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that the person obtaining consent could not answer him or herself. The allowance of this process in this circumstance led to more successful trials while still protecting participants and providing an adequate consent process.

At the height of the pandemic in April 2020, our health system had 3400 patients hospitalized with COVID-19. As of September 2020, we had treated 85,000 patients across all of our facilities (outpatient, urgent care, in patient). This is 20% of all COVID-19 patients seen in the state of New York. As the pandemic starts to pick up across the country, and even now again in New York, here are the lessons I take away from our experience in the spring and will continue to use as we move forward:

1. Regulations need to be followed but you can look for the flexibility in them and guide investigators to conduct quality research while being flexible.
2. Communication within research administration and to the study teams is essential. It is a fast moving environment and staying connected is important to assure efficiency of processes.
3. Communication between research and clinical care teams is essential. This pandemic shone a light on research. All of sudden everything being done to treat patients was research. A coordinated effort between research and clinical teams can help maintain focus so that we can learn as much as possible from every patient treated during this pandemic.

Clinical Research During the COVID-19 Pandemic

Sujatha Sridhar

When the news about COVID-19 spreading in various parts of the world and then in New York City was reported the first week of March, it still seemed very distant. It was work as usual, but we started noticing institutions all over the country discussing ramp down plans as stay at home orders were being issued in various parts of the country.

The week of March 9th, the University started discussing ramping down plans for research. Laboratory-based researches were well versed with emergency preparedness procedures. After the devastating losses suffered during hurricane Allison in June 2001, laboratory researchers had developed a robust plan for preparedness, which they put to use several times since during hurricane season each year. However, there was not a similar plan for clinical research. Developing a ramp down plan for clinical research proved very challenging. Every research study is different—a plan for an oncology clinical trial with an investigational agent needed to be different from a research study on learning methods for elementary school kids. It was helpful for us to focus on the main considerations, which was to ensure the safety of participants enrolled in clinical research studies, minimize exposure of patients, participants and research staff and to be mindful of availability of resources such as PPE and other clinic and hospital resources. On March 19th, when Harris County and several other surrounding counties started instituting stay at home orders, we were ready with a plan. In addition to asking researchers not to enroll any new participants in clinical research that would involve in-person visits, the plan asked researchers to make case by case decisions based on these same principles for any participants who were already enrolled in clinical research studies.

IRB Operations

Our IRB has been using a fully electronic IRB system since 2004, so we were sure we could keep the IRB operations going during the remote working period. However, conducting IRB meetings virtually was not something we were familiar with. We were very proud of our high tech conference room with laptops, large screens and teleconferencing capabilities. Our only experience having remote participation was when we had a consultant or an alternate call in by telephone, or occasionally video conferencing. Our IRB members enjoyed the in-person camaraderie and we joked that each of our 4 IRB Panels had a character. We were not ready to meet virtually—so for the first week, we

had 8 people in the large conference room, socially distanced, with the rest of the members on WebEx. It was a disaster. Most of the time in the meeting was spent reminding members in the room to speak up because those on WebEx couldn't hear them. It was not difficult to decide that our only option was to go a hundred percent virtual. It took a few meetings for us to learn how to conduct the meetings effectively and also practical matters such as recording votes of each member. Soon, IRB meetings were running smoothly with many members saying that they prefer this format and would like to continue to meet virtually even after the pandemic restrictions have eased. Most IRB meetings had record attendance and it was much easier to schedule investigators to join in to answer member questions. What had appeared to be an insurmountable challenge turned out to be an advantage.

In the first few weeks in this new era, we saw a slowing down of new submissions, mostly because no new enrollment was allowed in clinical research studies. Researchers must have felt there was no point in initiating new trials. However, this was just the calm before the storm. Within no time, there was a surge in research related to COVID-19. The number of new applications that our IRB received in 2020 was 25% higher than 2019. COVID-19 related research accounted for more than 20% of new applications to the IRB. Many of these COVID-19 proposals were urgent and the IRB office would receive calls and emails from Principal Investigators and research staff asking for an expeditious review.

In response to this urgency, IRB staff and members were asked to prioritize the review of COVID-19 protocols. IRB members also recognized the unique challenges researchers faced in conducting research during a pandemic. IRB members focused on ensuring that the rights and wellbeing of human subjects were not being compromised for the sake of expediency. For example, our IRB had advocated very strongly in the past for in-person informed consent discussions. However, in the light of this pandemic—while they agreed the necessity of remote consent process was necessary—they were diligent in working with researchers to develop a process that ensured that the remote process would be as robust as an in-person consent process.

In addition to the deluge of new COVID-19 related proposals, in the early months, the IRB staff had to also deal with several emergency use requests. For several weeks, IRB staff were on alert to deal with these requests all through the week, including weekends. We developed a system in which one staff member would be 'on call,' monitoring emails, and would activate a team of regulatory specialists, IRB staff, and IRB chairs to handle any emergency use requests. Often these requests meant we would have to drop everything else we were working on to ensure that all the regulatory paperwork to obtain the investigational agent were completed accurately and quickly. When we heard that the patient had received the agent, all the effort seemed worthwhile.

COVID-19 Research

Many of our frontline COVID-19 researchers and our clinical trials offices were receiving invitations to complete feasibility questionnaires for clinical trials for various COVID-19 treatments and diagnostics. Very quickly, we recognized that it would be important to have a process to identify trials that would be most beneficial to our patients and also trials that had the highest chances of successfully being done here in our institution. A COVID-19 clinical research workgroup was formed with a charge to select the most promising studies that could reasonably be implemented. The committee met twice a week every week to review all new COVID-19 related clinical trials. Only research approved by this group was allowed to proceed with IRB review. Reviewers scored protocols based on readiness, leadership, funding, supporting evidence, impact on field, and participant safety.

A COVID-19 subcommittee was formed to help integrate clinical trials into the already complex workflow. All researchers who were involved with COVID-19 clinical trials were invited to participate. This group met every other week by WebEx. This sub-committee developed a priority rotation schedule to ensure all trials have adequate opportunity for recruitment. Another workgroup was formed that consisted of research nurses and research coordinators who worked on COVID-19 clinical

trials. This group kept in close communication by sending daily emails with information on which patients are being screened and enrolled and which patients can be passed on to the next research team. We learnt pretty soon that it was important to communicate daily, and sometimes several times a day, to ensure that we were able to offer opportunities to participate in clinical trials to all our patients. It was also important for us to have current information on trial status—especially when trials were closed to enrollment by the sponsor, or when trials were being placed on enrollment holds by the sponsor for safety or other concerns so that other trials could recruit. We developed a dashboard, which was constantly updated so everyone working in this space had access to the most current information.

Conducting Clinical Trials During a Pandemic

While it was not too difficult to issue a rule to put a hold on new enrollment, it was a very challenging task to ensure there was a methodical and thoughtful resumption of new enrollment. Clinical trial investigators and research staff were invited to participate in regularly scheduled WebEx meetings to discuss concerns in conducting clinical trials during the pandemic and develop solutions. Our researchers and research staff helped us craft a plan for phased resumption of enrollment in clinical research. Researchers also shared tools they developed, such as standard operating procedures for home research visits to checklists for screening participants before study visits at the clinic. We were very thankful for the FDA guidance on conducting clinical trials during the pandemic and worked with research nurses and coordinators to develop guidance on remote study visits, remote monitoring, electronic consent, etc.

Lessons Learnt

The most important lesson we learnt was that communication is key. Looking back, perhaps we should have worked with clinical researchers and research staff before issuing the enrollment hold in the middle of March. Although it was necessary

and important, having at least a preliminary plan for phased resumption of enrollment might have been more helpful. While we did put together a recurring meeting for clinical researchers to discuss issues related to conducting clinical trials during the pandemic, we should have initiated these meetings much earlier in the process, even before the enrollment hold's announcement.

We quickly realized that sending multiple emails to our research community created confusion instead of clarity. Instead, we developed an intranet site and a Google Drive folder to share information with our research community. This site was continually updated as we received new information from regulators, or as we learnt from our fellow institutions around the country.

We also learnt that it was not easy for the Covid-19 committee to disapprove proposals. Our default mode was to work with investigators to improve the protocol. However, with numerous competing trials for the same patients, it was necessary to develop a rubric by which we could deny protocols that did not meet the committee's standards had set. Again, focusing on the first principles, which were ensuring access to the highest quality trials for our patients and only accepting trials that had a chance of successfully being implemented at our institution, helped with these decisions.

Communicating often and clearly with everyone is key. Ensuring we seek and listen to voices from as many groups of people as possible is very important. Being transparent about the process was helpful in gaining the trust of the research community as we all navigate these challenging times together and learn together.

Planning an Agile Response

John D Tupin

Our IRB reviewed just over 200 COVID-related studies with an additional 170 individual actions in relation to those studies.