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

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A week later, I send the email to our office telling everyone to go home for the duration, now going on a year. And another week later, campus leadership announces that face-to-face interactions with human subjects that are not directly therapeutic must stop. All research procedures that can be done remotely must be done so. And our ordinary sense of time at last slips away.

Presto

The blurring of time accelerates in April and May. We are drafting and posting guidance for our researchers as quickly as we can—often every day, sometimes twice a day. As forewarned, our office is fielding an almost overwhelming number of questions from study teams. With leadership on the clinical trials side, we coordinate on reviewing the influx of Covid studies that need approval yesterday. Staff are indeed stressed and to help us try to keep pace and informed, I send out daily COVID updates—today's new FAQs, news from the FDA, COVID studies in the pipeline. And I always include a signoff to be well, whatever that means.

Despite our best efforts to stay on top of everything, we are scrambling, particularly with issues we have never faced before. Do we have an FDA-compliant system for documenting informed consent? We do not, so we work on getting that moving. Do study teams need to submit changes to their protocols to reflect pandemic-related modifications? Sometimes yes and sometimes no. What online platforms for study visits are HIPAA-compliant? Two, and not the ones that study teams want to use most. We press campus on that, too. Do we need to report halts in enrollment? Please, please, do not. And many other questions, the answers for which we are both making up on the fly and relying on our colleagues across the country to help nail down. And—bless them—the FDA issues guidance we can shelter under. And messaging from regulators to IRBs is, basically, do the best you can.

We briefly catch our breath before discussion of resuming face-to-face research for non-therapeutic studies begins. And with it, another flurry of questions, consultations with other IRBs, and posting of

guidance starts all over. What about PPE for participants and study teams alike? What about infection control measures? How does the IRB review and approve plans we are not well suited to evaluate? How much hustle do we have left to manage this? Mercifully, and for the first time in the pandemic, we do not have to add more to our plate, and other entities on campus take the lead. And we can slow down, although at the same time, we are still moving quickly. Time folds and twists on itself.

Coda

Our list of Covid FAQs is now stable. Most higher volume research groups are in sync with our guidance. I stop sending out daily updates to staff by late June. We are in the groove of remote work and IRB meetings. We continue to provide highly responsive service to our researchers. We are grateful for the support of our colleagues, both internal and external. We are thankful to our research community for the work they continue to do and their willingness to partner with us as we sifted through more questions than we can count.

Time is not back to normal, though. If anything, we are in suspended animation, waiting. How and when will vaccines impact our research community and IRB operations? When will we go back to the office and what will that even look like? Will the predicted bleak midwinter come to pass? With new variants of the virus circulating even now, will we ramp down again?

As at the start, we have no idea how this will go.

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

Kebenei Enock Kipchirchir

The first case of COVID-19 was confirmed in Kenya in March 2020. The announcement made by the Ministry of Health created panic

in the country and many changes in the normal way of living. The Government of Kenya issued a number of directives to curb the spread of the disease. The containment measures affected all sectors of the economy, including health. The Kenya Medical Research Institute was at the epicenter in responding to the pandemic through testing, surveillance and systematic investigation into the novel virus. Scientists at KEMRI responded to the various calls for research proposals on COVID-19.

The KEMRI's Scientific and Ethics Review Unit (SERU) is a unit that houses the Research Ethics Committee (REC). All research proposals must be reviewed and approved by the ethics committee before study implementation. Prior to the announcement of the first case of COVID-19 in Kenya, KEMRI SERU operations were purely paper-based. We had to shift to the online submission system and virtual REC meetings to curb the spread of the killer disease. We had to respond to the increased number of proposals for review and keep the disease at bay. To date, the KEMRI SERU has reviewed and approved more than 50 new proposals related to COVID-19.

The new normal of providing research oversight with strict adherence to the various guidelines of curbing the spread of COVID-19 came with a fair share of challenges. The problems in reviewing and overseeing COVID-19 research ranged from administrative to logistical issues. Members of staff at the research regulation arm had to stay and work from home. We experienced challenges such as intermittent internet access and lack of equipment like computers, scanners, printers, and photocopiers at home. All research proposals on COVID-19 were reviewed on a quick turnaround basis. The challenge to this is to supervise staff who are working from home and ensure that they respond to urgent requests. All requests for ethical reviews were received through e-mail. There was a challenge in putting all documents in a centralized location because staff could access the email at home. Documents management requires a centralized system that can be accessed remotely. An upsurge in the number of expedited review requests strained the limited resources in the unit.

Our work involved issues of autonomy and respect for persons who test positive for COVID-19 and researchers want to use their samples for different research purposes. 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. Researchers must ensure that they seek informed consent from COVID-19 patients to use their collected samples for research purposes. The Research Ethics Committee has also found it difficult to conduct site monitoring visits due to travel restrictions. We have to rely on self-reported protocol deviations, violations, safety, and other notifications received from principal investigators to conduct passive monitoring of the study.

The KEMRI SERU made necessary adjustments to accommodate urgent review of COVID-19 research proposals during this period of the pandemic. One of the special accommodations made is the expedited review of all COVID-19 research—the unit endeavors to respond to the investigators within ten days. We have not increased the number of staff but considered motivating them further. The institute issued Telkom cards with sufficient internet bundles to allow the staff to access the Internet from home. The reviewers were also given a token of appreciation during this period. Expanded access requests are being reviewed jointly between REC and the national regulators. Initially, studies were reviewed by the REC and the national regulator sequentially. However, during this period, some studies have been reviewed jointly/concurrently by the national regulator and the IRB to reduce the turnaround time.

The review of an increased number of COVID-19 research proposals has taught us many lessons that we can share with other IRBs. It would be helpful to have separate reviewers for expedited reviews and motivate them during the pandemic. Such members will be on call anytime you have an urgent request to review studies responding to the pandemic. To the researchers, the welfare and safety of participants who test positive for COVID-19 remain paramount. It is advisable to observe containment

measures and seek appropriate consent from such participants or their family members.

Our experience of reviewing and overseeing COVID-19 research tells us that it is sometimes tedious to review protocols that are developed in a hurry. It is important to have peer reviews of COVID-19 research protocols before submission to the REC for ethical clearance. It was noted that many researchers did not comply with standard operating procedures due to the urgency to submit and start research work. It was noted that checklists were not being followed to the letter.