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

A Teaching Guide for IRB Professionals*

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The stories referenced in this study guide can be downloaded for free. Please see the "Research on COVID-19" volume of VOICES https://nibjournal.org/voices/

Art Frank has written a short reflection piece on learning from narratives for NIB. Please see the Narratives Page under the Education tab on the NIB website nibjournal.org to download the piece.

General Questions:

1. The COVID-19 pandemic forced institutions, investigators, IRB members, and research administrators to re-think many aspects of the research enterprise and to quickly make changes to long-standing IRB protocols, such as allowing informed consent to be obtained remotely or participants to collect their own specimens and ship them to researchers. What do we learn from these changes to protocols during the pandemic? How can we adopt a more flexible approach to research regulations while also maintaining strong participant safety standards?
2. Many industries had to make significant adjustments during the COVID-19 pandemic. Workplaces of all kinds tried new procedures and made adjustments to ensure the safety and well-being of their employees. Many of these changes were positive and perhaps provided long-term benefits, but there is speculation that many industries, including research industries, will revert back to old policies and procedures. Why do you think this is the case? Tradition? A change in the risk/benefit analysis? Something else?
3. Clear communication between institutions and IRBs, between IRBs and researchers, and between researchers and participants is key to a successful research enterprise. What

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communication weaknesses were revealed at the onset of the pandemic, and how did the authors overcome these weaknesses? Does your IRB have any current communication challenges? If so, what best practices could be implemented to address these weaknesses?

4. Several authors discuss the difficulty of assessing risks and benefits in the midst of a constantly fluctuating research environment. How do you assess risks and benefits for research participants during times of uncertainty or public health emergency? When might a more relaxed application of certain regulatory policies actually improve the research enterprise and lead to additional benefits? When is a more rigid approach needed?
5. How do you prioritize your own physical and mental well-being over your work demands? How do you separate urgent work demands from tasks that can wait?

Story Questions:

Therapeutic Misconception, Misestimation, and COVID-19 Research

Walter Dehority

1. Dehority asks, "Would any of our potential research subjects actually consider the warnings in a consent form about the possible risks and lack of proven benefit for an investigational therapy when offered the chance to participate in a COVID-19 clinical trial? How could our IRB best ensure subjects would be able to make informed choices as to whether they should grab these experimental lifelines and not just reach for them blindly out of fear?" As an IRB professional, how do you ensure research subjects are sufficiently informed about the nature of a study and possible benefits and risks? How (if at all) does research in the time of a pandemic or public health emergency change what it means for subjects to make an "informed choice?"

2. Dehority laments the large number of small, underpowered studies that proliferated in the early days of the pandemic and wonders if waiting for the results of larger, well-designed, multi-site controlled trials would have been wiser. Do you or your IRB have similar concerns about approving smaller studies at your institution? How do you decide which small studies are worthy of approval?

3. Therapeutic misconception occurs when research participants do not understand that the purpose of research is to produce generalizable knowledge and will not necessarily benefit them personally. What are some of the characteristics of participants who experience therapeutic misconception? When people participate out of desperation or hope for an effective treatment, what interventions can IRB staff put in place to curb therapeutic misconception and enhance the consent process? How do you balance the desire to make experimental therapies rapidly available to patients while upholding strong patient safety guidelines?

Eight Seconds of Panic

Edith Paal

1. Paal recalls the challenges (and benefits) of transitioning to remote work and virtual IRB meetings in a short amount of time. What do you see as the benefits and challenges of remote work? What virtual practices has your institution or IRB keep in place post-COVID?

2. Drafting new IRB policies can be a long and tedious process. At your institution, what has gone well when drafting new policies? What has gone poorly, and how could the process be improved?

3. How do you manage relations with clinical staff at your institution, particularly new researchers? What are some best practices for familiarizing new researchers with the workings of your IRB?

IRB Work During a Pandemic: Remember Your Values

Stefanie E. Juell

1. As an IRB professional, do you ever experience tension between "following the rules" and "doing the right thing," as Juell states? What is the difference?

2. Juell recalls a situation in which she, as a non-clinician, raised concerns about a potential study but was rebuked by a clinician board member. Do you ever feel pressure from other IRB members or institiution leaders to approve certain studies? How do you navigate political pressures from the institution or research community?

3. Juell says, "[E]ven though we weren't frontline healthcare workers, we all understood that our ability to quickly respond to questions from clinicians about the use of non-approved drugs might very well be the difference between life and death for patients in need of such treatments. I felt personally responsible for the lives of patients I never saw." Do you ever experience this added sense of responsibility when reviewing studies? If so, how do you balance this added responsibility with the need to ensure regulatory compliance?

Ethical PPE: Overseeing Research in the Time of COVID-19

Edward De Vos

1. De Vos's reflection is titled "Ethical PPE." What do you think he means by this? Do you see your work as providing "ethical PPE?"

2. De Vos writes, "COVID-19 is not only an important subject of study, but it has affected the context within which research is conducted, and the risk environment within which IRBs must deliberate." How, if at all, should the assessment of risk change when evaluating studies during pandemics or public health emergencies? What new risks

emerged during the COVID-19 pandemic in these stories or in your own experience serving on an IRB during the COVID-19 pandemic? How did the authors seek to mitigate these risks for participants? In what other ways could these risks have been mitigated?

3. De Vos worries that the "demands of online research may pose challenges to inclusion of more diverse populations," especially as historically underserved and marginalized communities may not have adequate internet access, bandwidth, or equipment to participate in research virtually. How does your IRB ensure equitable distribution of burden and benefit among potential research participants? Is virtual research a long-term sustainable solution? Why or why not?

Navigating the Ethics of a Crisis

Jennifer Randles

1. Randles talks about her personal transition from researcher to IRB professional and the work she did to immerse herself in the IRB admin world. What prior experiences and preconceived notions of IRBs or the research enterprise did you bring to your current work? How did (or do) these experiences help or hinder your work?

2. Randles writes, "I quickly learned just how many faculty experienced IRBs as a dreaded but necessary institutional hoop through which to jump, a potential obstruction to conducting research on which their professional reputation, tenure and promotion, and students' progress through degree programs depended." Do researchers at your institution have similar negative attitudes toward the IRB? If so, how do you change the perception of the IRB from adversary to ally?

3. Randles optimistically writes that the core principles of ethical research (minimizing risks, maximizing benefits, seeking truly informed consent, etc.) can guide our professional and personal lives as we navigate ongoing challenges. Do you agree or disagree? Why?

IRB Members Perspective During COVID-19

Brian Moore

1. The COVID-19 pandemic forced institutions and IRBs to make changes to long-standing IRB protocols, including changes to the way researchers obtained informed consent (e.g. allowing informed consent to be obtained virtually). In light of the pandemic, how has your institution changed or modified its informed consent process, especially for virtual studies? How have these changes strengthened or weakened the informed consent process overall? Which changes should be made permanent, if any?

2. According to Moore, the COVID-19 pandemic forced researchers and IRB members to think critically about what is required by the regulations versus what is institutional preference. What institutional preferences, if any, has your IRB had to re-evaluate or eliminate recently?

3. Moore writes, "Just as children practice the fire drill in their school, institutions and IRBs can learn and practice for future events." Does your institution and IRB have a plan for future pandemics or public health emergencies? If so, what types of policies do you have in place? What policies or practices are needed?

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

Sara Griffin

1. How do current regulatory restrictions and institutional barriers hinder the informed consent process? How might these barriers be addressed in order to increase flexibility while still maintaining a high standard for informed consent?
2. Griffin recounts an experience when guidance from the IRB office conflicted with hospital guidelines for obtaining informed consent. How do you coordinate institution-wide policies, and what are some of the challenges of coordinating with various offices?
3. How do you advise researchers who want to collect and store data and biospecimens for future unspecified research? What are some of the risks and benefits of this type of request?

IRB Tales from the Heart of the Pandemic

Hallie Kassan

1. Kassan writes, "Regulations need to be followed but you can look for the flexibility in them and guide investigators to conduct quality research while being flexible." How does your IRB remain flexible to the changing research environment? How does this flexibility strengthen the research enterprise?
2. Kassan speaks of the challenges of obtaining consent during the COVID-19 pandemic, especially finding people available to obtain consent. Ideally, who should obtain consent (in times of a public health emergency or otherwise)? Why?
3. In terms of communication (between research administration and study teams, between research teams and clinical care teams, etc.), what works well at your institution? What could be improved?

Clinical Research During the COVID-19 Pandemic

Sujatha Sridhar

1. Did your institution or IRB have emergency preparedness procedures in place for research before the COVID-19 pandemic? If so, how did these existing procedures help maintain research operations? If not, what type of procedures did your IRB implement post-pandemic?
2. What pandemic-related structural changes or restrictions (such as virtual IRB meetings) actually turned out to be beneficial to your IRB?

3. Sridhar mentions the cooperation between IRB staff and research nurses and coordinators as a key to successful research. What best practices do you have for coordinating with research staff? What practices could be improved?

Planning an Agile Response

John D. Tupin

1. The COVID-19 pandemic highlighted the need to prioritize staff well-being, but this focus on staff engagement and health ought to extend beyond times of crisis, as well. How does your institution support staff well-being? What do they do well, and in what ways could they improve?
2. What role can IRB offices play in making technologies accessible to underserved communities to ensure equitable access to research opportunities?
3. Tupin argues that researchers who study pandemic illnesses should begin to advocate now for policies, technologies, and emergency plans for the next pandemic. Do you believe it is the researcher's job to do this, or should it be the job of the human subjects research protection office? Why?

Shaken

Ann Johnson

1. Johnson recounts an experience in which she was literally "shaken" by an earthquake while also dealing with COVID-19. How do you balance personal challenges with work demands in order to maintain a work-life balance even in non-pandemic times?
2. Did your IRB have options for flexible review and conduct of research before the pandemic? How did this flexibility create agility? If your IRB did not have this flexibility, what new procedures are now in place to ensure that the research enterprise can continue even during public health emergencies?
3. Johnson shares a message she received from a grateful researcher whose study was reviewed and approved expeditiously. Have you ever received any recognition or notes of appreciation for your work on the IRB? How did they make you feel?

Emergency Response to COVID-19: An IRB Story

Joan B. Cobb Pettit

1. Cobb Pettit describes her "very remote" work situation from New Zealand. Many office workers have grown accustomed to working remotely and will continue to do so as employers meet the demand for worker flexibility. If you are a remote worker, how has remote work affected your work or team dynamic? What is the key to sustaining successful virtual teams? For those working in the office, what are the advantages of being onsite? What is your ideal—remote, in-person, or a hybrid work situation? Why?

2. During the COVID-19 pandemic, many interviews and focus group discussions moved to virtual platforms. What are the benefits and risks of conducting this type of research on virtual platforms? How has your IRB sought to mitigate some of the negative consequences of this type of research?

3. If your institution reviews international research, how do you respect local customs and practices while upholding US regulations or requirements established by your institution? With the assumption that the local practices sufficiently protect research subjects, should US regulations still be implemented? Why or why not?

Pandemics and Protections: How to Keep It All Together in 2020

Gabrielle (Gabby) Rebillard

1. Rebillard discusses some of the challenges of categorizing studies according to the Revised Rule. What gray areas do you think warrant further federal guidance in the Revised Rule? When the "regs" are unclear, how do you decide which studies are exempt and which require IRB approval?

2. Many IRBs collaborated and shared guidelines during the COVID-19 pandemic. Does your IRB receive or share guidance with other institutions? How does this collaboration shape your practices, either positively or negatively?

3. "The ethical and scientific principles that we apply to research are not lost on those of us who review the research. That consideration for risk/benefit goes for us too." What do you think Rebillard means by this, and what does this personal risk/benefit analysis look like in your own life?

COVID-19 Story From an IRB Member and Administrator

Howard Stone

1. How does your institution communicate changing research policies or regulations to your broader research community?

2. How do you balance "normal" tasks of IRB work such as staff development, recruitment, or updates to existing policies with pressing research review demands?

3. Stone discusses the ongoing collaboration needed between the IRB and research/institutional leadership. What makes a good leader? How does a good leader bring about productive collaboration?

Warping of Time

Carol A Pech

1. Pech describes the "twisting and blurring" of time caused by the COVID-19 pandemic. What are some busy times in your workplace, and how can you balance these times with periods of relative calm?

2. Before COVID-19, were you familiar with the public health exception in the Federal Regulations? How (if at all) did you implement this regulation for COVID-19 studies? How often do you use this exception when reviewing studies?

3. How have you relied on regulatory guidance from the FDA? Was this guidance particularly helpful? Why or why not?

Research on COVID-19: Story from the Kenya Medical Research Institute

Kebenei Enock Kipchirchir

1. Kipchirchir writes, "Human beings enrolled in research should be treated as autonomous agents regardless of the situation at hand. No one should disrespect the rights and welfare of research participants in the name of responding to the pandemic." When, if at all, do you think the rights and welfare of research participants are compromised? As an IRB staff member or reviewer, how do you avoid this?

2. How does your IRB conduct ongoing monitoring of studies? Do you think researcher self-reports of violations or adverse events are accurate? If not, why not? How do you improve researcher accountability?

3. Does your IRB require peer reviews or preliminary reviews of research protocols before submission? How might this ensure compliance and an efficient review once submitted?