IRB ADVISOR

YOUR PRACTICAL GUIDE TO INSTITUTIONAL REVIEW BOARD MANAGEMENT

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INSIDE



# IRB Experts Offer Advice for Changing Research Landscape

*How to enter next research era*

*By Melinda Young*

It is clear that clinical trials now exist in a different world from what researchers, IRBs, and sponsors experienced in 2019. The key challenges are how to restart clinical trials, how to return to in-person visits, and how to manage the growing number of studies related to COVID-19.

"Like many industries, the clinical trials industry is one that got very comfortable in its routines and patterns," says **David Borasky**, MPH, CIP, vice president of IRB compliance with WIRB-Copernicus Group (WCG) in Princeton, NJ.

"Even as ideas were coming out of various sectors of the industry to do things different ways, whether it was risk-based monitoring or remote and virtual clinical trials, people don't like change," Borasky explains. "It makes people nervous to do something in a different way, and that is often amplified when you're in a regulated environment because nobody wants to be the first one to do something new."

> "EVEN AS IDEAS WERE COMING OUT OF VARIOUS SECTORS OF THE INDUSTRY TO DO THINGS DIFFERENT WAYS, WHETHER IT WAS ... VIRTUAL CLINICAL TRIALS, PEOPLE DON'T LIKE CHANGE."

The clinical trial industry knew in 2019 what was acceptable to regulators, and they largely stuck with the familiar. In 2020, the familiar disappeared in the wake of the pandemic.

"It has really changed the landscape of clinical trials," said **Suzanne Caruso**, vice president of clinical solutions with WCG. Caruso spoke about the realities of restarting clinical trials at a May 6 WCG web conference.

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"The impact on clinical trials has been really significant," Caruso explained. "We're now at more than 950 trials that have started in COVID research in 2020."

To imagine a post-COVID-19 future, IRBs and research organizations will need to assess what worked and what did not in the pre-COVID-19 research world, suggested **Ken Getz**, MBA, deputy director and professor at Tufts Center for the Study of Drug Development of Boston. Getz spoke about the future of clinical research at a WCG web conference on April 29.

"It's quite a challenge to attempt to take on and tackle imagining what the future might look like, knowing that each and every one of us has been formulating and reformulating a picture based on highly fluid conditions that we face at this time," said Getz, founder and board chair of the Center for Information and Study on Clinical Research Participation, and a member of the WCG board of advisors. "We look to the past to frame our thinking about imaginings for the future. What did the world look like in 2019 and Q1 of 2020, which seems like so long ago?"

For instance, studies were highly complex, and there was considerable fragmentation and poor coordination, Getz said.

"These relate to the high degree of customization, which drives inefficiency, cost, and poor performance, and have characterized protocol development for a long time," he explained.

The near past also featured high levels of risk aversion, limited regulatory clarity, and mixed — but improving — public and patient engagement, he said.

A look at clinical trial trends over the past decade shows a high growth in the endpoints and scope of protocols and data collection. "The number of primary endpoints has not risen dramatically, and the number of key secondary endpoints has not risen dramatically," he added. "But, there's an increase in the number of exploratory and miscellaneous endpoints."

Data collection, as well as the diversity of data, has increased dramatically, Getz said. For instance, protocols can collect data from case report forms, laboratories, smartphones, electronic clinical outcomes assessments, electronic medical records, mobile health, wearable devices, and social media.

Another trend is in the decline of the size of pivotal trials. "That's a function in all of the studies we now support that target rare diseases and stratify patient populations," Getz explained. "Complexity also is associated with higher numbers of protocol amendments. The No. 1 reason to amend protocols is to relax eligibility criteria because it's so difficult to find subject volunteers."

One of the more challenging trends involves study enrollment, which has declined over the past decade. "Nearly half of all investigative sites underenroll or fail to enroll a single patient," Getz said. "Regardless of the clinical research area, clinical trials are typically doubling their planned enrollment period."

In the post-pandemic clinical research world, there is an opportunity to reverse some of the negative trends. For example, protocol designs in 2021 likely will include even greater complexity and customization, but might be supported by flexible and scaled capabilities, including more machine learning and analytical approaches, Getz said.

IRBs and research organizations should expect more trials using virtual and remote approaches, now that sponsors have a broader sense of these capabilities, he said. There also will be broader use of hybrid clinical trials with remote and virtual elements, including self-administered procedures and diagnostic assessments. These changes will help fuel a shift away from urban settings and increase study participation in rural areas.

"We will have an increased use of collaborative designs and shared development risk," Getz noted. "We anticipate more preauthorized and conditional-use trials, where we'll support speed by relying on collecting data in real-world clinical care settings."

IRB and research staff can expect to see workplace attitudes change in the post-pandemic world, as well. For instance, there will be increased receptivity to remote interactions, Getz noted.

"More places are receptive to working from home now. There's growing awareness of colleagues and life balance as we come into homes in our remote interactions," he said.

Organizations and employees are developing greater empathy toward colleagues and work-life balance, and people are better prepared for these virtual and remote meetings. "We're getting better at shortening the amount of time we have to make decisions," Getz said.

Changes from the pandemic could lead to improved research recruitment as more people might enroll in studies that do not require as many in-person visits. This means rural participants would face fewer transportation barriers.

Although the research industry knew improvements in recruitment were needed, they were willing to accept the status quo and mitigate recruitment failure by increasing the number of research sites, Borasky says.

"With the pandemic, all of that turned on its ear," he adds.

Some studies will need to continue in-person visits. But many others can adjust those schedules and rely more on remote visits. "You won't see oncology studies in the home," Borasky says.

In-person activities are necessary for Phase I studies where participants receive the study drug and blood draws in rapid succession for pharmacokinetics, he adds.

"There always will be research studies that are very intensive and don't lend themselves to be done remotely because they involve a lot of interactions with subjects or procedures that require trained medical staff," Borasky explains.

But Phase III studies that are screening participants with monthly or quarterly visits to review changes can lend themselves well to remote work, he adds.

"There are a lot of assessments that don't require intensive oversight or inpatient hospitalization to get that done," Borasky says. "Those are often the big multisite clinical trials that take up a lot of time and have trouble recruiting and sustaining their enrollment."

During the later stages of the pandemic, when many parts of public life have resumed, IRBs and researchers will need to decide whether it is better to resume in-person visits or continue with remote visits.

"If you changed your methods to do remote activities, do these have any impact on the risks to human participants in the study?" Borasky says. "That's case by case."

Questions include:

- Is it unwise to send participants home with the study drug/device?
- What are the potential serious adverse events?
- Can risk of COVID-19 infection be safely reduced for in-person study visits?
- Should blood draws be performed in a commercial lab, or in the participant's home by a health professional?

"IRBs would want to know how safety issues are managed in a remote setup," Borasky says. "Regardless of the setting, criteria for IRB approval remain the same, although IRBs might have questions about the ability to do it remotely and practical concerns."

Independent IRBs often are more flexible because they serve multiple sites simultaneously and must maintain rosters of IRB members from a wide variety of backgrounds and geographic areas. Unlike academic or hospital IRBs, they do not rely on internal talent, Borasky explains.

Independent IRBs have remote work systems in place that were quickly implemented when work-at-home orders were made.

"We miss seeing each other, but the work goes on uninterrupted, and, I would say, seamlessly," Borasky says. "It was a good transition."

After going through the huge and abrupt remote work changes forced by the pandemic, all IRBs will have similar experience and systems in place.

It is possible that many of these systems — especially remote study visits and remote IRB meetings — will remain after the pandemic.

"It is entirely possible that for people stuck in old ways of thinking, the scales will fall from their eyes, and they'll say, 'We could have been doing this all along,'" Borasky says. ■

# Q&A Part 1: IRBs Face Their Toughest Challenges with COVID-19

*Communication tops list of challenges*

**IRB Advisor:** What have been the most challenging changes your IRB made because of the COVID-19 pandemic? How did you handle them?

**Moore:** We have faced multiple challenges during the COVID-19 pandemic; some have been with the conduct of IRB activities, while others have been assisting study teams and investigators with transitioning their study activities to new study methods due to physical distancing requirements. Virtual IRB meetings through video and teleconference have been used consistently. This technology was used already for unaffiliated members, but was used more widely to achieve and obtain quorum during restricted and alternative work hours.

**Doksum:** We conduct mostly social-behavioral research. One of the first changes we made was to develop guidance for studies that involved face-to-face data collection (e.g., interviews, focus groups) — indicating they should switch to virtual modes (e.g., phone or web-based) or voluntarily pause. Most of our studies already were collecting data virtually, so only a subset of active studies were affected by the pandemic. The challenge was that the pandemic quickly evolved, so our guidance had to change with it. After a few weeks, we updated our guidance to require an exception request for face-to-face data collection. Fortunately, we were in frequent communication with peer IRBs to ensure our guidance was staying current with best practices.

**Anding:** Our office has been working hard to stay one step ahead of the changing landscape because of COVID. I've been involved from the IRB staff and members' perspective. Another colleague, Catherine Rogers, has done a significant amount of work with researchers and various institutional groups monitoring clinical research initiatives surrounding COVID.

**Cholka:** One of the biggest challenges our IRB faced was communicating to our researchers the difference between changes to research that reduce immediate hazards to participants and changes to research related to COVID-19

## IRB PANDEMIC IMPACT REPORT

In this question and answer (Q&A) special report, a dozen IRB administrators, directors, chairs, and other leaders from across the United States were asked about their facilities' experiences during the COVID-19 pandemic's early weeks. The leaders responded candidly about their toughest challenges, best new tactics, and how they supported their human research protection community

- **Gretchen L. J. Anding**, MA, assistant director, UW-Madison Health Sciences IRBs Office, University of Wisconsin
- **Cecilia Brooke Cholka**, MA, CIP, IRB specialist, University of Nevada, Reno
- **Francis J. DiMario, Jr.**, MD, MA, CIP, professor, pediatrics and neurology, The University of Connecticut; associate chair, academic affairs, department pediatrics; medical director, human research protection program (HRPP); chair of IRB, Connecticut Children's Medical Center
- **Teresa Doksum**, PhD, MPH, senior director of quality and research ethics, Abt Associates, Cambridge, MA
- **Harry McGee**, MPH, SIRB chair, Michigan State University
- **Brian Moore**, MS, CIP, director, HRPP/IRB, Wake Forest School of Medicine, Clinical Translational Science Institute, Winston-Salem, NC
- **Jon Newlin**, CIP, assistant director, HRPP, Feinstein Institutes for Medical Research, Northwell Health, Manhasset, NY
- **Linda Reuter**, CIP, director, BRANY IRB, Biomedical Research Alliance of New York, Lake Success, NY
- **Lisa Rigtrup**, operations manager, IRB, University of Utah
- **Catherine Rogers**, post-approval team manager and senior IRB analyst, UW-Madison Health Sciences IRBs Office
- **William Smith**, JD, IRB director, Nova Southeastern University, Davie, FL
- **Megan Williams**, MPA, CIP, director of research administration, academic affairs, Salem State University, Salem, MA

that require an amendment prior to implementation. To communicate with our researchers, we partnered with other components of our HRPP [human research protection program] to ensure we informed as many researchers as possible. These additional communication paths will be used after the crisis is over, because these paths strengthen our communication efforts.

**Reuter:** BRANY IRB meetings have been occurring via teleconference for several years, so our committee members made a seamless transition in response to physical distancing requirements. Several members of our IRB staff also had experience with telecommuting on occasion, and were equipped with laptops and the proper software to work remotely. Our biggest challenge was to transition a few IRB staff who had worked predominantly in the office up until that point to a remote working environment. We worked swiftly to provide them with the equipment and support they needed to work from home. A new strategy we employed was the use of a software application that allows for instant messaging, screen-sharing, and conferencing to facilitate communication outside of email, and we created several different groups based on certain projects or themes to keep communication flowing. This has been useful, and may be a useful tool even after the crisis is over and we return to the office.

**Williams:** Like all IRBs, the Salem State IRB shifted to online meetings to accommodate the pandemic. I anticipate we will continue to offer that as an option in the fall. Because faculty were asked to alter their course delivery online so quickly while also managing multiple personal priorities, the university issued a hold harmless statement for continuing scholarship. For some faculty, the social distancing order has given them the opportunity to increase their research, but for others, it has created significant stress to find the time around their teaching responsibilities. We also have had multiple faculty submit COVID-19 social-behavioral research projects, with an intense urgency for approval as the situation constantly changes.

**Rogers:** The most immediate challenge that comes to mind is the pace of information and how quickly that information can change, even from hour to hour (although that is slowing a bit now — until we gear up for re-entry, at which point this will start again).

**Newlin:** For COVID-19 treatment trials, applying the criteria for approval, and figuring out appropriate renewal periods, in an environment where the science is changing on a daily — sometimes hourly — basis has been an interesting challenge. For instance, our IRB was assessing an investigator-initiated treatment trial at the exact time when it was expected that the Food and Drug Administration (FDA) would issue the emergency use authorization (EUA) for remdesivir. Remdesivir was not yet the new standard of care, but it could be at any moment, or the EUA could have never come through. I was refreshing the FDA news and Gilead website every minute while IRB deliberations were taking place. When juggling assessments of clinical equipoise in that environment, all you can do is hold a lot of IRB meetings, have very tight data safety monitoring schedules built into the protocol, and pay a lot of attention to the news.

Since our institution was at the epicenter in New York, new studies came quickly, and in volume. An institutional challenge was to create an infrastructure to sort through which studies should move forward, which investigators should team up (if they had similar ideas), and which should wait for further down the road. Since all research goes through the HRPP, many researchers came to believe that we controlled this sorting process, when it was actually an administrative process outside of our office. But when the HRPP says "We can't review this because it needs approval from X group beforehand," the research community mistakenly thinks of the IRB as the delay. Spending time trying to explain that over and over has been a challenge.

**Rigtrup:** At the University of Utah, we are fortunate in these challenging times to have a director who holds a PhD in public health. Our IRB anticipated some of the actions we would need to take in preparation for social distancing, shutdowns, and the need for rapid study application turnaround times. We swiftly prepared and enacted several changes over the course of just a few days as we kept a close eye on global events and discussions from our institutional leadership.

**DiMario:** We created a set of guidelines for researchers and widely distributed them prior to implementation. We halted non-therapeutic or non-safety-related, in-person interactions with participants. As a corollary, we advised that if possible, principal investigators implement virtual study visits and submit planned study deviations, as opposed to a long-term study amendment to the IRB. This impacted study sample collection for non-safety-related collections, as well. If the PI wishes to continue this procedure long-term, then they will inform the IRB with a subsequent amendment.

**McGee:** We basically followed directives on social distancing. The university paused research that cannot comply with the directives. The exception is some research that could provide important information about treatment and prevention of COVID-19 and some research that provides direct benefit to participants or that would be a risk to suspend. We still process applications, modifications, etc. We all work from home and hold IRB meetings via Zoom.

**Smith:** Fewer of my studies have been impacted than most IRBs. A lot of survey/interview studies had to find ways to continue, but we had vanishingly few treatment studies that still were recruiting or treating participants. Most of them had wound down or had yet to begin those stages. So far, the biggest challenge has been getting investigators to think through the alternative logistics of doing their entire or remaining portions online.

**IRB Advisor:** Were there any new tactics or workflow processes that your IRB developed because of physical distancing challenges? Are you considering keeping these changes after the crisis is over?

**Newlin:** We were fortunate to be already set up, very well, to work remotely. Our IRB switched to a flex model, all over Zoom, in 2014, and we have a very good and reliable electronic system that is available online. I expect we'll allow for more remote work in the future. We had been one or two days per week for experienced managers, but at this point, we are going to have to get used to long-term remote working. That will likely be available even if we do head back to the office at some point. One of the immediate challenges, even though we are well set up for remote work, is that no one expected to be working remotely 100% of the time, with all their family members at home. We have team members working on ironing boards as standing desks, kitchen tables, wherever they can find a quiet space.

Figuring out how to get everyone set up with everything they need at home is our immediate ongoing challenge, and it will probably be a part of the job for the long-term future. Team members may come to a physical office, but they will need a parallel, equally functional work space at home. Many of us don't have that dedicated office at home, so we need to find a way to create one.

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**DiMario:** We have maintained daily virtual meetings and continued to work remotely. The positive result has been a more efficient virtual conversation as we practiced over time. The real negative impact with a return of normal operations will be the added family stress placed on those with school-aged children who may be continuing to attend virtual school at home. We may simply continue virtual meetings and more remote work activities.

**Rigtrup:** The most urgent thing we addressed was the need for transitional instructions for our research community as remote working requirements were implemented. We quickly issued a public statement that included guidance for investigators about how to prepare their existing research for COVID-19. *(The guidance is available at: https://bit.ly/2ArAi3i.)* The guidance included assurances the IRB would be fully operational throughout the crisis, and instructions for incorporating remote consent processes and virtual study visits into their approved protocols wherever prudent.

At the same time, we prepared our staff at every level for transitioning to remote working, which included quickly ordering supplies and any videoconferencing equipment our staff and board members might need for their home workstations while shipping speeds were still operating as expected.

We also developed and issued evolving guidance, procedures, and policies as needed for conducting virtual convened board meetings, a topic we had already been researching before the health crisis began. We plan to continue to use this format for some of our meetings in the future.

**Moore:** Our researchers and study teams are hardworking and diligent when it comes to the safety of study participants. However, many were unfamiliar with acceptable alternative methods of obtaining consent and conducting study visits. A significant amount of education has taken place for research to continue. Many investigators can continue their research from a remote setting, and have indicated they will continue these methods even after the physical distancing restrictions are lifted.

**Rogers:** In the early stages, frequently asked questions that were posted almost immediately needed revision as the landscape changed,

or new ones were drafted as new questions arose. The quick pace also has meant things that under normal circumstances may take months are now happening in a matter of days. For example, developing a complicated workflow to obtain plasma from convalescent COVID patients, which involved collaboration between at least four different entities on campus, came together in a matter of a few weeks. This also fostered an environment of consistent and productive communication between groups that I hope will last beyond the pandemic. Additionally, the pandemic has highlighted the need for the university to have adequate software to obtain e-signatures, something that is not just applicable to the current pandemic. The immediacy of the current need, though, means that this is being fast-tracked in a way that it might not have otherwise.

**Reuter:** BRANY assisted numerous sites as they grappled with changes to their research. Most institutions issued guidelines that affected the research team's ability to carry out their study procedures or visits as per protocol. This resulted in many protocol deviations, and the need for protocol amendments. Sites also were receiving correspondence from sponsors regarding accommodations for protocols, such as remote study visits and shipping study drugs directly to the subjects' homes. Coordinators were uncertain about whether this correspondence needed to be submitted to the IRB, or if the deviations needed to be immediately reported. BRANY swiftly issued guidance on how to deal with these rapidly developing changes, and clarified what changes qualified as "necessary to eliminate apparent immediate hazards to the subject," consistent with FDA guidance. Changes were quickly made to our electronic submission forms and processes to accommodate new types of submissions. Most importantly, BRANY staff was immediately available to answer questions and guide sites through the process.

**Doksum:** The only new workflow process was creation of a special review committee for requests for an exception to our policy of pausing face-to-face data collection. This special committee includes representatives to provide input on staff safety, which is an important priority for our company. We have yet to meet because all studies paused face-to-face data collection due to local restrictions. However, now that some parts of the globe are lifting restrictions, we are preparing to review studies that want to unpause or start new in-person data collection.

**Williams:** We have asked researchers to switch their data collection methods to videoconferencing rather than in person. We also have issued many pending approvals for students in clinical studies, such as social work and occupational therapy, who were unable to secure clinical research collaborations due to the pandemic. We do not anticipate that these practices will continue, but also understand that the pandemic is new to all of us and we must be flexible in our practices and institutional procedures. ■

# Q&A Part 2: How IRB Leaders Helped Staff, Board Members Cope with Uncertainty

**IRB Advisor:** As an IRB leader, how have you helped your members and staff cope with the uncertainty and stress they have experienced because of the pandemic?

**Rogers:** For IRB staff, strangely, I think seeing everyone in their home on weekly videoconferences while sharing the experience of quarantine has fostered a bit of a bond and has allowed people to get to know their co-workers in a way that might not have happened otherwise. Interoffice communication through an end-of-the day debrief email has been so helpful. While probably not necessary as a daily thing long term, I think it has kept everyone on the same page and made everyone to feel that important information is being shared in a timely and consistent manner.

**Newlin:** A team member had the idea of meeting each morning at 9:30 for a Zoom group huddle. We usually spend 15-30 minutes talking about issues facing the office, or the pandemic generally — who has been able to get groceries delivered, from where, etc. Just seeing everyone and meeting more often has been an important way to keep some sense of normalcy.

**Reuter:** We have found that IRB members and staff willingly intensified their efforts in response to the increased workload. The volume of requests related to COVID-19 research and emergency use requests picked up rapidly, and we found that IRB members were ready and willing to respond to our requests for

emergency IRB meetings and rapid reviews. IRB staff worked together with other BRANY departments to triage and process submissions. In particular, our New York clients were under extreme stress, and these institutions were given a high priority as we managed the work. At the same time, guidance was developed for sites that were grappling with how to submit for approval of changes for their ongoing non-COVID clinical trials.

**Smith:** As for leadership, we're using this time to work on projects that we had put off as secondary, since our primary workload has dropped. It helps keep them — and me — sane, but these have no deadlines that push things. I've had to lay off pushing progress to avoid stressing them out, but that's my nature.

**Anding:** With IRB members, our main goal has been to communicate with them frequently about meeting scheduling, attendance, and moving to a completely virtual meeting platform. We've been flexible from the start with IRB member schedules, knowing that members who have clinical practices likely have fluctuating schedules during this time. In addition, we reached out to IRB chairs and a few select members early on in the outbreak to ask if they could be available to assist with additional expedited reviews for studies that were moving to remote study visits only. Our office's administrative team quickly became familiar with our virtual meeting platform and created several user guides for IRB members and administrators. We increased the number of administrative staff who attend the meetings so we could efficiently and effectively monitor attendance and quorum needs in the virtual meeting platform. In addition, we drafted a virtual meeting etiquette expectations for IRB members, so they'd know in advance what was expected at IRB meetings (e.g., muting when not talking, announcing when they arrived or needed to leave the meeting). We also remind members of the etiquette expectations at the beginning of each meeting.

> "THE STRESS AND UNCERTAINTY OUR STAFF HAVE EXPERIENCED DURING THIS TIME HAS BEEN PROFOUND AND OF PARTICULAR CONCERN TO OUR MANAGEMENT TEAM."

**Doksum:** Our company leaders and human resources have been proactive in helping staff cope with uncertainty and stress. We have played an important role in helping researchers cope by anticipating their information and training needs. For example, we convened an expert panel presentation about virtual data collection options for focus groups and interviews to help researchers quickly switch from face-to-face to virtual.

**Williams:** The most significant contribution I can make to researchers and faculty members on the IRB is to be conscious of conflicting responsibilities and thoughtful about expectations, schedules, workload, and meetings. Subcommittee work was, for the most part, shifted to the fall. Committee members were given the option to attend meetings as their schedules allowed.

**Rigtrup:** The stress and uncertainty our staff have experienced during this time has been profound and of particular concern to our management team. Before social distancing protocols were initiated, we were as transparent as possible, and made sure our staff was aware of every bit of evolving information we could share with them. We assured them their leadership were following events closely and that preparations were underway to ensure their work lives could continue no matter what happened.

After the staff transitioned on

March 16 to working remotely, we started an instant messaging channel for each of our teams so they could ask questions, discuss issues, and get answers from their managers quickly. We also started a "water cooler" channel where the entire staff could post fun, informal messages like memes, photos of their pets and children, personal issues and questions, and uplifting messages, and we encouraged participation in virtual socialization. We increased the frequency of our staff meetings to help ground everyone at least once per week, and help the group feel connected to their co-workers.

**Moore:** We are fortunate to have a mature, veteran staff. Although none of us have experienced a pandemic before, the staff and board members easily and professionally transitioned to a work-from-home environment. We have a daily call to address any unusual or controversial situations, and save a little time to decompress if needed.

**Cholka:** The primary way that I have been assisting members and staff is to increase the frequency of check-ins to reduce feelings of isolation. There also has been a process to manage expectations so that members and staff know we are doing our best during these unusual times, even if we feel less productive than usual. The positive result of these check-ins is an increased sense of collaboration on issues that we typically would not have collaborated on. I hope that this collaboration will continue as we return to normal operations. ■

# Q&A Part 3: IRBs Learn Positive and Instructional Lessons from Pandemic

**IRB Advisor:** What positive results and/or drawbacks do you predict as your IRB returns to more normal levels of study review activity after the pandemic?

**McGee:** We all have tried to support each other. I believe that we may not ever go back to the way it had been. It will be a while before that could occur.

**Doksum:** Instead of preparing for normal levels of study review activity, we are adapting to a new normal of more time-sensitive review requests. For example, we are getting a lot of amendment requests related to our evaluations of government programs to assess the effects of the pandemic on outcomes related to education, employment, health, food security, and housing. Overall, the Abt IRB is responding to the pandemic by ensuring we keep up with evolving best practices to protect human subjects.

**Reuter:** IRB managers stayed in close touch with the members and staff to make sure they were OK. Some were dealing with illness in their own families, and support was given as needed. Most importantly, each IRB staff member was encouraged to communicate if they were feeling overwhelmed or burdened so they could receive whatever help they needed. Overall, the members and staff have handled this crisis at a level of excellence, and the BRANY IRB functions have continued without interruption. We have learned a lot about the resilience of our IRB members and staff to cope in the face of crisis. As we move toward the post-pandemic phase of COVID-19 recovery, we will come back together with a newfound appreciation of the need for ongoing communication, the willingness to extend ourselves beyond our normal job roles when needed, and the value of community, which I believe most of us took for granted before we were forced to socially distance from each other. I look forward to the post-pandemic phase, and am confident BRANY IRB will emerge stronger than ever.

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**Williams:** The positive result of this is that we've all learned to be more flexible, and hopefully kinder, to one another in our work. At times, the stress levels are intense, and flexibility makes a huge big difference to individuals' daily lives. In contrast, one significant drawback has been a decrease in research by both faculty and students. In addition, planned upgrades to our homegrown IRB systems have been shelved because of staffing issues and institutional priorities.

**Moore:** I think the longer we stay in a work-from-home situation, the more difficult it will be to return, especially with other commitments and responsibilities such as child care,

when not all other industries may be reopened yet.

**Rigtrup:** IRB submissions and overall workload increased tremendously with the influx of amendments to existing studies and new study applications related to COVID-19. We made sure to check in often with everyone regarding their workload and our expectations for their productivity. We encouraged staff to take time off whenever they were able, even if only for a brief "mental health staycation," and we checked in with each other just to see how everyone was doing. We were flexible with work schedules when staff needed to take care of children and family members. Most importantly, as layoffs and unemployment spread across the nation, we assured our staff as soon as we had confirmation that their employment and benefits were secure. We repeated this assurance each time social distancing protocols were extended.

I'm hopeful that as our IRB moves through these challenging times, our staff will have retained an increased sense of camaraderie, having come through an unprecedented and sometimes frightening time together as a team.

**Smith:** In the meantime, we're finding out just how much of this work can be done via email and call-forwarding. We are not returning to the same old routine, so that's a positive (aside from my emails at 6 a.m.). Beyond that, we're not looking at the light at the end of the tunnel for clinical or in-person research just yet. I have my eyes on August for that, at the earliest — except for clinical treatment studies.

**Newlin:** One benefit is that because of the extra attention to COVID-19 research at an institutional level, everyone has seen the benefits of building quality into protocols early in the process and making sure sites have the resources and funding to perform the research. This extra attention has been useful for the IRB, as we spend less time reviewing protocols that don't have that quality built in.

The drawbacks of the next stage are all around uncertainty — about levels of work, where we'll be working, and the consequences of the pandemic generally. This stage has been a lot of critical work, with folks getting COVID treatment trials up and running very quickly. It has been a very meaningful time to work at an IRB. It's unclear to me how the next phase will play out. If there is a second spike, IRBs could be bombarded again, or if there is a slow simmer, it could be a return to half-normalcy. No one knows for sure, and dealing with that uncertainty will be an ongoing challenge. ■

# Research Organizations Face Challenges New and Old

*Stress safety, documentation*

As current studies resume and new studies are approved, IRBs and researchers should keep basic safety and regulatory practices in mind, according to experts on the front lines of human research protection and clinical trials.

Research organizations have been adaptable, resilient, and trustworthy in the face of new challenges this year, said **Bernadette D'Souza**, MD, scientific advisor with Evolution Research Group (ERG) in Seattle. D'Souza spoke at a WIRB-Copernicus Group (WCG) web conference on April 15.

D'Souza noted these chief challenges for ERG and other research organizations during the COVID-19 crisis:

- Complying with quarantine and stay-at-home orders, which have caused disruptions in supply chains and a fear of the unknown;
- Ensuring staff and research participant safety;
- Developing best practices in uncertain times;
- Coping with study design changes.

"We call our subjects the day before. If they have any respiratory symptoms or illness, we ask them to stay home," D'Souza said. "The same goes for our staff — if you're sick, stay home. We have gatekeepers who screen all patients and visitors."

Screening questions include asking participants about their health and checking their temperature and oxygen levels.

"We've continuously stressed to staff the importance of documentation," D'Souza explained. "Our management team is very active and working long hours."

Research organizations will still be challenged in keeping their studies

moving forward during the crisis, particularly as social distancing and mobility affect research, noted **Mark G. A. Opler**, PhD, MPH, chief research officer with MedAvante-ProPhase. Opler also spoke at the April 15 web conference.

## Assess Each New Trial Aspect

Research organizations should assess each new aspect of conducting clinical trials during the COVID-19 pandemic and recovery period, Opler said. He recommended these questions:

- If study participants or staff cannot go to the site, how does the research organization continue to evaluate safety and efficacy?
- Which clinical endpoints are accessible through remote methods?
- What is the right modality to ensure adequate data collection?
- How can organizations establish methodology and manualize procedures for remote use?

"These are challenging decisions because it's not just about what the best method would be in the perfect universe," Opler explained. "What is feasible and practical?"

For instance, it might be desirable to use high-definition, high-bandwidth videoconferencing capabilities. But this may not be realistic for participants at home.

"There is a need for guidance and structure and to create as much certainty as we can in an uncertain time," Opler says. "Part of our responsibility in doing that is to make sure that when investigators connect with participants remotely, they can have every path."

Another challenge is how participants perceive remote study visits. Logistical problems or distractions may occur, D'Souza noted.

"We ran into some problems where they'd say, 'You can call me and I'll be home,' but the call comes in when they're cooking dinner and they think they can handle the call," she explained. "Often times, we have patients who gave us the wrong number, so this means we had some tight screening windows. If we couldn't finish screening, then we would lose these patients as potential subjects."

## Experiment with Remote Visits

As IRBs and research organizations navigate uncertainty during the pandemic, they are serving as experiments in discovering what works well with remote visits.

"Before the pandemic, there were not a lot of people pushing the envelope or trying new things on a consistent or regular basis," says **David Borasky**, MPH, CIP, vice president of IRB compliance with WCG in Princeton, NJ. "There might have been a component of someone doing something different, but it was more of an outlier and not a consistent thing."

The pandemic's role in pushing remote visits and strategies has helped the research community gain confidence in alternatives to in-person study visits. For example, researchers can use an interface that observes patients while they are at home, taking their medication, D'Souza explained.

When investigators compared data between pre-COVID-19 compliance rates and six weeks of post-COVID-19 rates, they found an initial dip in compliance that reverted to the regular range, D'Souza said. If more studies show positive outcomes with remote visits and use of investigational products, this could lead to post-pandemic study designs that include remote visits.

Another change involves study monitors. Due to travel limitations, study monitors have not visited most study sites. Instead, they engaged in remote monitoring, D'Souza said.

## Focus on the Next Phase

During the next phase, research organizations should focus on these key points:

- Reassure and retain staff;
- Become more involved in decisions about study design and study execution;
- Recognize the increased financial and time burdens — even when there are fewer study visits.

"We want to express our desire to be strong partners in the research ecosystem as it exists," D'Souza added. ■

## COMING IN FUTURE MONTHS

- IRB director describes challenges in social, behavioral, and education research world
- Tactics to improve participants' health literacy
- Standardized metrics model can guide quality improvements
- Latest information on COVID-19 clinical trials

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## CME/CE QUESTIONS

1. **According to Ken Getz, MBA, a look at clinical trial trends over the past 10 years shows that there has been a high growth in:**

   a. primary endpoints.
   b. key secondary endpoints.
   c. exploratory and miscellaneous endpoints.
   d. final visit endpoints.

2. **Which is a good question to consider when deciding whether a study should shift to remote activities?**

   a. What are the drug's potential serious adverse events?
   b. Which institutions will be conducting the trial?
   c. Have investigators received CPR and life safety training?
   d. How new is the subject's home computer?

3. **What did investigators find when they compared data between pre-COVID-19 compliance rates and six weeks of post-COVID-19 rates?**

   a. Compliance rates were identical from start to finish.
   b. There was an initial dip in compliance among post-COVID rates, but returned to regular range.
   c. The pre-COVID compliance rates were 20% higher than the post-COVID rates.
   d. The post-COVID compliance rates were 5% higher than the pre-COVID rates.

4. **In addition to participant study visits, which clinical trial activity shifted from an in-person activity to a remote activity?**

   a. Study monitor visits
   b. IRB submissions
   c. Administration of oncology drugs and serological tests for safety
   d. Study participants' symptom diaries