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INSIDE

RELIAS MEDIA

Research Community Seeks to Enroll More Minorities in Clinical Trials

Pandemic puts more focus on disparities

By Melinda Young

Several months of data from the COVID-19 pandemic showed that African Americans and other people of color (POC) were disproportionately dying from the disease. As the crisis continued into the summer, George Floyd was suffocated by a police officer in Minneapolis. Hundreds of thousands of people across the world took the streets in protest.

Both events highlighted the need for systemic societal reform. This includes examining how underrepresented minorities are treated by the healthcare industry and in clinical trials.

"We need equity in health in this country. We must eliminate all the contributing factors to poor outcomes," said **Edith Mitchell**, MD, director of the Center to Eliminate Cancer Disparities, Jefferson Hospital clinical professor of medicine and medical oncology, and a past president of the National Medical Association. Mitchell spoke at a WIRB-Copernicus Group (WCG) web conference on June 3.

> "WE NEED EQUITY IN HEALTH IN THIS COUNTRY. WE MUST ELIMINATE ALL THE CONTRIBUTING FACTORS TO POOR OUTCOMES."

"COVID-19 disproportionately affects people of color in the United States," Mitchell explained. "Can we use the awareness of the disproportionate impact of COVID-19 and the need for research representation to bring awareness to the larger issue of ensuring diversity in all clinical research?"

Disparities in how COVID-19 affects minority communities highlight

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long-standing difficulties in achieving health equity in U.S. society, said **Damani A. Piggott**, MD, PhD, an assistant dean for graduate biomedical education and graduate student diversity and an assistant professor of medicine at Johns Hopkins School of Medicine. Piggott spoke at the Infectious Diseases Society of America's May 15 web conference.

Multiple Factors Add to Disparities

Contributing factors to the disparity include other diseases that affect African Americans disproportionately, such as hypertension, kidney disease, heart disease, and diabetes. Other factors relate to disparities in income, employment, housing, educational opportunities, transportation, and incarceration, Piggott noted.

"For IRBs, focusing on the principle of justice and its application with participant selection is a really great way to improve diversity in biomedical research," says **Brandy M. Mapes**, MLIS, translational research manager at Vanderbilt University Medical Center. "The study design can present barriers, and we should not exclude people because of too restrictive criteria or because [certain groups] are harder to reach."

IRBs and research institutions should keep those principles in mind and prevent unintentional bias, restrictions placed on inclusion criteria, or strategies that could prove a barrier, she adds. *(See story about expanding diversity in clinical trials in this issue.)*

The glaring disparities uncovered during the pandemic have shown the world how poorly the American healthcare system fares in caring for minorities.

"With COVID-19, we find, again, poor outcomes," Mitchell lamented. "We also recognize that participation in clinical trials gives us awareness of the disproportionate impact of participation, but also of outcomes."

Demographic data on COVID-19 deaths, through July 20, showed that Black Americans died at a rate of 69 deaths per 100,000 people in the population. White Americans experienced a rate of 27 deaths per 100,000 people, and Latino Americans 33 deaths per 100,000 people. *(For more information, visit: https://covidtracking.com/race.)*

"Many people of color are essential workers," she explained. "They are exposed to the public in greater numbers, and many had no access to personal protective equipment and other protective gear." Also, minority communities include more multigenerational households, which contributes to infection risk for older adults.

Data on clinical trials ethnicity in the United States in 2019 showed that 80% of clinical trial participants were white, 6% were Black, and 10% were Asian, noted **Annick de Bruin**, MBA, director of research services at CISCRP in Boston. De Bruin spoke at the June 3 WCG web conference.

One challenge of enrolling more underrepresented minorities in clinical trials is the economic logistics of some trials, such as pediatric oncology research. At some children's hospitals where patients are racially diverse, there might be one or two patients who meet the criteria for a particular study. But activating a clinical trial based on one or two patients is resource-intensive, says **Nupur Mittal**, MD, assistant professor of pediatrics at Rush University Medical Center in Chicago.

One solution is for research sites

and IRBs to form collaborations that allow for resource sharing. *(See story in this issue on how pediatric oncology research increased minority participation.)*

Ingrained health disparities contribute to more illness among communities of color and the need for intensive care unit (ICU) care, noted **Kevin Smith**, MD, FACP, FAAP, chief medical officer at Loyola University Medical Center. Smith spoke at the June 26 web conference about COVID-19 and communities of color.

The pandemic is not necessarily a time when the healthcare and research community can fix health disparities, but they are seeing the consequences, Smith said. Healthcare providers saw evidence of the virus spreading widely through communities of color. When clinicians asked POC with COVID-19 if any family members were exposed to the virus, they often heard this answer: "Everybody else in my family had it," he added.

Physicians and others on the frontlines of the pandemic witnessed a population-level view of COVID-19 and its outcomes by race and ethnicity, said **Eli Rosenberg**, PhD, associate professor in the department of epidemiology and biostatistics at the University of Albany (NY). Rosenberg also spoke at the June 26 web conference.

By focusing on outcomes in the Black community vs. the non-Hispanic, white community, researchers discovered the disparities are multilayered. "It could be many, many social and structural factors that simply expose minority groups disproportionately compared to other groups," Rosenberg explained. "We see differences in the likelihood of needing hospitalization by race and ethnicity — again, with African Americans needing that intensive level of care."

Recruitment methods are an issue when studies try to attract more underrepresented minorities. Researchers should develop a multilingual, targeted recruitment plan for minority communities, Mitchell said. The plan should emphasize the unequal risk and the importance of solutions that include clinical trial participation.

"We have to look at our discussions and presentations in those communities," Mitchell said. "We should have a formal diversity strategy for recruitment, utilizing community organizations, including churches and individuals who are recognized and respected in the community."

> "FOCUSING ON THE PRINCIPLE OF JUSTICE AND ITS APPLICATION WITH PARTICIPANT SELECTION IS A REALLY GREAT WAY TO IMPROVE DIVERSITY IN BIOMEDICAL RESEARCH."

Research organizations also should work with institutions that have the infrastructure to conduct research in minority communities, she added.

Researchers should pay attention to enrollment and create diversity enrollment plans for studies. "This is not something that just happens," Mitchell explained. "Engaging communities must be planned [early]."

For example, IRBs and research organizations could build relationships with minority institutions, including churches, and prepare multilingual recruitment plans and materials.

"Collaborate with organizations that have a history of engaging underrepresented minorities in our community," Mitchell said. "It is so important that we recognize the factors that disproportionately affect people of color in the United States. We must utilize the information that we are learning and have learned from COVID-19."

Data show online peer communities can help attract these groups. "Online peer communities are of high interest to underrepresented minorities," de Bruin said. "Thirty percent are very interested in discussing and getting participation advice from peers online in a patient community. Forty-five percent said they were somewhat interested."

IRBs could recruit more underrepresented minorities to their boards. Research organizations could encourage more minorities to become investigators. These efforts also could help with clinical trial recruitment of minorities.

"We recognize there are fewer minority investigators; therefore, one of our efforts is related to increasing the number of physicians and other clinicians from minority communities," Mitchell said. "While African Americans account for 13% of the population of the U.S., African American physicians only account for 4%."

To address the problem of too few minorities in clinical trials, research offices should look at all components contributing to this disparity.

"We should make sure there is equity in clinical trials," Mitchell said. "We have one of the major efforts related to increasing the number of minority investigators and investigators who understand minority populations." ■

Diversity and Inclusion Go Beyond Race and Ethnicity

Researchers assessing the demographic statistics of All of Us Research Program participants prioritized enrolling racial, ethnic, and other minorities that, historically, have been underrepresented in clinical trials.[1]

The All of Us Research Program set goals of enrolling at least 1 million participants and increasing diversity in research.[1]

"One of the most interesting parts of this research is that there is an enormous amount of evidence for some groups, like racial minorities. But other groups, such as sexual minorities, are understudied and unrecognized," says **Brandy M. Mapes**, MLIS translational research manager at Vanderbilt University Medical Center.

The researchers also prioritize enrolling participants from other minority groups, including:

- people with inadequate access to medical care;
- people with an annual household income below 200% of the federal poverty line;
- people who live in rural or nonmetropolitan areas;
- people with less than a high school education or equivalent;
- people with cognitive or physical disabilities;
- people who are intersex or identify as a sexual minority.

The researchers concluded studies need to incorporate more diverse factors as key variables to ensure inclusion and identify barriers that limit research participation.

"Researchers are not asking those questions that help us to track those characteristics when doing studies," Mapes says.

For example, with race and ethnicity, the traditional model asks whether a person is white, Black, Asian, and Hispanic, but does not drill down into ethnic/racial categories, she explains.

"There is a lot of diversity within that. We're not able to drill down, so we're not getting that someone is Middle Eastern, for example," Mapes says. "Also, we see researchers asking about race and ethnicity as a single question."

Sexual Diversity Needs More Representation

In the area of sexual health and sexual orientation/gender, there are areas with poor data collection. "It's not always because people don't want to be asked, but because researchers feel uncomfortable asking, or they don't imagine that is something they should ask as a variable in their study," Mapes explains.

A study that included more variables related to underrepresented minorities of various types would have multiple benefits. "It would be a more inclusive approach. People would feel more invited to participate," Mapes says. "We don't know what would be discoverable unless we provide them with enough variations and diversity of data to try it out. Researchers could do a significant amount of work on health disparities if they just had the data."

In addition to asking for more questions related to diversity as key variables, research programs and IRBs could encourage investigators to be open to changing criteria for enrollment to enable more diversity.

For example, due to COVID-19, researchers might require participants to have access to broadband internet at home. This could prevent some rural and low-income people from enrolling in the study.

"You just need to figure who you are looking for in exclusion/inclusion criteria," Mapes says.

IRBs and researchers should look at whether the hypothesis could be answered with a change in the exclusion criteria and whether certain groups are excluded based on their proposed study design.

"Also, there is a lot of pressure to expedite timeline. Researchers have to work quickly," Mapes says. "But that doesn't mean we cannot take a step back and be mindful about what we're designing and make it more inclusive, even if it means doing a little more work or taking some extra time."

Increase Diversity in Data Collection

With the pandemic and social justice protests happening in 2020, there is an opportunity for the research community to acknowledge this moment. Collecting diversity data can help motivate researchers and IRBs to make big changes that could lead to more inclusive research projects and clinical trials, she explains.

In one sense, this has already happened: "There are traditional barriers to digital resources, but right now, we're seeing more people adopt digital resources and technology out of necessity," Mapes says. "During the pandemic, this is a wonderful opportunity for researchers to

leverage that. More people are using it than they did before, so researchers can leverage that with more success than before."

IRBs and experienced researchers can lead the effort to improve enrollment diversity through example. "I'm fortunate to have great mentors who showed me different strategies for ensuring diversity," Mapes says. "There are a few things we've seen work well, including consulting with community representatives who have meaningful relationships with underrepresented groups."

Studies also can provide value to participants through compensation or providing information from the study, she says.

"When everything fails, creativity, flexibility, and perseverance go a really long way," Mapes says. "You have to be open to the possibility that you will try something new and may not see the results you want, so you will have to shift gears and try again." ■

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Research Group Increased Minority Participation by 533%

Study is from Children's Oncology Group

One barrier to enrolling minorities in research involves resources. For some studies, such as pediatric oncology clinical trials, there might not be enough resources to enroll one or two patients at a single site.

The Children's Oncology Group, which represents more than 200 institutions worldwide, has helped create solutions to this problem. The group enrolls thousands of children, adolescents, and young adults in a single trial at a variety of sites.[1]

"The significance of this program is that historically, if you look back before the program was established, the number of enrollment, individually, was very low," says **Nupur Mittal**, MD, assistant professor of pediatrics at Rush University Medical Center (RUMC) in Chicago. "The population we see are a majority — 60 to 70% — African American," Mittal says.

The University of Illinois at Chicago (UIC) and RUMC had pediatric oncology research programs, but there were fewer than 10 clinical trials open, she says.

"If the number of patients is less, then you can't justify the resources and open that many trials," Mittal says. "Not all the patients would get access to clinical trials for different disease types and conditions, relative to a cancer diagnosis."

Create a Collaboration

The solution to improve access to clinical trials to more patients, including underrepresented minority patients, was to form a collaboration.

RUMC, UIC, and the John H. Stroger, Jr. Hospital of Cook County formed a collaboration. They relied on the National Cancer Institutes' IRB of record. They developed inter-IRB agreements that allow the three institutions to expedite enrollment in pediatric oncology trials, Mittal explains.

"We share resources and infrastructure, and some portion of the program is funded by a foundation," she adds. "It's too much work to activate a trial for one or two patients; it takes a lot of resources. Now, because of the fact that there are three institutions and there could be 10 patients, it has increased the volume of patients on the trial, and it has put more resources at our disposal. We now have research staff and infrastructure to activate the trials."

The tri-institutional Children's Oncology Group program saw total studies open to enrollment increase by 100%. Enrollment of ethnic minorities rose by 533%. Enrollment of Hispanic patients increased by 925%.[1]

The goal is to improve access and outcomes for children with cancer, Mittal says.

From the IRB's perspective, there is an arrangement in which the central IRB approves all clinical trials. Each institution's IRB also approves the clinical trial before activation. The entire process is expedited because of the IRB agreements, Mittal explains.

"When a patient walks in and there is a clinical trial that is not active at Rush, we can get it activated within days because the agreements are already in place," she says. "Forming that collaborative IRB was an important first step. Then, we share clinical research resources and nursing staff. In the pediatric world of medium-sized community hospitals,

one of the overarching problems is resources, whether it's physician time, IRB stuff, or all of those resources that go into successfully running of a clinical trial," Mittal says.

The collaboration has led to physicians working together in enrolling patients in trials, a type of cooperation that is challenging in places that have not developed such a collaboration. Since forming the collaboration, the number of open trials increased from about 10 to 45, she adds.

The collaboration and inter-IRB agreement took about a year to form, Mittal says.

"This has not happened overnight," she adds. "It's really important that the physicians and clinical research staff work together to make sure patients are given access to any available clinical trial." ■

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Keeping Open Dialogue Part of Virtual IRB Meeting Plan

The IRB of Capella University of Minneapolis had a big advantage over its peers when the COVID-19 pandemic hit and forced research institutions to move operations and meetings to virtual space.

"We are a solely online university, so we've only functioned with an online IRB," says **Angela L. Bruch**, PhD, senior core faculty and university IRB chair of Capella University. Bruch was a scheduled speaker at the Northwest Association for Biomedical Research 2020 virtual IRB Conference on July 30.

"I feel like once people go to virtual meetings, they won't ever want to go back," she says. "It is so efficient in terms of a meeting space. I am a strong advocate for it."

The Capella IRB consists of 10 members from seven states and several time zones. Meetings are held weekly, except during quarter breaks.

"We're always navigating unique opportunities or weather differences," Bruch says. "For community members, we look for someone who is a more national citizen."

At quarterly business meetings, the IRB focuses on the meeting structure and how to maximize time to place most of the focus on studies, she says.

"We've worked hard to create an open and responsive approach so there's a quick turnaround on review," Bruch says. "Researchers have an open access point to meet with the point person on a study and with me about the decision letter."

Virtual meetings can include teleconferences and videoconferences, but either method can work. "We hold our IRB meetings in the online space, and a number of the things we do to make sure," Bruch says. "We only use a phone line. We do not do the Zoom process."

Once an IRB chair hones skills for virtual meetings, it can be a rewarding experience, she notes. "I've done this for so many years, and I actually like the online environment because it removes some of the intimidation of body language," Bruch says. "There is no eye-rolling or arms crossed in front and furrowed brows," she explains. "It removes all of that in your decision-making. You rely totally on the tenor of the verbal discourse." *(See story on building rapport without handshakes in this issue.)*

The entire board shares documents for any study they will review before the meeting. "The IRB team reviews all materials and asks questions in advance," she adds.

Bruch offers these best practices on operating IRB's virtual meetings:

• **Impose structure.** "Something I learned early on as chair of the board is that I needed to find a way to impose structure, something very predictable, in the virtual meetings," Bruch explains. "We have evolved and tweaked our meetings. We started with a semi-structured approach to each review, using federal guidelines."

Every meeting proceeds in the same order by following the guidelines and using a modified Roberts Rule of Order. "Our approach is to start with the study, calling for a motion of the study to be put into discussion," Bruch says. "We begin with concerns about the design of the study, the risk-benefit ratio, and then we move into recruitment of participants."

Each study follows the same routine. This part of the meeting immediately follows the roll call and approval of the previous meeting's minutes.

"We go through studies in the order in which they were received in case we run out of time," Bruch says. "Generally, the meetings end at two hours. If we're just minutes from voting on a study, we'll buy five extra minutes and maintain quorum."

The board has grown accustomed to the two-hour meetings and will say they can send their redlining notes offline or make a motion to table something to the next week, she adds.

"When someone gets off on a tangent or commands too much of the floor, it's my job as chair to reel them back in," Bruch says. "I will say, 'I think we heard that point, let's go on. If you don't feel like it's been addressed, we can continue.'"

Then, Bruch will return to the pontificator to make sure they feel their point was heard.

"As you do online meetings, you become more savvy as to who your membership is and those personalities," she says.

• Follow best practices with minutes. "We follow all federal guidelines and regulations," Bruch says.

First, there is a roll call to ensure quorum is maintained. "We do not record any of our minutes," Bruch notes. "Our IRB specialist is assigned as the minutes-taker. He types minutes as they unfold."

Bruch also takes notes by hand at each meeting. She compares the meeting minutes with her own.

"We post minutes within 24 hours of every meeting so board members can go in and look at those," she says. "Our first action of every meeting is a motion to approve or amend the minutes."

The minutes are about 1.5 pages of condensed notes for each study, the study's discussion, and motions.

• Invite guests, as needed. "If we have a prison study, we will have a prison representative that attends and serves as a voting member for prison studies," Bruch explains. "If we have a study that is unusual, internationally, we have an international expert as a consultant. Sometimes, we have a topic that is very new and cutting-edge. We invite an expert to inform the board so we have a deeper understanding of the subject."

• Meet with investigators outside of meetings. Investigators rarely attend meetings, but they meet via teleconference with someone from the IRB after the board's vote, Bruch says.

"We have a separate process where an IRB point person and an IRB specialist meet with the investigator and their research supervisor to go through our decision letter and talk through the study," she explains. "We make sure we're all on the same page about what we ask as an IRB, and we make sure we didn't misunderstand something."

Clearly explaining decisions in a letter and talking with investigators helps improve the IRB-researcher relationship. "Because we're solely online and so much can get lost in translation, we think we wrote a brilliant decision letter," Bruch says. "We find having an open opportunity for the researcher to talk with us creates a good relationship with the IRB, and that is paramount to our success as a board."

• Keep technical issues to minimum. The IRB asks members to make sure they are in quiet spaces before they enter the meeting teleconference. This helps reduce distracting background noise and conversations.

"We ask that they not use speakerphone," Bruch says. "We have those moments, like everyone does, where it would be helpful if they could be on mute."

If someone forgets to unmute when they are asked to comment, Bruch will remind the person he or she still is on mute and no one can hear them. "It adds a little levity to the moment," she says.

Sometimes, a member will drop the call and then have to call back in. For instance, one member's call ended when a lightning strike hit a cell tower in the member's area, she recalls.

"If there's quorum, we can continue even if we lose one of the board members on the call," Bruch says. "If there's not quorum, we'll table that until next week; but it's very unusual that we have super significant issues." ■

IRB Members Can Build Good Relationships in Virtual Space

Rapport does not require a handshake

One long-time virtual IRB has learned how to develop camaraderie and rapport among IRB members without ever meeting in person — or seeing each other's faces.

"It's incumbent on the IRB to create safe space for members of the board to speak their minds," says **Angela L. Bruch**, PhD, senior core faculty and university IRB chair of Capella University. Bruch was a scheduled speaker at the Northwest Association for Biomedical Research 2020 virtual IRB Conference on July 30.

An IRB chair can facilitate this safe space in a virtual arena, whether it is a teleconference or videoconference. Methods include acknowledging people by name, encouraging everyone to contribute, and to follow up meetings with emails or phone calls.

Take Handwritten Notes

Bruch takes handwritten notes during meetings and jots down what board members say about each study. These help her keep track of who is talking and what concerned each member.

"Handwritten notes are more effective for most people in terms of learning and memory," she says. "I have volumes of notes. It serves me well, especially if we have to review the notes to put myself back to this meeting."

Using her notes, Bruch will repeat some of the comments, using it as an opportunity to ensure IRB members feel like their opinions and points are acknowledged.

"Calling out names, especially as we have reflection and recitation of what we discussed, initially was a reminder of who said what and making sure everyone's voice was heard," Bruch notes. "I feel like, as the chair, I have to be on top of what exactly has been said. It's my responsibility to capture the tenor of the meeting and make sure everybody has been heard."

Even without the benefit of body language, Bruch has learned to read people's moods. "I can recognize their voices," she explains. "I can recognize the sigh of someone on the phone, and I'll say, 'I'm hearing a little concern here; let's talk about that a little bit. I think I hear Mary's voice on this.'"

Ensure Everyone Is Heard

Bruch ensures everyone has been heard in the meeting. If someone has not contributed much or anything during the meeting, Bruch will check in with the person, saying, "Mary, I feel like you were quieter than usual. Did we miss anything?"

It is a good device to use to keep track of everyone, Bruch says. "You want relationships to develop among the board so you feel safe to speak your mind. That comes with a level of comfort and respect for one another," Bruch says.

"If a meeting gives us a last couple of minutes at the end, I will make minor commentary," she continues. "I might know someone had a grandchild or someone has a new home and is moving. I will mention that in the meeting, and it creates some of those connecting points."

It is important to establish a collegial relationship and dialogue during the meeting. "We treat each study as a sacred space where we discuss the study and have no offline, behind-the-scenes discussion," Bruch says.

To keep things moving along, the chair needs to jump in to steer discussion back to topic.

Managing an IRB meeting virtually might feel a little like Double Dutch jump rope where someone is trying to jump between two sets of quickly swinging ropes, Bruch notes. "I've become more comfortable over the years with just butting in. You know there are members of the group where a certain study will hit on their passion point."

For instance, someone might raise the flag on readability levels, or the researcher's documentation. In these cases, the chair might need to jump in and bring discussion back to topics necessitated by the regulations. When a board forms a rapport and members work well together, this should not cause a problem.

"We have such a special board, where even if there is a little pique or frustration, it is so respectful," Bruch says. "Sometimes, I say we've moved a little bit afield, so let's reel it back in, and then come back to Thomas and say, 'I promise we'll come back. I'll make sure you feel comfortable about this after we discuss the guidelines for our review.'"

Bruch will keep her promise, returning later to the discussion,

repeating the member's concerns, and asking the board if they missed any points in the discussion.

When even these measures do not do the trick, Bruch will follow up with the unhappy board member after the meeting. "If, after a meeting, I feel like someone was frustrated with how a decision went, I will circle around to make sure that person felt heard," Bruch says. "I start with an email and say, 'I appreciate you were the dissenting vote on this study, and I want to make sure you felt like you were heard. Is this something we need to think about for future studies? Do you want to talk on the phone a little bit about this?'"

The point is to keep the dialogue open. "Our IRB has been static in membership for four years now, so we know each other really well," Bruch says. ■

SBER Programs Face Challenges with Revised Common Rule

Another challenge involves FERPA

Social-behavioral-educational research (SBER) programs have always faced challenges fitting their work into the parameters of human research protection rules and regulations devised with biomedical research in mind. But the revised Common Rule has produced new issues with informed consent.

"I think the challenge for us as an SBER program is fairly consistent with the challenges we've always had in that a lot of changes made are geared toward biomedical types of research, such as the requirement for key information to be put in the beginning of the consent," says **Linda Mayo**, CIP, director of the IRB office at the University of New Mexico.

"In the SBER world, we've worked really hard to simplify informed consent over the years," Mayo explains. "We're usually working with minimalist research. Our template consent form for most survey focus groups and things like that is very brief — less than one page — but it contains all requirements under regulations."

Mayo and her colleague **Jennifer B. Dier**, CIP, CCRP, CHRC, senior IRB analyst at the University of California, San Diego, elicited feedback about key information. They found when this requirement was discussed and developed, it was geared toward clinical trials and complicated biomedical consent forms — but not necessarily toward SBER, Mayo says.

"There's no official guidance on that," she adds.

Avoid Redundancy

Mayo and Dier studied ways for SBER programs to follow the new key information requirement without producing unnecessary redundancy. For example, an informed consent form for SBER research could be one or two pages. Producing the one-page key information would be just repeating what is easily seen on the regular informed consent document.

"Typically, we say the consent form that goes beyond four pages is a more complicated type of study, and the IRB would need to look to see if the key information page is needed," Mayo says. "By default, there is flexibility in how institutions implement the requirement."

Many IRBs use the informed consent document's length to determine when to apply the key information requirement, she adds.

"If you look at the preamble that talks about the key information, what it says should be included is consent elements one through four," Mayo says. "It's meant to make the consent form concise. If you already have a consent form that is one page long, then you're being pretty concise."

SBER IRBs can ask principal investigators to make a judgment call based on the institution's policies. For instance, policy might say, "If your consent is over this length, consider whether the use of a key information section would give your consent more of a summary," Mayo suggests. "If they send it to the full board, and we think it would benefit from a key information section, then we'll require it. The key information section is used in a very small percentage of our studies."

Addiction and substance use studies often use a key information section. "If a study is randomized, that's where consent forms can benefit from having that summary up front," Mayo says.

If a study is a clinical trial, includes multiple procedures, or risks that need to be clearly stated, then it probably should use a key information summary.

The University of New Mexico

IRB and other institutional IRBs use templates for key information summaries that other IRB professionals can access online. Some key information sections have longer, concise summaries. But the typical key information section contains four or five bullet points, Mayo explains.

FERPA Presents Challenges

Another challenge SBER programs face involves the Family Educational Rights and Privacy Act (FERPA), which requires schools to obtain written permission from the parent or eligible student before they can release any information from student's educational record, except for certain conditions that are not related to research. *(For more information, visit: https://bit.ly/32cLj4s.)*

"We've struggled with the interpretation of getting clinical records," Mayo says. "When the pandemic hit and things shut down on campus, we had a lot of educational researchers getting signatures in-person. We didn't have the ability to do that. I had to go back to the registrar and asked for flexibility: Is there a way to get permission under FERPA for a change?" she asks.

IRBs can waive the informed consent signature for research studies, but they cannot waive the FERPA signature, Mayo adds. Instead, the institution received guidance that digital signatures could work.

"They would accept permission for students to access academic records for research by logging into the system and giving digital signatures," she explains. "That's brand-new for us."

This flexibility enabled educational research to continue even as students were not physically in the classroom.

"Previously, we had to have signed permission. Now, the sign-off person says we can do it this way," Mayo says. "They can continue educational research that uses records, such as maybe faculty are doing pre- and post-survey work and accessing course work."

Surveys and interviews can be performed remotely. Researchers can obtain electronic permission through FERPA. "Every IRB has a little flexibility in how it can deal with this pandemic," Mayo notes. "We said, 'If you are in the middle of data collection and you said you were going to do in-person interviews, and now you have an interview scheduled and you want to do it by Zoom, then just go ahead and do it.'"

If it is minimal risk research, investigators do not need IRB approval. "We've had much more flexibility to transition to a more virtual environment," Mayo says. "It's important to keep research going. We can't be a big barrier, especially during this time when important research needs to be done. We've had behavioral studies come through on COVID-19. People want to do surveys to see how it's impacting students because there is less risk of surveying someone online about COVID."

The SBER IRB's work has been steady through the pandemic. "We have not seen a loss in studies," Mayo says. "There was a few-week period where we had quite a few COVID-related studies come through."

The IRB uses an online submission process with a digital database. It also can hold meetings online, Mayo says.

"We can transition to online, keep up with our workload, and be responsive to the research community," she adds. ■

FDA Releases Q&A for COVID-19 and Clinical Trials

Guidance covers consent during pandemic

The Food and Drug Administration (FDA) recently released updated guidance on conducting clinical trials of medical products during the COVID-19 pandemic. The new version of the guidelines includes a question-and-answer (Q&A) section that clarifies some emergency changes affecting human research protection policies and procedures.

"The first guidance that was issued by the FDA was giving folks a good deal of latitude in the changes they needed to make in response to COVID," says **James Riddle**, MCSE, CIP, CPIA, CRQM, vice president of institutional services with Advarra in Columbia, MD. "This updated guidance provides more concrete examples of how FDA viewed flexibility."

"FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health

Emergency," updated July 2, is intended for industry, investigators, and IRBs. The Q&A section provides good examples of the flexibility the FDA had in mind with the original guidance, Riddle explains.

Obtain Informed Consent Remotely

The updated guidance explains how to obtain informed consent when the researcher and participant cannot be together. It clarifies how to obtain informed consent from a quarantined hospital patient. It also provides information on how to handle situations where a prospective trial participant can receive an informed consent document electronically, but cannot sign it electronically or print it for signature.

"The FDA is not saying to not get consent, but they're giving people flexibility on how to document informed consent," Riddle explains.

For example, question 10 and its answer are as follows:

• "How do I obtain signed informed consent from a hospitalized patient who is in isolation when a COVID-19 infection control policy prevents us from entering the patient's room to collect a signed informed consent form?"

• Answer: "FDA regulations generally require that the informed consent of a trial participant (in this case, a hospitalized patient) be documented by the use of a written consent document that typically includes the elements of informed consent, as described in 21 CFR 50.25, and that has been approved by the IRB and signed and dated by the trial participant or their legally authorized representative at the time of consent (21 CFR 50.27(a)). When feasible, we recommend a traditional method of obtaining and documenting informed consent using a signed paper copy of the consent form, or use of electronic informed consent. If neither of these approaches are possible, the following procedures would be considered to satisfy FDA's informed consent documentation requirement." *(The guidance is available online at: https://bit.ly/38P8lPX.)*

"The updated guidance makes it very clear the FDA expects electronic consent to comply with regulations," Riddle adds. "While I see FDA encouraging the use of electronic consent, I don't see a relaxation of standards relative to e-consent."

The revised guidance and Q&A do not change the FDA's original guidance, but it provides more details.

"It says, 'We understand this is hard, and we know you need to make changes and deviate from existing protocol, so go ahead in the interest of patient safety, but document what you did,'" Riddle says.

The underlying message is the FDA wants IRBs and sites to document everything. Include documentation of these changes in the research record with explanations about how the changes affect data integrity. "They'll look for records of why changes were made for each individual patient or participant," Riddle says. "The other underlying message I take away from the guidance is to remind people that the guidance is directed for during the pandemic."

When the pandemic ends, it is likely the FDA's flexibility also will end, Riddle says.

"FDA doesn't come out and say that in the guidance, but there are quite a few spots where it indicates 'during the pandemic' and 'in response to the pandemic,' which suggests it will come to an end," he adds. "You should document what you did, and keep in mind the guidance is designed for flexibility during the pandemic."

For questions on clinical trial conduct during the COVID-19 pandemic, please email the FDA at: Clinicaltrialconduct-COVID19@fda.hhs.gov. ■

IRB ADVISOR

CME/CE INSTRUCTIONS

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CME/CE QUESTIONS

1. **The COVID-19 pandemic highlighted existing racial disparities in healthcare, including research. Through July 20, the rate of COVID-19 deaths was 27 per 100,000 people among white Americans. What was the death rate among Black Americans?**

   a. 32 deaths per 100,000 people
   b. 26 deaths per 100,000 people
   c. 69 deaths per 100,000 people
   d. 88 deaths per 100,000 people

2. **The "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency" provides examples of what researchers, IRBs, and sponsors can do to meet regulations during the pandemic. Which best describes their guidance?**

   a. Relaxation of standards
   b. Traditional interpretation
   c. Clarification of initial guidance
   d. Compliance with all regulations

3. **According to Linda Mayo, CIP, social-behavioral-educational research programs should consider using a key information page in the informed consent:**

   a. if the study involves a survey of primary education children.
   b. if the consent form contains more than one sentence about risks and benefits.
   c. if the study involves underrepresented populations of volunteers.
   d. if the consent form is more than four pages long.

4. **Which is a pragmatic way to ensure fewer technical problems when holding virtual IRB meetings?**

   a. Give every member the same type of cellphone for the call.
   b. Make sure IRB members remain quiet and do not use speakerphone during the call.
   c. Ask members to call from a landline.
   d. Use videoconferencing instead of teleconferencing.