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IRB Members Perspective During COVID-19

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principles of ethical research can guide us along a path to coping with these challenges and facing the daily dilemmas of the COVID-19 era. Should we resume in-person instruction? Should we get together with friends and family? Should we continue our research agendas, and if so, how? We can find guidance in the fundamental principles of human subjects research ethics: minimizing risks, maximizing benefits, seeking truly informed consent, ensuring scientifically sound decision-making, avoiding prejudicial assumptions about others, and especially protecting the most vulnerable among us. These are not only the guiding principles of IRB administrators. Respect for personhood, beneficence, and justice are collective promises that reflect our core humanity. As such, they are the best guide for how to navigate this crisis—in our IRB offices, our classrooms, our research encounters, our homes, and our relationships with one another.

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March—Week One

Our weekly staff meeting comes to a close. Some people linger for study—they have specific questions, while the remainder pack up their legal pads and spiral notebooks before retreating to their offices. There was some rumor of remote work and some vague plans discussed but with the assurance that ample time would be provided to make alternative accommodations. Little did we know that a week later most in-person research would be shut down and a wrench thrown in the finely tuned cogs of our infrastructure.

March—Week Two

Despite a carefully worded and comprehensive message to the research community my email box is bursting and my phone, forwarded to my

personal number, rings non-stop. It is often stated in professional circles that each study is different and must be handled based according to the nuances and details of the particular trial. This is never truer than trying to fit all the different shaped pegs into the round holes of the regulations. Some studies fit smoothly. To the disgust of investigators, some will not fit no matter how hard we try. Most are able to be re-shaped to fit the regulatory requirements and the needs of the researchers within the restrictions placed by the institution. The most common questions revolve around what alternatives are available regarding the process of informed consent, and continued research visits through a remote process.

We completed a 100% virtual IRB meeting today. This has only been used for inclement weather situations in the past, but will soon become the new normal. The board members are patient and open to the new format. The discussion and vote are consistent with our in-person meetings, so we adjourn satisfied that although not sitting side-by-side, we have fulfilled our ethical, moral, and regulatory obligations. Several members who are either unaffiliated with the organization or located in an outlying clinic location previously participated in the meetings remotely. This approach has proven invaluable for having the resources already in place for a more long-term plan.

May—Week Seven

Most in-person research activity is still shut down but that doesn't mean that continuing review expiration dates can be extended. Many new COVID-19 related trials are being submitted. There is some degree of urgency for these submissions, however, the established process of review, discussion, and documentation is upheld. Sometimes COVID-19 trials are triaged to be assigned for review ahead of others, but we don't take any shortcuts or skirt any corners of the regulations. We have implemented a platform to compliantly document electronic signatures for informed consent documents. This was probably overdue, but the use case was very compelling and is of great assistance to our investigators in terms of both compliance, and practicality

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.

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

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,