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T. Howard Stone

Introduction

Declaration of the COVID-19 national emergency has had and continues to have a profound effect upon what human research studies are permitted, how permitted studies are conducted, review of these studies, and the guidance that is provided to the research community at the university where I am an IRB member and administrator. From the almost instantaneous cessation in all human research activities to more recent discussions about phasing in permitted human research, human subject safety and well-being has been the touchstone. Ensuring that every corner of the University's research enterprise is provided current, relevant, accurate and useful information and resources about COVID-19 and human research, is a priority but resource intensive in the review and oversight of human research. Until the COVID-19 emergency is lifted however, COVID-19-related limitations on human research will remain in effect.

Cessation of Human Research

Prior to and very soon after the March 13, 2020 issuance of the Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, University leadership issued a series of announcements about imposing a wide range of scaled-up steps to prevent the spread of COVID-19, including new disinfection procedures, quarantine and isolation requirements, remote teaching, cancellation of events and activities, and remote work. These steps were often tailored to the context and environment in which human activities and interaction took place, including, for example, local, national, or international locations; office, classroom, laboratory, off-campus or clinics; teaching, service or research settings; and student, staff, faculty and visitor populations. Considering the precautions that were imposed, the Vice President for Research, Office of Research, and I discussed the implications of the national

emergency and University actions upon research involving human subjects. The discussion centered on plans for the University's research leadership to announce a halt to all on-going and planned human research with reference to some possible, limited exceptions to be later explained. The halt impacted OHSP and IRB's operations and reviews, staff and member safety, initial and on-going messaging, and other avenues of communications that the OHSP and IRB provide to the research community. Thereafter, on March 23, research leadership announced as a policy matter, the cessation of research activities that involve in-person interactions or interventions with human research participants ("cessation"). The announcement provided general information about the cessation, specific exceptions, links to additional information and contacts for further questions or concerns. The objective of the cessation was to immediately stop any in-person face-to-face human research activities except for COVID-19 research that involved substantial likelihood of direct and meaningful biomedical or behavioral health-related benefit or outcome. Certain clinical trial activities taking place in licensed health care facilities or offices within the context of a necessary clinical care visit for which activities could not be performed remotely were also allowed to continue. Particulars of the cessation were subsequently provided to the state university system's Board of Governors for their own deliberation of COVID-19-related precautions.

Early Actions

To help ensure the broadest possible dissemination to the University community of the cessation policy, the announcement of the policy was published on the main public-facing web pages of the University, Office of Research and Office for Human Subjects Protection (OHSP)/IRB. The University and Office of Research pages included links to the OHSP/IRB home page. Additional information and links to a special COVID-19 and Human Research Studies page were provided. Prominently arranged on this special page is first stated the underlying policy for the cessation and their links. The list of research activity exceptions and their criteria

(e.g., no persons deemed at higher risk for severe illness from COVID-19, including persons aged 65 or more years may be included at subjects in any in-person research activity) followed. Requirements for excepted studies (e.g., remote activities where possible; COVID-19 screening; maximizing social distancing; use of protective equipment such as masks) were next. Then, specific instructions for halting non-excepted study activities, such as notices to enrolled study subjects and minimizing risks to subjects for whom halting study activities may be harmful; submitting for IRB review modifications of study activities to remote or virtual interactions; and links to new standard operating procedures, templates (including for COVID-19 screening and consent), and other OHSP resources (e.g., worksheets, a COVID-19 human research decision algorithm, FAQs and other COVID-19-related guidance). IRB members were informed of the requirements and the information and resources provided to the research community.

Additionally, a March 31 COVID Town Hall hosted by OHSP/IRB for the University's human research community was widely publicized, held via Zoom, with an audio recording and the slide deck of the Town Hall also published on the OHSP/IRB COVID-19 and Human Research Studies web page. To sustain dissemination and discussion of COVID-19-related information relevant to research generally, through Mid-September the Office of the Vice President for Research hosted widely publicized virtual weekly meetings for the University community. At these Zoom-based meetings, current and developing information about federal, state, and campus initiatives, funding and policies were shared. Researchers could pose comments and questions and participate in Zoom chat functions. Links to resources and points-of-contact to obtain additional information were provided. As OHSP Director, I participated in each of these COVID Town Hall meetings to provide human research-related information, be available for human research-related questions and concerns, and to take back suggestions, requests or ideas about how the OHSP/IRB might improve upon our COVID-19-related human research resources. A frequent and common outcome of these Town

Hall meetings were the expressions of research community participants' appreciation about these meetings and their value.

Accompanying these early actions was of course ensuring continuity of human subjects review operations, certainly as a matter of regulatory compliance and as a measure of allowing important human research to safely continue. In the summer of 2019, all human research protocols were submitted and reviewed using an off-the-shelf electronic protocol management system (EPMS), allowing for paperless handling, documentation, record-keeping, and archiving of human research studies. The EPMS, as well as the routine use of other electronic and telephonic communications with the human research community, meant that very few researchers visited the OHSP/IRB physical offices, which incidentally were located nearby but off the main University campus. The availability of a wide range of information, instructions, and other human research review resources also allowed people to find what they needed without having to visit the physical office. When remote work was imposed for the OHSP/IRB, any disruption to workflow or communications with the University human research community was minimal. Desk telephones were forwarded. Email signature blocks included emphasis on electronic communications and use of EPMS for any study-related concerns or questions. Physical visits to OHSP/IRB became internet- or telephone-based. IRB meetings, discussion, and voting, were hosted on Zoom and agenda items and related review documentation and decisions were posted to the EPMS. Notices about remote review and operations were posted on the OHSP/IRB web page and outside of the physical office doors. OHSP/IRB members and staff, as well as the human research community, expressed satisfaction with remote staffing and review of studies.

Review Processes

Considering the urgency of mitigating COVID-related risks to human subjects, the OHSP/IRB prioritized its review of human research. This prioritizing was conveyed to the University research community through the Town Halls and web pages,

related online materials, IRB meeting announcements and emails, OHSP staff meetings, and as needed through ad hoc communications with individual researchers. The imperative of protecting human subjects' health and welfare compel that review precedence be given to any report of COVID-19-related issues or unanticipated problems. This includes subjects or study staff that test COVID-19 positive or have been exposed to persons with COVID-19. These reports are handled in an expedited or convened review pathway depending upon the circumstances and need for changes to study procedures. The OHSP/IRB FAQs were developed specifically to ensure that study teams, OHSP staff, and the IRB know how to respond to such issues or problems. Non-COVID-19 incidents that implicated human subjects' health and welfare received similar precedence.

Next in review priority are modifications to currently approved or exempt research when these modifications involve transitioning in-person to remote or virtual activities. Using early available OHSP/IRB instructions and templates, these modifications are readily processed with few hiccups. After these modifications, precedence is given to submissions for COVID-19 research, either as new studies or modifications to currently approved or exempt research. The potential to explore or advance COVID-19 knowledge was considered inherently important given the paucity of such knowledge, enough to be prioritized above other non-COVID research. There have been many more modifications to transition to remote or virtual activities than new COVID-19 research activities. Finally, once any prioritized research is processed and scheduled for review, other studies or activities not included above are placed in the review queue. That could include modifications to currently approved or exempt studies and new studies, including other studies that are excepted from COVID-19 requirements (e.g., certain clinical trials only taking place in licensed health facilities or studies with a substantial likelihood of direct and meaningful biomedical or behavioral health-related benefit or outcome).

Some new procedures have been added to the human research review process. First, all study

submissions undergo an augmented pre-IRB review to determine that COVID-19-related requirements are satisfied (e.g., remote or virtual in lieu of in-person activities, involvement of persons not considered at higher risk for severe illness from COVID-19, and COVID-19 precautions for excepted in-person research activities, including social distancing, use of protective equipment and sanitizing.) Use of OHSP/IRB provided instructions and templates (including a COVID-19 information sheet to provide to study subjects) help to ensure that study staff are aware of and implement these requirements. If not, these instructions and templates provide the OHSP/IRB with ready references to which study staff are pointed. OHSP staff communicate their pre-IRB review findings to IRB members assigned as primary or expedited reviewers. IRB members provide another layer of ethical and regulatory review that will also consider COVID-19-related precautions and considerations.

Second, an ancillary review process involving Office of Research leadership was put into place for research activities that would otherwise receive IRB approval in accordance with federal regulatory criteria but for which social distancing is not always feasible. Before study teams are notified of IRB approval of their studies, ancillary review provides University leadership with a formal means to consider whether to allow studies for which social distancing for one or more study activities is not practicable. Such studies have included blood draws, affixing wearable devices or equipment, and EEG or other procedures where a researcher must have some physical contact with a study subject. The ancillary review process was easily incorporated into the EPMS and involves an additional review step after IRB approval. OHSP/IRB staff submit an ancillary review request that is electronically routed to research leadership (which also sends an email communication to the ancillary reviewer outside of the EPMS indicating a need for ancillary review and providing a link to the EPMS to obtain study details). The EPMS request highlights those specific study activities for which the University's social distancing requirement is not feasible but for which activities the study team has documented justification or rationale. Research

leadership documents their review decision within EPMS, which becomes part of the IRB record as an institutional review under section 46.112 of the applicable federal regulations. OHSP then conveys the ancillary review decision as part of the IRB review outcome for the study that is communicated to the study team.

Conclusion

Development and implementation of COVID-19-related requirements for human research studies occurred in tandem with the University's early cessation of in-person research activities and required that the OHSP/IRB pivot away from other priorities at the time, including staff development, recruitment of new IRB members, and updates to existing policies and templates. With University leadership and the Board of Governors' policy and support, there were no barriers in enforcing COVID-19-related requirements for human research. Early and constant communication and messaging, dissemination and ready availability of instructions, guidance and templates, use of remote technology and an EPMS, and a careful process for conducting COVID-19-related reviews, has clearly facilitated the handling of human research review in the difficult and challenging COVID-19 environment that early on besieged the University. In some respects, the altered review process has become routinized, which for better or worse, may be the new normal for a while longer.

Warping of Time

Carol A. Pech

Nearly a year into the pandemic, we are too familiar with the twisting and blurring of time it has brought us. I find it hard to remember how our sense of time worked before COVID crashed over us. If you happen to be a musician (guilty), you know how to read through

new-to-you complex pieces of music to see how it goes—slow here, fast there, tricky in places. Although I had the same instinct in the run-up to the pandemic, we had no such luxury. We played as we went, and this is part of that story.

Prelude

I would not characterize myself as a prepper, but so I become by early February. I advocate for getting ready, and my colleagues ask whether I think we truly need to start preparations now. The virus isn't in our community yet—or so we think. My response is that I believe so, since if the virus comes—and we do not know that it is already in our midst—my sense is events will unfold quickly. This is the best guess I will make about time all year.

Shortly afterward, leaders further up the chain of command ask for our continuation of operation plans (COOPs). I work in the institutional review board (IRB) office at a large research university with an equally large human participant research program. IRBs of our size always need to be in continuous operation, so the COOP exercise seems like administrative busywork, although at least it gives us the sense that we are actually preparing. For exactly what, though, we have only a vague idea.

This changes in mid-March when, while searching for Covid resources on other IRB websites, I find a west coast research university with a list of FAQs for researchers. As we start liberally borrowing from them, we meet with their IRB director for advice. What we hear: figure out how to implement the new public health exception in the federal regulations, which we have not yet used. Prepare for an influx of emergency, one-time use requests for remdesivir, presuming we can get any. Working remotely and handling a flood of information will stress staff, with no easy fix. Figure out how you will obtain informed consent from patients in isolation—we have never had to think this through. Researchers will have a ton of questions. Get ready. And good luck.

Around the same time, our biggest viral research lab reaches out about collecting samples from COVID-positive patients since we already have community spread. This is sobering news.