PROJECT MUSE®

IRBs During COVID-19: Tried and True

Gianna McMillan

Narrative Inquiry in Bioethics, Volume 11, Number 1, Spring 2021, pp. 89-94 (Article)

Published by Johns Hopkins University Press

DOI: <https://doi.org/10.1353/nib.2021.0038>

➔ *For additional information about this article*

<https://muse.jhu.edu/article/800075>

Commentary

IRBs During COVID-19: Tried and True

Gianna McMillan^{*†}

**Loyola Marymount University*

[†]Correspondence concerning this article should be addressed to Gianna McMillan, DBE, Loyola Marymount University Bioethics Institute—UNH 4517, 1 LMU Drive, Los Angeles, CA 90045

Email: Gianna.McMillan@lmu.edu

Conflicts of Interest. The author reports no conflicts of interest.

Abstract. The COVID-19 pandemic threw health care logistics and clinical research processes into disarray. This collection of narratives describes the challenges faced by IRB administrators, staff, and committee members as they navigated the SARS-CoV-2 pandemic. The authors transitioned to remote meetings, adjusted to ever-changing information, and untangled the ethical implications of supporting open studies while making room for an influx of new protocols that addressed the pressing public health emergency.

Funding. The work to put together this symposium was supported by the National Institutes of Health [3R01AG058254-03S1 (James DuBois, principal investigator)].

Keywords. Bioethics, Clinical Trial, COVID-19, Human Research, Human Research Protections, Institutional Review Board, Medical Ethics, Narratives, Research Ethics, SARS-CoV-2

The unexpected global spread of the SARS-CoV-2 virus was unprecedented. While the rate of infection and mortality projections were shared concerns, retailers worried about business, employees wondered about their next paychecks. Parents and children were alarmed about the loss of classroom time, and state and local governments struggled mightily with the logistics of managing a public health crisis of this magnitude. There was immediate attention on health-care providers, scientists, and drug developers as the frontline defenders of our communities. We expected medical personnel to treat the emergent sick, researchers to find an answer, and pharmaceutical companies to mass-produce the solution.

Weged between the scientists and the drug developers are legions of largely unrecognized

but vital facilitators of the therapy-development process—the Institutional Review Board (IRB) administrators, staff, and committee members. They are taken for granted, much like the street system in every town, but they are literally the road upon which science travels to reach the answers to our health questions. These twelve IRB narratives describe how their normal lives and human research protection processes were upended by the COVID-19 pandemic and what happens when what might be considered a staid and administrative-heavy occupation becomes super-charged by the realization that it is a crucial component in the fight for continued life on this planet.

In this commentary, I will remark on the stages of IRB experiences that can be characterized as “panic,” “initial response,” and “settling in.” Then I

will offer a discussion of three themes that underly the entire journey, and how these are related to principles that guide the practice of ethical research.

Panic

"... urgent rethinking of the full scope of our human subject research program and its oversight." Edith Paal

"I watched as panicked physicians, patients, and media outlets turned to the research community for answers, desperately hoping cures, vaccines, and preventive measures could be produced." Walter Dehority

"... [Staff] truly felt their lives were at stake" if they were physically present in the office. Stephanie Juell

The above are not the sort of statements one would normally associate with the review of clinical research studies. In my twelve collective years on IRB committees, my fellow committee members and I, and our IRB staff, understood that our work seemed uninteresting (and even dreary) to family and friends who asked polite questions. Methodical paperwork, compliance checklists, decision pathways, record keeping, ongoing training, meeting logistics, and subject interactions—all of these intersected with ethics in a way that was difficult to explain to outsiders. We might admit to elements of the IRB "grind," but as insiders, we knew the importance of our work—and this kept us motivated. Imagine the shock to find that normal IRB operations were suddenly the gateway to the search for treatments for and protection against a virus that was attacking the planet! As Doherty mentions above, *all* eyes were on the IRB—or at least pointed in that direction. The authors share that the scrutiny was keenly felt.

These narratives describe being pulled in many directions during the weeks of March 2020. They use the words "terror," "urgency," "overwhelmed," and "weary." These authors wondered: How do we continue to work safely? Is remote work feasible? Will confidential data remain secure? Are there aspects to an ethical review process that *must* be done face-to-face? Does the pandemic dictate modification of requirements and timelines? They

also asked: What exactly *is* our work? How do we manage existing open protocols and applications already under review? How should IRBs weigh the unknowns of COVID-related research questions against a dire public emergency? Who decides the parameters of all the above? These IRBs didn't know how to gauge if they were acting too quickly to be safe or, conversely, too slowly to save lives. There was "self-imposed pressure to make experimental therapies rapidly available," says Doherty.

The panic was elevated by confusion regarding who had the authority to modify the normal sequences of operation. While the public struggled to untangle inconsistent federal, state, county, and city-wide messaging—IRBs wondered who defined the boundaries and pace of their immediate actions. "Investigators were confused and not sure whether they could move forward or not. They needed direction," says Hallie Kassan. And Paal notes that "The IRB fielded many queries . . . but these decisions were made at the institutional level . . ." John Tupin describes "unavailability of the institutional decision maker and no process for emergency delegation." And finally, "We HRPP folks are compliant by nature," says Juell. "We want to do the right thing. And we want to follow the rules and the laws," but she was distressed by the initial tension between "following the rules" and "doing the right thing."

Initial Response

"Small, uncontrolled studies began to appear in the literature, many bypassing peer reviews, feeding scraps of pilot data to a frightened medical community." Walter Dehority

"Most of the dilemmas I faced while reviewing COVID-related research can be attributed to the seemingly endless review of overlapping research." Sara Griffin

"We needed a rapid turnaround time for this review. The struggle was giving the IRB members enough time to perform an adequate review." Hallie Kassan

Mid-March 2020 is referred to, with somber awe, as a time when "the emergency hit," "we grappled with our personal fears," and "rumors started flying." "I wept as my students and I discussed the suffering

that would likely ensue,” shares Jennifer Randles. But after the initial shock, there was a universal gathering of wits. IRB administrators and staff are nothing if not problem-solvers, and they worked tirelessly with investigators and committee members to keep the workflow moving as everyone transitioned to remote interaction. Trial and error led to frustration. Sujatha Sridhar shares that her first online IRB meeting was a disaster, but after a few tries, “what had appeared to be an insurmountable challenge turned out to be an advantage.” Brian Moore notes in his journal that online IRB “discussion and vote are consistent with our in-person meetings, so we adjourn satisfied that we have fulfilled our ethical, moral, and regulatory obligations.”

Flexibility was the key for untangling logistics, modifying policies, and juggling new data. “Flexibility created agility,” says Ann Jonson, but it was not the answer to everything. Griffin shares that “Most of the flexibility [for consent] that has been granted during the pandemic is applicable only to COVID-related populations . . . researchers who continue to conduct research in non-COVID populations have been left with few options.” Juell warns that “Pandemic work . . . requires flexibility and creativity in terms of meeting regulatory requirements but it is crucial to remember that the regulations themselves serve a larger purpose.” She goes on to describe an ethical balancing act, wondering about “expectation and responsibility; law and ethics; written law and the intent of such laws.” Edward De Vos points out, “If in the short term we assign higher priority to minimizing risk, we risk paying less attention to equitable distribution of burden and benefit.” Dehority speaks of deliberation “sacrificed on the altar of speed and efficiency.” These are not flippant depictions of administrative mindset but are indications that skilled professionals felt torn between opposing forces.

Settling In

“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.” Sara Griffin

“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.” Hallie Kassan

“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.” Sujatha Sridhar

As weeks turned to months, programs developed strategies to meet their new needs: streamlined application processes, especially trained “consenters” for hospital-isolated patients, rubrics for decision-making, small committees on call, and automated emails in response to frequently asked questions. De Vos notes that IRBs are charged with assuring that investigators and IRB members are adequately trained to protect human subjects—and that this responsibility did not change during the pandemic. It is no surprise that compliance issues were in the forefront of everyone’s mind, and many authors discussed their learning curve dealing with Emergency Use Authorizations and the need to assign expert “teams” to address this.

In the majority of the narratives, the tone of the authors changes about halfway through. Distress takes a back seat as they describe the ways that staff and committee members collaborated to keep their research review ethical and timely. They are “proud,” “dedicated,” and “thoughtful.” Our office worked “Herculean hours,” says Paal, and “we are especially proud of the creation and approval of our expanded access protocol.” “We recognized that it would be important to . . . identify trials most beneficial to our patients and that had the highest chances of successfully being done here in our institution. A COVID-19 clinical research workgroup was formed,” relates Sridhar.

With experience under their belts, came other realizations. “Studies, which several weeks prior we hurriedly approved during emergency IRB meetings, were now being hurriedly assessed for closure or suspension due to newly identified risks in the rapidly expanding medical literature,” notes Dehority. John Tupin makes several good points: Telemedicine is a good strategy but “what about

rural patients, the homeless and impoverished, or my 86-year-old father who uses his laptop as a paperweight?" How HIPAA compliant are all the new online transmission and storage tools that we are using? And importantly, "I worry that some of the actions we took will result in a disqualification of collected data."

These narratives were written six to eight months after the onset of the pandemic. There are unique touchpoints in each journey, but the authors' personal and professional growth and the evolution of their affiliated programs are evident as the stories progress. Three themes are woven into the thoughts, actions, and responses: the impact of stress on the human element of research review, the importance of communication, and the value of common-sense application of existing ethical principles.

The Human Element

"Our Board members and IRB staff were exhausted, scared, frustrated, overworked, and overwhelmed. Our conference rooms had been turned into hospital rooms. The library had been turned into a medical storage facility. Clinicians were working overtime all the time and trying to catch naps on chairs. And our frontline healthcare workers were getting sick. Some passed away." Stephanie Juell

"... employed mothers ... pushed to the brink at home themselves as the already thin lines between work and home blurred even more ..." Jennifer Randles

The authors discuss many layers of stress. New Yorkers who lived through the first terrifying wave of the crisis felt like they were "on top of each other" as they traveled to and from work before the decision was made to operate remotely. Salt Lake City was doubly traumatized by a mid-March earthquake. One author was stuck abroad after travel became restricted. Parents juggled home-schooling as they met remotely for IRB meetings, commandeered kitchen tables and bedroom corners for makeshift offices, and tried to maintain healthy personal lives while they felt the weight of responsibility. "The world was turning to the research community for answers," says Dehority. The stakes were high—the difference between life or death for

patients. "I could not allow myself to succumb to the pressure of desperation," declares Juell. "It was difficult to disapprove proposals," adds Sridhar.

Dehority offers a thoughtful discussion about therapeutic misconception and misestimation, noting that incorrect assumptions about potential benefit are largely grounded in hope—and affect investigators, staff, and institutional officials, as well as patients. He worries that hope might have prevailed over scientific caution in his own mind, but notes, "Such insight, more easily achieved after the fact, is difficult to rely upon when a pandemic finally reaches your borders and comes knocking on your door." And the moment when most would welcome—even require—the professional and personal support of in-person work environments, and opportunities for serious discussion about the ethical implications of pandemic-era decisions, everyone was ordered to stay home. Jennifer Randles says, "We are social beings primed for empathy and compassion, and we feel the collective stress and strain of the pandemic, even if our lived experiences are steps removed from its worst outcomes."

The authors share different versions of the same challenge: they are fundamentally concerned with promoting the immediate ethical review of clinical research, while simultaneously managing misgivings about their own safety, that of their loved ones, and, even, existential reflections about global danger. Juggling so many layers of subjective and objective stress is certain to have impact on quality of decisions and interpersonal relationships, and as professionals, they know this. Readers can see them struggle to access their own skills and expertise, while trying to discern the larger context of their responsibilities. We watch them second guess themselves, before they ultimately settle on two guiding principles, which I identify as "communication is paramount" and "existing principles hold."

Communication

"... the pace of communication ... was not keeping up with the swiftness of change." Sara Griffin

"The challenge was how to implement these changes in a compliant way without overloading the IRB and

the IRB member-reviewers, and avoid confusing investigators by communicating clearly to faculty, staff, and students.” Joan B. Cobb Petit

“Communication within research administration and to the study teams . . . and between research and clinical care teams is essential.” Hallie Kassan

“Communicating often and clearly with everyone is key.” Sujatha Sridhar

The parameters of each author’s role, and the ways they interacted with other members of their team, were diminished, expanded, distorted, or reframed. Tried and true networks of communication, already fine-tuned to accommodate the intricate process of research review, were dissolved or rerouted. New data about the virus, short-term exploration for treatment, and long-term plans for prevention changed, sometimes, on a daily basis. No matter what aspect of the pandemic this new information related to, the practical logistics and ethical processes were affected. Decision pathways were like chains of dominoes—a choice at one end of the row instigated a cascade of action. It was important to make sure the dominoes were lined up, that the pattern was orderly, that momentum was maintained, that the pieces fell in the right direction, and that the right person pushed the best tile. Each program eventually found what worked for them: automatic email responses about specific topics, dedicated websites that outline new guidance, FAQs and live Google docs, regular memos from leadership, frequent check-ins between task-specific committees, and weekend or late-night calls. “Staying connected is important to assure efficiency of processes, says Kassan. And Sridhar shares that, “We learnt pretty soon that it was important to communicate daily, and sometimes several times a day . . . [and to] and listen to voices from as many groups of people as possible . . . 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.”

The point here, is that these IRB teams realized they were a conduit of information, and the intersection between several branches of response to the pandemic. Already accustomed to serving as a bridge between competing agendas and

stakeholders who often did not speak the same language, they were able to focus their energy on the most crucial of components for successful movement forward: efficient pathways of communication. They intuitively knew and/or logically came to the conclusion that their work required collection and dissemination of accurate and timely data, and it was up to them to make sure others understood the content and acted on the import.

Existing Principles Hold

“Respect for personhood, beneficence, and justice are collective promises that reflect our core humanity . . . [and these] guide us along a path to coping with these challenges and facing the daily dilemmas of the COVID-19 era.” Jennifer Randles

“Maintain confidence . . . adhere to principles . . . protect subject rights . . . act as a leader . . . be consistent . . . publish guidelines . . . stay human . . . practice selfcare . . .” Stephanie Juell

The dire circumstances of the pandemic inspire compassion for the suffering and dying, and anxious desire to spring into action, but this “new situation” does not mean we need “new rules.” The old rules—our existing tradition of ethical research practice—are still valid, and in some ways, even more important, given the magnitude of potential harm and ethical dilemmas we face as we try to address this global emergency. How should an IRB deal with the therapeutic misconception and therapeutic misestimation that Dehority mentions, when it attacks subjects *and* investigators? How should IRB committees guard against the ways that widespread “images of death” might affect a valid consent process? The answer is not to invent *new* strategies, but to wield, with confidence, the tools that have already stood us good stead.

When Edward De Vos worries about rural populations having access to vaccines or telemedicine, this is not based on a “new” theory of justice. And when he questions whether confidential information will remain secure spread over a patchwork of internet access points, or whether remote research might not be as carefully validated, he is not inventing a new standard of HIPAA or novel Common

Rule standard for science. These are existing tenets of ethical research practices. Time and time again, we see in these narratives where the authors are shocked at first, but then catch their breath and realize they can trust their common sense to use the tools they are familiar with: respect for persons, beneficence, justice, best practices for consent, and the flexibility built into the federal regulations. Despite the urgency of the COVID-19 crisis, the corner stones of research ethics still held.

Conclusion

The latest edition of *Institutional Review Board: Management and Function* (2021) reminds us that ethical reasoning involves identifying the moral question, understanding the facts, drawing on ethical frameworks and principles, weighing the various moral considerations, and making a considered moral judgment. “While the IRBs process,” the editors write, “rarely involves this kind of step-by-step moral reasoning, knowledge of ethical principles and reasoning processes can be key in navigating complex situations or those not covered by the regulations.” (p.4)

In the face of novel crisis situation, the authors fall back on the ethical principles they are accustomed to and use their practical know-how to implement them. Moore writes that the pandemic emergency “shone a light on many areas of weakness,” and others describe modifications that “needed to be made anyway.” As a collection, these stories describe well-trained professionals taken aback by a crisis, but “having emotions isn’t unprofessional. It’s human,” observes Juell. The IRBs catch their stride—and they take care of business because, as we are reminded by Doherity, “Interventions without proven clinical benefit need clinical trials.” Finally, as much as I would like to close this commentary with a bit of original wisdom, Jennifer Randles offers what I believe is the underlying sentiment of this collection: “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.”

References

- Bankert, E. A., Gordon, B. G., Hurley, E. A., Shriver, S. P. & Public Responsibility in Medicine & Research, (PRIM&R) (Eds.). (2021). *Institutional Review Board: Management and Function* (3 ed.). Burlington, MA: Jones & Bartlett Learning.