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

A Teaching Guide for Researchers*

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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 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 while also maintaining strong scientific and 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? Do you have any current communication challenges? If so, what best practices could be implemented 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. As a researcher, discuss your relationship with your institutional IRB. Do you find their guidance helpful or restrictive? How might you improve this relationship?

Story Questions:

Personal Narrative About COVID-19 Research

Gary Schiller

1. What makes someone an "essential worker?" Should research personnel be considered essential?
2. The COVID-19 pandemic forced researchers to change many aspects of their work, particularly their mechanisms for monitoring. What mechanisms do you have in place to ensure safe and effective monitoring, and how do new technologies help or hinder your monitoring activities?
3. Schiller bemoans the lack of systems in place for gathering and documenting signatures, especially when electronic signatures are not possible. Does your institution have a robust documentation system in place? What works well, and what could be improved?

Not What Anyone Signed Up For: Unnecessary and Insurmountable Barriers Encountered in Conducting Clinical Trials in COVID-19

Westyn Branch-Elliman and Paul A Monach

1. Branch-Elliman and Monach ask, "should we provide approved medications off-label or conduct a clinical trial?" How should researchers and clinicians decide when a clinical trial might be more appropriate than off-label drug use?
2. Usually, research consent processes require investigators to emphasize that patients may not benefit from participation in a clinical trial. However, Branch-Elliman and Monach argue that this concept is divorced from reality in COVID research or in other public health emergencies when both patients and researchers want to try "something." How should you manage therapeutic misconception in research during pandemics or public health emergencies?

3. In your opinion, are clinical trial regulations and patient protections protocols too strict? Are we literally "protect[ing] [our patients] to death?"

Clinical Research Through the COVID-19 Pandemic: Crisis Response, Consequences and Innovation

David Altschul

1. Altschul writes that at the beginning of his research during the COVID-19 pandemic, institutional concerns about public health messaging led to data being restricted. He says, "No one wanted to be considered the system that was doing a bad job managing the pandemic or their patients." Does your institution ever limit access to data due to public health messaging or image concerns? How do you get access to the data you need?
2. When many researchers are interested in working with the same population, how do you collaborate with other researchers to get access to the patients or data you need and to prevent overlapping research ideas?
3. Altschul writes, "I believe that, during the worst months of the pandemic, it was likely very hard for the IRB to ensure compliance for researchers actually conducting research." In times of public health emergencies, do you think the IRB should do a better job of ensuring research compliance? How might compliance oversight be improved?

COVID-19 Clinical Trials: A Voice From the Front Lines

Eric Lenze

1. Do you agree or disagree with Lenze that "regulation and apathy" contribute to recruitment challenges? How might regulations be changed to better support recruitment efforts?
2. Lenze discusses the challenges of including pregnant women in research during the COVID-19 pandemic. What sorts of assumptions do you make about excluding "vulnerable" populations when conducting research, and how do you ensure that these vulnerable populations are included, when possible?
3. Do you agree or disagree that there needs to be "more cooperation in the US to support and advocate clinical trials?" Why or why not? How might this cooperation be accomplished?

We'll Deal With That Later

Lauren T. Southerland, Jennifer A. Frey & Russell Williams

1. Southerland and colleagues bemoan the various single-use supplies that had to be used and thrown away during the COVID-19 pandemic for safety reasons. What measures have you put in place, if any, to minimize the environmental impact of your research?

2. At one point, Southerland and colleagues used plastic eyeglasses from a child's Nerf gun birthday party as personal protective equipment. Have you ever had to use makeshift supplies or supplies intended for other purposes in your research? If so, what was it and how did it work?

3. How do you manage staff shortages and burnout, even in non-pandemic times?

Practice-Based Primary Care Clinical Research During the COVID Pandemic

Barbara P. Yawn

1. Yawn discusses some particular challenges of conducting research in primary care settings. What specific features of your research site (multi-site, rural, primary care, etc.) posed challenges (or may pose challenges in the future) to initiating or continuing research during a global pandemic or public health crisis? How might you mitigate these challenges?

2. The COVID-19 pandemic forced researchers and IRBs to rethink many of their traditional protocols, including the informed consent process. Yawn notes that several IRBs expressed concerns with the e-consent process in particular, so her research team provided "IRB talking points, e-consent examples/templates, and embedded questions within the e-consents assessing potential participants' understanding of the e-consent" in order to garner support. If you utilize e-consent processes, do you face similar pushback from IRBs? Do you think e-consent is (or should be) a valid form of consent? Why or why not?

3. The COVID-19 pandemic brought about significant funding challenges for many facets of research. What funding challenges have you faced? How do you adapt your research based on the changing funding landscape?

What's a Hospital to Do? Equipoise, Pandemics and Single-Site Clinical Trials

Todd Seto

1. The ethical basis for enrolling patients in different treatment arms of a clinical trial is clinical equipoise, when there is professional disagreement among the community of expert practitioners as to the preferred treatment. However, some clinicians use individual equipoise as their standard for enrollment—when an individual health care provider is uncertain as to the preferred treatment. How might these different understandings of equipoise contribute to enrollment issues? How do you seek to resolve the tension between different enrollment standards among clinicians?

2. Seto laments the difficulty of joining a large multi-center clinical trial. What difficulties have you experienced, or can imagine, when trying to join multi-center trials? How might regulations be amended to facilitate this collaboration?

3. Seto wondered, "Does the world need another single-site, underpowered clinical trial? Is the importance of a clinical trial only in the data that are generated? We mulled over these questions and agreed that there is more." Do you agree or disagree that there

could be more benefits to a trial than only the data that is generated? What might some of these benefits be?

Teaming up with the IRB: The Power of Collaboration

Rebecca Erwin Wells

1. The COVID-19 pandemic forced many researchers to shift their research activities from in-person to virtual, and Wells wondered about the best way to obtain informed consent virtually. What best practices have you implemented for collecting e-consent? How could these practices be improved?
2. Wells reached out to an Italian colleague to offer support at the start of the pandemic, and this relationship sparked a research idea. Describe the importance of collaboration in your own research: how do continued networking and casual relationshiops lead to new ideas and research agendas? In an age of Zoom and virtual connection, international collaboration is now easier than ever. What are some of the negative consequences (if any) of virtual collaboration?
3. Talk about a time when you worked well with your IRB to facilitate your research. What was good about that experience? Discuss a time when the IRB hindered your research? How could that experience have been improved?

Reflections on Conducting Research From Home During COVID-19

Laleh E. Coté

1. When did you first hear about COVID-19? What did you hear? As a researcher, what was your initial reaction to this "novel coronavirus?"
2. Coté writes, "How could I claim to understand my study population without incorporating the larger context in which their experiences sit?" Even in non-pandemic times, how do you seek to understand the broader life context of your research participants? How does this consideration strengthen your research?
3. Coté talks about the "emotional burden" of conducting research during a global pandemic, especially when data analysis is disheartening. How do you manage the emotional burden of your work when your findings are disheartening?

Assessing Risk When Everyone's Afraid: The Challenge of Seeing Health Care Workers as People When Our Need for Them Is So Great

Rebecca C. Hendrickson

1. Hendrickson argues that IRBs and researchers utilize a different (and sometimes competing) framework for risk assessment: for IRBS, the risks associated with action are the focus, but for researchers, the risks of inaction weigh more heavily. Do you experience this tension with your IRB? How do you ensure regulatory compliance while also pushing to implement a potentially helpful intervention?

2. Hendrickson writes, "the ability to step back and see our most immediate concerns as part of a larger set of risks and benefits, and to discuss our perspectives effectively with those who had a different view, became more and more challenging the more intense the anxiety about the impact of the pandemic became for all of us." How do you discuss your perspectives or opinions (on your research, politics, etc.) with those who disagree with you? Are these conversations fruitful or futile?
3. Hendrickson wonders "if we are misled by our belief—perhaps hope—that we are somehow shielded from the influence of human emotions in our professional lives." When have you experienced this conflict between personal emotions and professional work? How has your research work forced you to confront your own emotions, your own humanity, and your own limits?

Reflections on Conducting Pediatric Mental Health Research as a Result of the COVID-19 Pandemic

Patrick W. Romani

1. Talk about a time when you were forced to shift gears on your research trajectory or change your usual research methodology. How did you leverage changing circumstances to your advantage?
2. Do you feel as though you have a strong relationship with your IRB? How might you strengthen this relationship?
3. Romani reflects on the challenges of being a parent, an educator, and a researcher at the same time. How do you balance the myriad different roles you play in your professional and personal lives?

Remote Research Hinders Recruitment of a Diverse Sample

Beth Prusaczyk

1. What are some of the logistical challenges of recruiting a diverse participant sample? How do you ensure that under-represented populations can be included?
2. Prusaczyk notes, "Fully virtual/remote research, whether done out of convenience or necessity, brings with it a significant cost to recruiting and enrolling diverse populations who are often excluded from research to begin with." As more research becomes virtual or remote, how might you mitigate some of the barriers to research participation for low-income or vulnerable populations?
3. Prusaczyk discusses the challenges of advertising one's study on social media, especially when "bots" access an online survey. Have you been able to use social media to successfully recruit participants? If so, how do you prevent fake or unwanted users from participating?

Caring for Others, But What About Us?

Francisco José Barbosa Camacho

1. Camacho states, "When one is excited to start a new project, one can lose track of basic protective measures." Based on lessons learned from the COVID-19 pandemic, how will you prioritize the safety and well-being of your team in addition to the safety and well-being of your participants in future projects?
2. Camacho highlights the importance of communication in order to avoid information loss or misunderstandings. How do you ensure effective communication during all facets of your research, from recruitment to data collection to analysis?
3. Camacho comments that during the pandemic, a remarkable number of new articles were published on COVID-19-related research. With the increase in submissions and faculty confronting new challenges of working during a pandemic, journals scrambled to find peer reviewers. Many researchers experienced significant delays in receiving reviewer comments. How do you manage the ethical imperative to participate in the peer-review process when you have a heavy workload? How does your experience as a reviewer shed light on the journal publication process as a whole?

Development of a COVID-19 Patient Registry in Central Illinois

Carl Asche, Mohammad Almoujahed, Sharjeel Ahmad, Anthony Dwyer, & Sarah Stewart de Ramirez

1. In their research, Asche and colleagues collaborated with several different organizations including the county department of health, a local university, and three healthcare systems. What are some of the challenges of coordinating research with different organizations, and how do you overcome these challenges? What are the benefits of this type of collaboration?
2. Asche and colleagues specifically wanted to study rural populations. Why is it important to study this population, and what are some of the challenges of conducing research with rural populations?
3. Asche and colleagues aimed to develop an up-to-date electronic registry of COVID-19 cases in order to identify risk factors more quickly and investigate health outcomes. What other populations or clinical or social problems might benefit from this type of registry?

Adaptive and Pragmatic Approach to Clinical Research: The Silver Lining of a Global Pandemic

Emanuele Chisari & Javad Parvizi

1. When unprecedented events cause a delay in research, how might you strive to mitigate future negative health implications?
2. Chisari and Parvizi claim that the "common approach to clinical research should and can be improved." Do you agree or disagree? Why?

3. Chisari and Parvizi discuss the importance of platform and adaptive trial designs in order to "jumpstart the future of disruptive clinical research." In your opinion, why are funding agencies and regulatory pathways hesitant to implement these types of trials? What are the risks of moving from "traditional" trial design to these new models, and what are the benefits?

Another Good Idea Dies in the Nest

Michael Korenfeld

1. Korenfeld discusses his new device and the challenges of getting FDA approval to get the device into practice. In what ways might these regulatory guidelines be important patient safeguards, and in what ways are they detrimental to improved patient care?
2. How might the medical device approval system be revised in order to ensure that safe and effective tools can be made available quickly in times of emergent need?
3. Korenfeld is critical of the medical device approval system in the US. Do you share his negative appraisal? Why or why not?