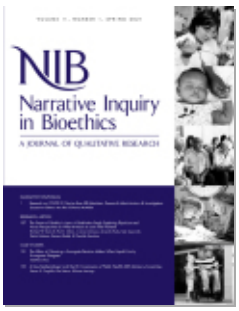
Shaken

Ann Johnson



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emergency support available. We are covering and meeting our standards, but we are unable to address new non-urgent submissions.

As to the advice we have for other IRBs that review research on pandemic illness: we lived by the belief that subject and staff safety always came first. To that end, we made adjustments on the fly to reduce or eliminate contact, community travel and non-essential staff presence at our facilities. The good news is it seemed that we were slightly ahead of adjustments being made by regulatory agencies, subject communications and form of documentation, but I worry that some of the actions we took will result in a disqualification of collected data. My team will be creating a large-scale event management plan based on highly a contagious viral threat that will allow our team to continue to be highly agile and effective.

Another piece of advice for IRBs: be prepared! Have an effective HIPAA and part 11 compliant system for moving data. We have had 15% staff take extended time off and one abruptly resign. Allow your staff to flex their hours and take mental health days, know that you will lose members of your staff due to stress, family care and illness and accept it. This isn't normal and trying to maintain normalcy is a fool's errand, but if you put a priority on staff wellbeing, there is a possibility that you will end with an intact team.

Researchers who study a pandemic illness should begin to advocate now for policies, technologies and emergency plans for the next pandemic. Without researchers' pushing there is a possibility of returning to our old normal.

Shaken

Ann Johnson

In response to the COVID-19 pandemic, work-at-home mandates for the university where I work in Utah began on Monday, March 16, 2020. The University's IRB approached the work-at-home situation with a can-do attitude. We weren't sure exactly how this pandemic was going to take shape, but we were going to make it work. We started marking things off of our checklist with semi-confidence:

- We figured out our virtual conferencing platform.
- We wrote some initial rules of conduct for the convened meetings and disseminated them to our members.
- We bought everyone a new set of headphones with a microphone in hopes we would have sufficient sound quality.
- We trained two of our staff members to be meeting hosts (affectionately referred to as 'meeting Yodas'), to guide everyone to virtual meeting bliss while trouble shooting all technical problems and helping IRB discussions to go off without a hitch.

On Monday, March 16, we felt good. We had taken on the initial pandemic stress and subdued it into submission. We were ready for our first virtual convened IRB meeting at noon on Wednesday.

Then Salt Lake City experienced a 5.7 magnitude earthquake at 7:09 AM on Wednesday, March 18.

The thing that stood out most to me about the earthquake was how loud it was. Many of us in Salt Lake City were still in our beds at 7:09 AM and we were not only shaken awake, but startled from sleep by the rumbles and groans of our houses. My house rattled and boomed around me as I clung to my newborn baby and my husband ran for our toddler. The IRB staff spent the morning checking in with one another, feeling out our emotions and reporting on the state of our foundations, our pets, our WiFi. Luckily the whole of Salt Lake City experienced very little damage and the population was safe; no injuries or fatalities. We hadn't been devastated, only shaken. We decided everything was okay enough to go forward with our virtual-convened IRB meeting scheduled at noon. We experienced more than four dozen aftershocks that day. The largest—a 4.6 magnitude quake—occurred at 1:12 PM, smackdab in the middle of the convened IRB meeting. The IRB chair paused in his review, while everyone watched each other shake in their

video squares on the screen. We continued to feel aftershocks for a few weeks, and each one would trigger that rudimentary fear for one's safety, the fear of the unknown, and the fear of losing control.

The day of the earthquake brought a dark cloud over the IRB staff's personal confidence for mitigating the cumulating stress. Our mood toward the pandemic's onset turned from inquisitive to somber. Though the pandemic and the earthquake were not correlated in any way, a new level of seriousness washed over us as we grappled to understand how to re-exert any modicum of control over our changing lives. We yearned for normalcy in a way distinct from the rest of the world who was also being upended by COVID-19.

Many of us at the IRB found there was one thing we *could* control: the review of research. Projects to study the various aspects of SARS-CoV-2 infections, testing, treatments, and pandemic social conditions came pouring in, with 32 pandemic-related projects reviewed and approved by the IRB within the first 30 days of the work-at-home mandate. We threw ourselves into the fervor for getting these studies reviewed and approved quickly, feeling it was our way of contributing to the pandemic's eventual end. We were able to prioritize these studies and complete our reviews in a fraction of the time were they to have entered our normal review queue (although, it required that non-COVID-19 studies be pushed back in the review queue). We convened some urgent IRB meetings that were not part of our regular schedule; because we had a panel with a quorum of three, we were able to quickly and easily find three IRB members at a time (out of over 100) who were willing to do urgent reviews and convene off-schedule. Having this panel already established pre-pandemic was one of the keys to our success.

We also took a flexible approach to using a single IRB process for multisite research. In cases when deferring to an external IRB would save time and resources, we did so, recognizing the value of previously established reliance relationships that we could benefit from easily. We also noted cases where using a single IRB process would actually create greater time delays and burden for the study team, and thus opted to perform the reviews locally. This flexible approach ended up being something notable to the federal Office of Human Research Protections as well, as they granted an exception to the requirement to use a single IRB for cooperative research initiated during the pandemic "where reliance on a single IRB would not be practical".

Lastly, we solidified guidance for conducting remote consent processes and assisted investigators one-on-one to create situationally appropriate consent processes that met the conditions of the regulations. Except for a few pandemic-induced consent process exceptions for clinical trials granted by the Food and Drug Administration, all of the consent processes we approved fit within the existing regulatory framework. We, as well as investigators, were reminded of the many options for obtaining informed consent that already existed and have noted that their use should continue post-pandemic to the benefit of our varied participant communication needs.

Overall, our IRB's success came down to pre-existing options for flexible review and conduct of research. While we had not planned for these options to be specifically useful in a pandemic situation, they ended up being instrumental in reducing the number of barriers a COVID-19 project would experience. The flexibility created agility, which reduced our stress and restored our morale. The IRB was an effective partner in COVID-19 research, doing our part to benefit the wellbeing of our community and lay a foundation for future normalcy.

Late in the evening on Friday, March 20, I received an email from a physician after the IRB had approved his protocol at an off-schedule meeting that afternoon. After a tumultuous first week of pandemic life, it was a message that soothed me and has stayed with me for the rest of the year. It continues to put the pandemic—and the IRB's work in it—in perspective, despite an earthquake or any other emotionally destructive force.

> "Forty-eight hours ago, we had an idea about how we might help these COVID patients. Since that time, we created a team, drafted a protocol, and filed an IRB application that was expeditiously reviewed. I'm not one for the heavy emotional thing, but the speed and cumulative

institutional effort to make this happen was inspiring. Whether or not this is a viable therapy remains to be seen; our commitment to patients, however, remains truly exceptional."

Emergency Response to COVID: An IRB Story

Joan B. Cobb Pettit

In past "normal" times, when IRB members and leaders think about "emergency response," we imagine hospital emergency departments or public health mobilization efforts in the face of an epidemic or other health crisis—with the focus on helping others. COVID introduced a new perspective because the emergency we faced affected us personally and professionally, in addition to our researchers and our study participants. It forced changing so many facets of our work: halting in-person human subjects research activities to reduce risk, moving IRB operations to remote work, minimizing unnecessary submissions when studies shifted from in-person to remote work, providing guidance on how to safely collect data using remote mechanisms, and working with University leadership on how to safely re-start human subjects research. And it was all so sudden—or at least it seemed that way.

At the Johns Hopkins Bloomberg School of Public Health (JHSPH), we have an office of 10 people and two IRBs that meet weekly. We process about 500–600 new applications per year, including Exempt, Non-Exempt, and "not human subjects research" submissions. Our portfolio includes research all over the world. In late February, 2020, our Vice Dean for Research, who oversees the IRB Office and all research activities at the School, was involved in discussions with JHU leadership anticipating that the University would need to move to remote work. He asked me to come up with a plan for the IRB Office. I worked with my staff of 9 and on Monday, March 2, I sent him an email outlining what we came up with:

1. Communications: Change our telephone voice messages to tell folks to communicate via email. Inform the IRB Chairs and Members about our plan and help them access Zoom if needed.
2. Computers: Make sure all staff have computer access at home—and let them take office computers if needed.
3. Internet access/firewall: Have staff test access to office databases and systems from home and obtain IT assistance if necessary.
4. Office files: Create electronic files for any hard copy files that we maintain in the office.
5. Zoom: Set up Zoom accounts to permit our weekly IRB meetings to proceed electronically. Learn about Zoom—who needs to have accounts, how to host meetings, send new meeting invites for all standard meetings with Zoom link.

And finally,

6. Set up a test day for staff to work from home to make sure everything worked.

We chose Monday, March 16, as our test day and spent the rest of the week having staff check out and resolve internet access issues from home, scheduling Zoom meetings with each other, and trying to work out the kinks in our plan. By the time we had thought through all the logistics of transporting computers back and forth, we decided that it would be better to have us schedule a test week instead of a single day. So the plan was to work from home the week of March 16.

But then, life and COVID intervened. The virus was spreading and a shutdown loomed. By Wednesday, March 11, the School and University began communicating the possibility of having everyone go home and initiate remote work. Thank goodness we had a plan and everyone knew what to do.

My personal story has a little twist. We have a son and daughter-in-law living in Wellington, New Zealand. They were expecting their first child in late March, with no other family nearby. We planned to visit in April. On Wednesday, March 11, they called us and said that the New Zealand government was calling all Kiwis home in anticipation of a border closing. The message was, "Come now or you won't