of the study's challenges involves how to advise participants on what to do to get rid of their firearms, Carter notes. Some cities hold anonymous gun turn-in

programs, but there are no such programs in the study region. "We have talked with local police about it and haven't found much success," he says.

This means that if participants choose to safely dispose of their guns to reduce their own violent tendencies, then they might have to place themselves at risk. In many cities, the safest way to dispose of a firearm is to give it to the police. But, in this case, the police would perform a background check on the gun. If it has been used in criminal activity, then the person who turned it in could be questioned or charged.

While the city had an anonymous gun buy-back program, it was available very infrequently, he explains.

"We made participants aware of that risk," Carter says. "We want to keep participants safe from adverse outcomes, and it also would be nice if there was a clear option to offer to the youth because as we hope to decrease their violent behaviors, their having firearms isn't safe."

Another challenge when studying people involved in violent acts is that their acknowledgements of past legal issues must be kept confidential, Carter says.

"One thing we've heard IRBs address as a concern or potential concern is enrolling folks who may have been involved in the criminal justice system in the past, and there are concerns about confidentiality with the information they provide to us," Carter says.

"The way we've addressed this concern is by making sure we have a very good informed consent process," he adds. "This is a population that we think is crucial to having in our studies, and excluding them would be a detriment to studying the interventions we're doing."

Investigators discuss potential risks and threats to confidentiality up front. They also obtain a certificate of confidentiality from the National Institutes of Health, and they ensure data are protected and encrypted. All gang information is confidential.

Gun violence in the United States is a huge public health problem, and the amount of research currently performed on the issue does not meet the need, Carter notes.

"There is a need to do more of this research," he says. "This research can be done in a safe way that respects the issues with informed consent and protects participants while investigators study the interventions and programs needed to decrease gun violence and injuries." ■

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IRB Methods for Reviewing Gun Violence Study Protocols

Expert knowledge is important

Gun violence studies can be among the most sensitive for a participant's emotional risk. Researchers and IRBs should take the following steps to ensure participants' protection:

• **Find experts.** "An IRB always does well and wise to hope there is a mental health expert or consultant on the research team, even if the focus of the study is not mental health," says **David C. Clark**, PhD, director of the human research protections program at the Medical College of Wisconsin in Milwaukee.

"It's always wise to have at least one mental health expert on the IRB review team because there always are these psychological aspects to the study," he adds.

Investigators should have mental health professionals on their team to review surveys and identify items that might be upsetting, Clark says.

"In this area of gun-related violence or death, a huge number of people are going to have trouble thinking about and talking about these events. The investigator needs a sophisticated screening process, and will be willing to say, 'I don't think you are ready for an interview. Let's call it a day and make sure you're getting the healthcare you need,'" Clark adds.

• **Be open with participants.** "Make sure that informed consent is complete and thorough," says **Patrick M. Carter**, MD, assistant professor of emergency medicine at the University of Michigan Medical School. "Address potential issues that might come up in the course of the study," he adds.

For example, if research involves gun violence victims who are

involved in gangs or criminal activity, researchers need to disclose that they must notify authorities if participants reveal plans to harm themselves or other people after recovering from injuries, Carter says.

"We worry about retaliation, and so we assess that and address it with appropriate protocols," he adds.

When gun violence research involves surveys, it is important to let people know what they are going to be reading and answering questions about, says **Kimberly J. Mitchell**, PhD, research associate professor of psychology and senior research scientist at the Crimes Against Children Research Center at the University of New Hampshire.

"We let them know that especially if they have any personal experiences, it could be upsetting," Mitchell says.

Researchers should give participants an opportunity to skip questions they find upsetting, she adds.

"Most of our questions are 'yes,' 'no,' 'not sure,' or 'refuse to answer,'" Mitchell says. "And they just click on that, and go on."

Investigators then look to see how many times participants chose to not answer a question.

"If it's a large amount that is missing, that's interesting in itself," she adds.

• Research using de-identified data can be low risk. When researchers studied neighborhood gun violence and birth outcomes in Chicago, they collected de-identified data from birth certificates, census information, and police reports. The study found that race and ethnicity were associated with birth outcomes, regardless of exposure to gun violence.[2]

"None of the institutional review boards had any concerns about the study or raised ethical issues, probably because it's all de-identified data," says **Nana Matoba**, MD, MPH, assistant professor of pediatrics in the division of neonatology, department of pediatrics at the Ann & Robert H. Lurie Children's Hospital of Chicago.

The study did not highlight specific communities, so there were no concerns about stigma or the research shedding an unfavorable light on particular groups or neighborhoods, she adds.

WHEN GUN VIOLENCE RESEARCH INVOLVES SURVEYS, IT IS IMPORTANT TO LET PEOPLE KNOW WHAT THEY ARE GOING TO BE READING AND ANSWERING QUESTIONS ABOUT.

• Hold community meetings. Matoba and co-investigators did not hold community meetings before performing their study about gun violence and birth outcomes, but it could have been helpful, she says.

"The violent neighborhoods are really all over the city, interspersed in neighborhoods," Matoba notes.

Since there was not one compact community that researchers could target for focus groups or meetings, and since the risk of stigma was low as the neighborhoods were not identified, they did not believe it was necessary to hold community meetings.

But even in this case, some sort of community meeting could have been positive, Matoba says.

For instance, after the study closed and researchers concluded that gun violence was not a significant factor alone in poor birth outcomes, Matoba spoke with community members and learned that they were affected by many more stressors that could harm birth outcomes. These included poverty, unemployment, lack of education, and daily life in Chicago.

"A woman would say, 'There are gunshots, but that won't impact my pregnancy by itself,'" Matoba says.

"Maybe if I had worked with a community from the outset, it might have been clear that it's not just gun violence," she adds. "This was a humbling experience, and I'd probably do it differently next time. I'd try to find out what are the other factors within the community."

• Consider nuances in the effects of gun violence. Many gun deaths are the result of suicide. Participants who have lost loved ones to gun homicides or suicides experience a type of trauma that researchers and IRBs should consider when approaching study participants and writing survey questions, Clark says.

"It's a very troubling sort of grief," he explains. "An investigator thinks, 'I'll contact the next of kin a month or two after the coroner calls it a death by firearms, whether it's suicide or homicide.'"

Often, family members are so traumatically affected that the interviews can be counterproductive, harmful, and exceedingly troublesome for them, Clark says.

"Sometimes, they're altruistic and want to help, but they're not ready and they don't know how to gauge their readiness to answer questions," he says. "They've never been investigated before, and the

investigator wants more details. These are details that can be very upsetting."

Even when people are willing to speak with investigators, they might find it difficult to recount details about the trauma and their feelings about what happened, he notes.

"Sometimes, people are willing to speak with investigators because they assume the investigator is a mental health professional, and they see this as some free time with a counselor or mental health professional who will answer their questions or help them with their mental health burden," Clark says. "But rarely are research teams able to go into the field, do those interviews, and be prepared to make on-the-spot counseling or do referrals."

When researchers investigate the effect of gun violence on shooting survivors, the same emotional issues can occur. Also, people who attempted a gun suicide often are not reliable sources of information about what they were thinking or feeling before they made the suicide attempt, Clark says.

"They often can't remember what happened weeks or months later," he says. "They can only guess what was in their minds. They are the same person, but they were in an altered state, so the investigator is pressing them for details. The person can't recreate their mental state, and they can get pretty upset."

• **Employ well-trained staff to conduct interviews.** The people hired to interview gun violence victims should have some experience with mental health and in asking sensitive screening questions, Clark says.

"Even if they are not talking to people within days, months, or weeks after the traumatic event, they are often dealing with people who have complicated grief," he explains.

"It's one thing if someone dies tragically of a natural cause — the grief can be full and especially difficult if the person was young," he adds. "But when it's a suicide or homicide, the violence adds a layer of being stuck with wondering about the violence done to the body and what it felt like."

The research staff screening these participants must be sensitive to the fine line that separates people who are not emotionally ready to spend a lot of time going through the details and those who are, Clark says.

What IRBs and researchers do not want is for their interviewers to be "mops," which are people who leave a mess for someone else to clean up when they leave, Clark suggests.

For instance, when research teams interview students who have been affected by gun violence, they might find the youths to be as expected: They are experiencing some grief, but are steady and capable of handling the questions. Then, a few days later, researchers learn that the surveys started something that resulted in the students becoming inflamed, very upset, and excited. For some days they are emotionally distraught, making things worse in the school, Clark explains.

Researchers who work with youth directly affected by gun violence are very sensitive to the emotional impact of the research.

"Our interventions are done with an approach that emphasizes empathy for what the patient/participant has been through," Carter says. "Our therapists are trained to assess whether patients are experiencing any distress, and address that by referring them to available resources." ■

Small IRB Shows How to Handle Challenges

HRPP streamlines policies

One small IRB has evolved in less than a decade from a board that had no full-time or part-time IRB professionals to having its own IRB administrator with part-time assistance.

"When I first started here about seven years ago, it was to primarily assist with some policy writing. The IRB didn't have full-time or part-time support staff," says **Andrea Rossing McDowell**, PhD, IRB administrator and business communication lecturer at Seattle University.

McDowell's role grew with the IRB, but budget and staffing constraints remained.

"Limited staffing is the number one issue most small research programs face," she says. "Our IRB chair gets a stipend, and I also have a graduate student worker with part-time hours. But a small IRB is compromised in how much bandwidth it can take on."

McDowell describes the following challenges small human research protection programs (HRPPs) encounter and how they can overcome these:

• **Focus on flexibility.** "Our IRB chair and I attended national conferences and brought back ideas

about streamlining policies in a way that's beneficial for our researchers," McDowell says. "We have a very small program in a small university that is almost exclusively social behavioral research, and it tends to be minimal risk. There are typically only two to four full board reviews a year."

Most of the reviews are exempt, and there could be about 40 expedited reviews in a year, she adds.

"We've developed institutional policies that are appropriate for research conducted here, and it took some of the administrative burden off our office and off researchers," McDowell explains.

The key to running the program well was to establish flexibility, making changes that now are encouraged with the updated Common Rule.

"We expanded on what we considered exempt studies, and we tried to cut down on unnecessary paperwork for us and researchers," McDowell says. "We overhauled our website to make it more user friendly."

• **Create a website that can answer most questions.** By reconfiguring the program's website, the information is researcher-centered and easier to find.

"One of the main factors when you're dealing with staffing limitations is to make sure your website and other communications are really effective," McDowell notes. "Most researchers don't care about regulatory language itself, but they want to know how they can get their study approved and what they need to do."

User-friendly language is a positive change for everyone, she adds.

"Since we've revised the website, we've gotten tremendous feedback," McDowell says. "But we're trying to be intuitive for people filling out the applications. That cuts down on the number of phone calls."

• **Be proactive.** The IRB provides pre-submission consultations for researchers.

"They can talk with me or a graduate student assistant about anything from, 'Here's an idea I have,' to "I think my draft is finished, will you look over it?'" McDowell says.

"We don't meddle with their methodology, but we ask how many identifiers they truly need," she explains. "The number and nature of identifiers might reduce review level."

Thanks to the consultations, the protocol submissions go through much more quickly, and researchers benefit from a more personal one-on-one with the IRB, she adds.

• **Educate faculty and students about the IRB.** McDowell meets with faculty and attends their classes, discussing the IRB.

"When I go to departments, often I will clarify that our goal is to help them do their research — not to be a hindrance or to prevent them from doing what they want to do," McDowell says.

Since it is a small university, McDowell is able to build personal relationships and trust with many members of the research community.

"I answer questions about the process, different levels of review, and what kinds of services we provide, like pre-consultation," she adds. "People feel it is a more personable office that is looking to help them."

Discussions might take 10 minutes and cover issues like culture shifts and overapplication of regulations. McDowell also talks about the IRB's new flexibility.

For instance, she will discuss how the old policy was to send any study involving minors to the full board, but that is no longer required.

"We changed it so that if a study involving minors is minimal risk, we can have it expedited," McDowell says.

An example would be a study that collects biometrics with heart rates of high school students. It collects only de-identified information that cannot be tracked back to individuals, and the goal is to look at heart health. This could be an expedited review study, she explains.

• **Play to the smaller IRB's strengths.** The biggest benefit of running an IRB in a smaller research institution is that there can be a flatter organizational structure, McDowell notes.

"We have more decisional authority," she says. "For example, when the chair and I go to a conference, we hear amazing ideas and learn so much about different

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policies. We come home and bring these ideas to our board, and we get members' feedback."

Sometimes, the IRB can implement a change within weeks — or even days.

"At a huge institution with multiple IRBs, IRB chairs, and a far more hierarchal structure, you don't have that flexibility to be responsive to policy changes," she says.

One change the IRB enacted quickly involved broadening the definition of exempt studies.

"We developed a very brief, four-page exempt application," McDowell says. "It gathers enough information, but doesn't put a huge burden on researchers to create an entire protocol for something that doesn't need to be read by the IRB."

Once an investigator submits the exemption form, the IRB will make a quick determination.

"Rarely, we say we need more information," McDowell says. "We can turn those exempts around quickly, within a week."

Seattle University's application for exemption from IRB review asks for investigators' names and contact information, the project title, and anticipated study start and closure dates.

It also asks for a list of all funding agencies and non-monetary support, as well as the research location and research question or hypothesis. Other items include the following:

- Descriptions of procedures, psychological tests, educational tests, and experiments;
- Subject population and recruiting process;
- Anticipated maximum number of recruited participants;
- Minimum number of participants needed for study completion;
- Incentives participants will receive;
- Individual and societal benefits;
- Risks of participation;
- Direct or indirect identifiers;
- Informed consent process.

• **Meet budget challenges.** Small academic IRBs often are from small universities with budgets that fluctuate according to student enrollment, McDowell notes.

An IRB administrator will need to protect the IRB's budget by tying its work to the institution's mission and making sure institutional leaders know about regulatory mandates.

"This is not a program that someone would love to have, but can cut; it's necessary," McDowell says.

"When there are budget cuts, we need to clarify and make sure the administration understands we are tasked by the federal government, and we need to make sure studies are in compliance, following the Common Rule, and so forth," she says. "This means that we might make do with a smaller budget, and we'll rely on our good board members and try to be proactive." ■

Ensure Study Participants Understand That Biobanking Is Research

By Gary Evans, Medical Writer

In a recent study, parents in a pediatric ICU (PICU) were approached to give consent to storage of their children's specimens in a biobank for future research. In surveying parents afterward, the researchers found that almost half of those asked about the biobank did not seem to understand that storage of clinical specimens was a research pursuit.[1]

"Despite the research team's approaching all 80 parents with a modified consent form to enroll their child in a pediatric biobank, only 54% indicated that they were approached to enroll in any research during their child's current admission to the PICU," the authors reported.

This finding raises issues of informed consent for biobanking at a time when vast troves of genetic material are being gathered and stored for research, such as in the National Institutes of Health's All of Us project. Indeed, a follow-up study is underway to see if a video explaining biobanking could improve the informed consent process, says lead author **Erin Paquette**, MD, JD, MBe, associate chair of the Ethics Advisory Board at Ann & Robert H. Lurie Children's Hospital of Chicago, and a critical care pediatrician at Northwestern University.

"It is important that we communicate effectively when we ask people about their willingness to participate in biobanks, that they understand that it is not for clinical purposes but for research purposes — even if those research purposes are not known at the specific time that they are enrolling," she says.

Paquette and colleagues conducted a survey of parents of

hospitalized children in a PICU to assess perceived barriers to research. A prime objective is to improve recruiting, both in numbers and diversity of children enrolled. As a baseline assessment based on prior studies, they reported that parents who typically enroll their children in research may be motivated by a sense of altruism, the perceived benefits of the trial, and an existing relationship with the clinicians and researchers. Established barriers include risk to the child, the perceived added burden of research, and the timing and approach of requesting participation.

The latter concern was a prime focus as Paquette and colleaues assessed how parents preferred to be approached, and by whom. "Of the 80 parents who completed the study survey, 45% indicated that they (or their child) were involved in research prior to this PICU admission," the authors reported.

About half were confused about the biobank consent. However, of the 43 parents who said they were approached during the study period about any research, 93% agreed to enroll their child in a study. Of the 76 respondents who said they had been asked to enroll in research during their child's current PICU stay or a previous admission, 56 reported that they felt respected, and 50 said they had adequate time to make a decision.

Of those who answered questions about motivators, 84% said it would help children in the future. The majority said the research was low-risk and the process was not burdensome.

Barriers were reported less frequently, with the most common answers being perceived risks to the child, and feeling their child was too sick to participate. Eight of 17 respondents cited the burden of research as a barrier.

A Need to Be Explicit

IRB Advisor sought further comment from Paquette in the following interview, which has been edited for length and content.

IRB Advisor: Can you elaborate on the apparent confusion among respondents about whether biobanks are a part of research?

Paquette: In the study, all patients were eligible for enrollment in a biobank. Despite this, only about half of them actually acknowledged that [biobanking] was a research approach. That taught us how people see biobanking research, particularly if they are approached in a general fashion rather than as part of a research study. That has some implications for how we think about biospecimen research, particularly when we are approaching parents of children. There is a need to be explicit about the fact that it is a research activity.

The other thing that was interesting — with respect to diversification among people who indicated they had been approached about research. We had lower rates of Hispanic individuals indicating that they were approached. Despite the fact, that as I said, all individuals in our PICU were approached about this biobank study over the same period.

IRB Advisor: Was there a language barrier to informed consent?

Paquette: Depending on the study, the consent forms could be in Englis, or short forms in different languages. There were eight studies recruiting in our PICU at the time that we did this investigation. Different studies had different language requirements. The forms for the biobank study that everybody was approached about were available in English and Spanish. We don't think it was a barrier in terms of getting the consent form in a language that was understandable, at least for the biobank study.

IRB Advisor: Biobanks are a little bit of an abstraction from what people may normally consider human research.

Paquette: We learned that maybe people don't think of that as research in the same way. It is not about a particular research question. It is more about having samples available for research in the future. The implications are that it is collected not for clinical purposes, but for research studies.

One of the follow-ups that we have done in response to this finding is create a research video on biobanking. We are in the process of rolling out a study where we will add the video to the consent form for biobanking to see if it improves people's comprehension of it as research, and that research may follow from it. We will test the video in the context of a study recruiting for a biobank.

One of the things we are paying attention to is whether it impacts enrollment across diverse populations. We're tracking not only enrollment, but sociodemographic data, literacy levels, trust in the healthcare system, and trust in research.

IRB Advisor: Can you elaborate on the responses from parents about being approached to enroll their child in research?

Paquette: One thing that we were particularly interested in was whether approaching an individual regarding multiple studies would create a burden on them, making them less likely to participate. We actually found that the more studies people were approached for, the more they

agreed to participate in research. One could say that they were potentially compelled to participate because they were asked, so we probed for factors like whether they felt burdened or overwhelmed by being asked. Some people reported that, but it was not an overwhelming number that said it was a barrier to participation. We found that our sample was quite amenable to research participation.

Respondents didn't seem to be particularly burdened by having our research team approach them about having their child eligible for more than one study.

IRB Advisor: Did you find that most parents preferred a single contact for multiple research requests, although that may not be a common practice?

Paquette: Yes. The majority of people prefer to be approached by one contact for multiple studies rather than having each individual research team approach them. Most people preferred either their treating doctor to approach them or a single research staff contact. We are doing some prospective data collection about factors related both to recruitment and retention in research in our PICU. We are looking at a variety of interaction-related variables between researchers and parents. These include the timing, who is doing the approach, how many studies are they approaching for, and how many times are families approached. This could help develop some best practices.

I think that, historically, individual study teams have made research approaches. For people in one place who might be approached by multiple teams, it might make more sense to have a more streamlined, single point of contact. We are testing some of those approaches within our unit. ■

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Testing an Intervention to Reinforce Ethical Research Practices

Historically, the value of scientific research has been undermined to some degree by lack of reproducible results, unpublished data, and studies that achieve statistical significance but are "false positives," says **Donald Sacco**, PhD, chair of the IRB and assistant professor of social psychology at the University of Southern Mississippi.

Some of these trends are fueled by researchers' acceptance of "questionable research practices (QRPs)," Sacco and colleagues noted in a recent study.[1]

"A confluence of factors has likely contributed to low reproducibility rates in scientific research, including publication biases, a lack of direct replications, or a focus on statistical significance without considering sampling error," they reported. "However, some evidence suggests certain factors significantly influence engagement in research behaviors that may undermine ethical scientific conduct and contribute to lower research reproducibility."

They created a one-hour training course designed to "mitigate endorsement of research practices that raise ethical concerns and are detrimental to reproducible science in psychology graduate students." The researchers assessed attitudes toward QRPs one week prior to the training, and one week after. This was followed by a two-month follow-up.

"Participants reported QRPs as less ethically defensible one week following the intervention compared with one week prior, with attitudes at two-month follow-up falling in between these time points," researchers found.

IRB Advisor asked Sacco to comment on the implications of the study in the following interview, which has been edited for length and clarity.

IRB Advisor: As chair of your institution's IRB, can you comment on implications of this social science research for other IRBs?

Sacco: I don't want to extrapolate too far beyond the limited data we have. The IRB's primary responsibility is human subjects research, but they may want to have a conversation about principal investigators submitting data management plans, much like granting agencies now expect. It is a well-defined plan on the data you are going to collect, the sample size, and the analyses you will be doing. It is then transparent that you are not going to be engaging in any of these potentially detrimental research practices.

IRB Advisor: Can you describe in more detail some of these research practices?

Sacco: What we use — and these have probably been developing over the last decade — are what are known as researcher "degrees of freedom."

In various stages of a project, you can make decisions on how you implement your methodology. These include how you sample participants, when you stop sampling, the various ways you might choose to analyze your data in terms of variables included, and whether you report all of the analyses that you have done. There is a variety of benign decisions a researcher can make, but statistical simulations have shown that some of these practices actually inflate what are known as Type 1 error rates. They can lead to statistically significant results, but not because those results are meaningful scientific outcomes; they are just idiosyncratic, statistically significant results.

IRB Advisor: Can you give an example of this kind of error?

Sacco: Some examples are things like if you have multiple dependent measures of the same construct, analyze those independently, and then create a composite of those. Anytime you increase the number of statistical analyses you are doing, you occasionally get a statistically significant result that is a false positive. Some people will engage in these multiple statistical analyses that inflate the likelihood of these type of errors.

Another is when looking at your data and seeing it is approaching significance, collecting additional data to try to get your results to reach significance. [You should have] a hard and fast data collection stop rule at the beginning of your study. These are all decisions a researcher can make throughout the process that can have negative consequences.

IRB Advisor: You found heightened awareness of these problems, but the effect faded to some degree.

Sacco: We did an assessment of peoples' attitudes of the ethical defensibility of these various practices. We found a statistically significant reduction that these were ethically defensible from time one — a week before the intervention — to time two, the week following the intervention. At two-month follow-up, the mean value of ethical defensibility was somewhere between where their attitudes were before the intervention and at the one-week intervention. Their attitudes didn't return to baseline, but they also were not maintained faithfully at two-month follow-up. There was some dissipation. Maybe to have more lasting impact we would need to implement something that was a little more impactful than just a one-hour intervention. It could be a series of seminars over the course of a semester.

IRB Advisor: What are the ethical implications of not publishing all of the data generated by a study?

Sacco: In the context of detrimental research practices, a researcher could have an entire program of research that involves multiple studies. All of those studies are, hopefully, going to converge to a relative amount of support for a series of hypotheses. Maybe they put forward a research question and hypothesis, and they run five total studies that they anticipate producing supportive findings. But, say only three of those studies actually generate support for the predicted hypothesis. So, a researcher, unbeknownst to the larger research community, could publish the three studies together that seem to support the general hypothesis. They could omit publishing the two studies that "didn't work," the idea being that they didn't work because [the results] were not supportive of the overall hypothesis. The research community would get what they would think was a clearly supported picture of this research idea because of the selective publication of favorable results — and omission of those that might give a more comprehensive picture. ■

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Social Media Research Presents Many Unresolved Ethical Issues

Direct-to-consumer wellness products, location-tracking apps, and access to personal data on social networks present both exciting opportunities and significant ethical worries for researchers.

"The digital revolution is rapidly influencing how health research is conducted. We can now passively observe and record people 'in the wild' and 24/7," says **Camille Nebeker**, EdD, MS, founder and director of UC San Diego's Research Center for Optimal Data Ethics.

The use of artificial intelligence and active assisted living robots in the health sector also is increasing. "While there is amazing potential, the digital health ecosystem is not consistently regulated. We are in the Wild West of digital health research," says Nebeker.

The authors of a recent paper proposed steps the scientific community can take to ensure social

media data are used ethically.[1] The paper was prompted in part by the recent Cambridge Analytica scandal, involving allegations that the firm used data improperly obtained from Facebook to build voter profiles.

"Many of my colleagues are conducting research using social media platforms," says Nebeker, one of the paper's authors.

IRBs and researchers are struggling to navigate this new territory, sometimes unsuccessfully.

"When something goes wrong, as it did with Cambridge Analytica, it compromises public trust and jeopardizes research that is in progress," says Nebeker.

The following are two central ethical concerns:

• Researchers may need to cover additional information during the informed consent process.

Commercial products — such as fitness tracking devices — are used as measurement tools. This means privacy policies and terms of service should be considered.

"These terms might influence the study risk assessment," explains Nebeker. Potential research participants also need to factor in this information to make informed decisions.

"In many cases, the terms of service directly conflict with the federal regulations for human subjects protections in that a participant, if harmed by the product, must agree to arbitration," notes Nebeker.

• Not all tech companies comply with federal requirements for research.

Federal regulations for human subjects protections must be followed if research is funded by the U.S. Department of Health and Human Services. However, many tech companies that are involved in biomedical research are not regulated. "We need to develop common standards that govern digital health research," says Nebeker.

Researchers using social media data are operating in an unregulated environment. Thus, there is growing concern about potential harms. "This is another case of how technology has evolved faster than regulations," says **Sherry Pagoto**, PhD, director at the University of Connecticut Center for mHealth and Social Media.

Privacy breaches are possible — intentional or not. "This poses risks to everyone involved: researchers, social media companies, and, most importantly, the general public," says Pagoto.

For example, few Twitter users are aware that public social media posts can be used by researchers.[2] Notably, the majority believe that researchers should not be able to use their tweets without consent. Also, users of commercial products do not always understand privacy implications.

"We cannot fault them, though. These policies are very lengthy, and written in ways that are difficult to understand," says Pagoto.

The following changes are needed, according to the study authors:

• Public education on the research performed with social media data, why it is important, and how researchers protect user privacy.

"Consultation with an expert in health tech ethics is critical if being proactive and diligent about human research protections," says Nebeker.

Stakeholders — including researchers, IRBs, potential participants, or policymakers — may not be fully aware of how data are collected, used, or shared by social media platforms. "This lack of knowledge will influence risk assessment and information included in the informed consent process," notes Nebeker.

• Federal regulations on the use of social media data in research.

"We can anticipate that the technology and research landscape will only continue to evolve, and rapidly," says Pagoto. IRBs rely on federal regulations for guidance on the ethical conduct of research. These regulations are outdated as they pertain to the use of data generated by new technologies like social media. Thus, says Pagoto, "universities, funders, and researchers need to be more vigilant about potential harms and begin to craft guidelines for the purpose of self-policing. We need a code of conduct."

• "Tech ethicists" working alongside researchers as they attempt to use social media data.

Someone with tech ethics expertise could comment on the ethical implications specific to technology used in studies and conduct training for clinicians. "It would also be useful for these folks to advise on grant applications, even serving as consultants or co-investigators," says Pagoto.

Someone on the IRB could take on this role. "But if limited expertise is available on campus, external expertise should be commissioned," says Pagoto.

IRBs also should have the expertise to properly review social media research. "Adequately attending to research ethics will require an investment," says Pagoto. "We want to nudge institutions to make this investment." ■

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CME/CE QUESTIONS

1. **Which amendment of the late 1990s resulted in a broad chill on federally funded gun research?**

   a. Dodd-Franklin amendment
   b. McConnell amendment
   c. Dickey amendment
   d. Gifford amendment

2. **An application for exemption from IRB review might ask researchers for which of the following information in order to make a determination?**

   a. How the informed consent process works
   b. Incentives participants will receive
   c. Professor/teacher mentors
   d. Transportation to screening sites

3. **In a study of parents of pediatric ICU patients, researchers found that almost half of respondents had what perception of biospecimen banks?**

   a. Biobanks are unethical.
   b. Biobanks are not related to research.
   c. Biobanks are critical for children in the future.
   d. Biobanks cannot be protected.

4. **Donald Sacco, PhD, said research occasionally may result in statistical significance that is a "false positive" under which of the following conditions?**

   a. Inflating the effect of a population subset
   b. Conducting multiple statistical comparisons without adjusting for the number of analyses
   c. Withholding negative results
   d. Use of a vague hypothesis

CME/CE OBJECTIVES

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

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