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Research on COVID-19: Stories from IRB Members, Research Administrators, & Investigators

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in obtaining and documenting the informed consent process.

The IRB staff have been working remotely for six weeks. There are still some technical issues and limitations. Communication is good and with some creative work-arounds we are able to maintain our normal meeting schedule and near-normal times for approval. There have been personal challenges regarding remote education for my children. These types of challenges have forced many of us to flex our work hours to fulfill the needs of multiple groups, while also supporting the IRB members and researchers in a time of crisis.

September—Month Six

We are six months in to a long journey. At the beginning of the COVID-19 outbreak, I reminded our staff that this was going to be a marathon, to not burn-out or expect everything to magically return to the “old normal” overnight. Periodically, through the process, I have told them that we are on mile 2 of the 26.2 mile marathon. They rolled their eyes, but at this juncture there is no immediate change in sight. However, there are many lessons learned and reflections on things that both went well and things that can be improved.

The Good

1. IRB meeting formats had to be changed, but the cadence of meetings was sustainable.
2. Having a list of readily available alternates was helpful for establishing quorum for the meetings as everyone’s time is even more precious than before.
3. Significant amounts of education have taken place. Whether on the different options for obtaining consent or collecting data during adverse situations, researchers and IRB members were forced to think critically and make a careful evaluation of what is required by the regulations versus what is the institutional preference of normally doing things.
4. New technology and alternative methods were instituted that made research during the time of the pandemic more feasible and may help for planning of future studies as well.

The Bad

1. The initial reactions and sudden need for alternative arrangements shone a light on many areas of weakness. Just as children practice the fire drill in their school, institutions and IRBs can learn and practice for future events. Having a disaster plan and periodically testing remote work capabilities would be prudent in the future.
2. Work-life balance has been a struggle for many individuals, due to lack of childcare, school closings, remote education, and caring for loved ones. These situations have forced us to be more adaptive throughout the day.

At the end of the day, the IRB and researchers at our organization have similar objectives—to promote the safe and respectful conduct of high-quality research. Each party has a different perspective, and sometimes timelines differ, but the underlying concepts of respect, justice, and beneficence have shown through. Researchers and IRB reviewers now have a greater appreciation for what is best and safest for study participants and how to be flexible in accommodating their needs.

Editor’s Note. This story complements Rebecca Erwin Wells’ story, which is included among the researcher stories in this symposium.

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Sara Griffin

From my perspective, as both an IRB staff member and IRB Committee member, the COVID-19 pandemic brought to light many opportunities for improvement and better collaboration in the review of human subject research (HSR). In my experience, the pandemic exacerbated issues that commonly arise in the review of HSR,

and it also brought challenges that were previously unanticipated. This reflection first focuses on the issues I experienced as an IRB staff member along with the remedies to those issues and then pivots to my experiences as an IRB member. I hope that this reflection will serve as a comfort to those who experienced similar issues and perhaps felt isolated in the struggle and as an aid for those still struggling to navigate the review of research during this time.

A key aspect of my role within the IRB Office is to assist teams with the consent process and manage the research consent form templates utilized at the institution. Pre-pandemic, I would often receive requests to ease consent restrictions within a project even though the project did not even meet the regulatory requirements for a waiver of consent or documentation of consent. While I could often sympathize with research teams seeking to lessen the burden of a lengthy consent process on subjects, these requests could generally be denied without ill consequences to subjects or the feeling that a disservice has been done. In the case of the pandemic, however, there was a strong desire on the part of both researcher and IRB staff to allow as much flexibility as possible due to the unprecedented nature of the pandemic restrictions and the potential risks involved in consenting subjects in person. While some flexibility was possible, it quickly became clear that there were many consenting options that would simply not be possible for the foreseeable future due to regulatory restrictions and institutional barriers. Most of the flexibility that has been granted during the pandemic is applicable only to COVID-related populations. While this is understandable and appreciated, researchers who continue to conduct research in non-COVID populations have been left with few options. The issues relating to consent during the pandemic that have arisen ignited a number of institutional departments to pursue electronic consent options for FDA-regulated projects, but since this was reactionary, a significant amount of time passed during the pandemic in which researchers could not utilize electronic consent for research. This resulted in a continued barrier to conducting certain types of

research and a feeling of helplessness on the part of IRB staff.

Another pain point at the outset of the pandemic was that the pace of communication within the larger Human Research Protection Program was not keeping up with the swiftness of change. Given the pandemic's impact on in-person interactions, one of my duties as the consent analyst within the IRB Office was to release and maintain guidance for consenting subjects during the pandemic. After spending numerous hours strategizing and studying the regulatory guidance on the consent process, it was a welcome relief to release the requested guidance. Only a few days after release, however, it came to my attention that revised hospital policies did not align with the main consent process highlighted in the guidance and recommended by the IRB Office. Not only was it slightly embarrassing to have been left out of hospital policy notification, but it also presented yet another limitation on how consent could be obtained and documented. Although this example alone was not the driving force behind the formation of a multi-institution committee that kept abreast of all COVID-related changes, this committee's formation did alleviate this recognized pain point and prevented situations similar to the one described above from occurring.

The difficulties and remedies described thus far in this reflection stemmed from my experiences as an IRB staff member, but I also experienced a set of different challenges while reviewing research as an IRB member.

Most of the dilemmas I faced while reviewing COVID-related research can be attributed to the seemingly endless review of overlapping research. Due to the pace at which everyone was moving at the outset of the pandemic, it was difficult to know whether or not someone at an institutional level was monitoring the number of projects proposing to recruit the exact same subject population. It was also troublesome to see a large number of separate projects seeking to collect and store data and biospecimens for future unspecified research. While these concerns reflected issues beyond IRB purview, the fact that the IRB could be the only entity witnessing this disorganization concerned me. Thankfully,

these issues were short-lived and occurred very early in the pandemic. Partly due to concerns raised by IRB members and staff, a committee was established on an institutional level that monitored all projects seeking to enroll COVID-related populations. Also, institutional resources were used to mobilize established institutional banks as brokers for COVID-related data and biospecimens. This streamlined the process for collecting and distributing data and biospecimens related to COVID-19, which benefitted researchers and prevented the creation of countless standalone banks.

While this reflection has drawn attention to flaws that presented themselves during the pandemic, I hope the quick institutional action and commitment of those in the HRPP are also apparent in the simple yet effective remedies described. Although the pandemic has presented numerous challenges to all involved in human subject research, it has also highlighted the research community's perseverance and dedication.

IRB Tales from the Heart of the Pandemic

Hallie Kassan

The week of March 9, 2020 started off like any other week in an IRB/HRPP office. Two new staff had started in our office within the past two weeks, and we were training them. There was talk of coronavirus and COVID-19 in the news as it had made its way to the US, but our health system was not yet feeling a major impact. Then, as each day passed, there were new developments. Rumors started flying that someone in the building in which the HRPP office is housed had come down with COVID-19. Staff started panicking. Leadership at work and within research reassured everyone that if we all follow the basic guidelines, we will stay safe. Those guidelines were wash your hands, cover your mouth when you sneeze and cough, and stay home if you feel sick.

By Thursday morning, March 12, 2020, it was clear that staff did not feel safe coming in to work any longer. The challenge that day was setting everyone up (including two new employees who had been with us for less than three weeks) to work remotely, as our work force was generally not remote. My assistant director and I worked with IT support to make sure everyone had a functional computer to use at home, with which they would be able to login to our network. By the end of the day Thursday, all the HRPP staff had been told they could work remotely until told otherwise.

Once the staff were settled, I was able to focus on work in the office and decisions that had to be made:

- Do we need to put out a notice closing down research? Or can we allow investigators to make their own choices regarding their studies and continued activity as long as it was in compliance with the health system policies being put forth to combat COVID?
- Will research studies be opening up? What IRB will be reviewing them? Our health system's IRB or an external IRB?
- For studies coming through the IRB, what type of turnaround are investigators expecting?

It became clear that research leadership had to put out a memo providing direction on how ongoing research studies should be handled. Investigators were confused and not sure whether they could move forward or not. They needed direction. Thus, over the course of a weekend, the HRPP worked together with clinical research operations.

Together, we sent out a notification requiring enrollment on open studies be halted. In addition, we asked for research activities to be paused, unless the studies were of potential benefit and pausing activity could cause harm to an enrolled subject.

The next agenda item was determining which COVID-19 research studies we should open within our health system. A small group was formed to vet all the COVID-19 trials that were coming our way and determine whether they were feasible to move forward. The decision makers felt very strongly that we should try to limit our trials to randomized controlled trials, in an effort to put the best science forward. The first trials we opened were industry sponsored multi center studies, for which we relied