

Report on Research Compliance Volume 17, Number 6. May 21, 2020 Institutions Adopt Phased Approaches, Engage PIs in Fraught Task of Safely Resuming Research

By Theresa Defino

Just as principal investigators are anxiously waiting to re-enter their labs, eager—but cautious—compliance officials and leaders of institutions are laying the groundwork to ensure studies resume under circumstances that present as low a risk as possible that PIs, staff, students and research subjects will be exposed to COVID-19.

But officials acknowledge that the risk won't be "zero," a fact they say is important to communicate and which underlies a recommended phased approach to resumption of research.

With the exception of COVID-19-related studies and clinical trials deemed therapeutic, most bench as well as bedside research on campuses have been dramatically altered over the last several months, with some shut down entirely or operating in a version that is proceeding through remote and electronic means when possible.^[1] Courses are being taught online, and personnel, including research administrators, are teleworking.

Now that some states are lifting stay-at-home orders, colleges, universities, medical schools, hospitals and others are grappling with how to restart the research enterprise. It's a tall order—and they are taking care to include stakeholders in their plans. At Providence College in Rhode Island, for example, some 100 individuals and 12 subcommittees are devising a plan that best accommodates its students and undergraduate research programs.

"The key word is 'responsibility,' in terms of what we are going to allow and when," said Kris Monahan, Providence College's director of sponsored projects and research compliance.

Harvard University is coordinating its reopening efforts "not only with the schools for research [but] with our affiliated hospitals as well," and there is also "significant coordination" on a daily basis with those planning the return of administrative staff as well as undergraduates, said Chief Research Compliance Officer Ara Tahmassian, noting "research is not done in a vacuum."

At the University of New Hampshire and elsewhere, there won't be a one-size-fits-all strategy, as plans are being drawn up for individual labs with specific attention to health and safety of undergraduates, as appropriate for UNH. As Louise Griffin, senior director of research and sponsored programs, put it, "they are students first and researchers second."

Monahan, Tahmassian and Griffin shared their reopening plans during a recent webinar sponsored by the New England region of the National Council of University Research Administrators. They were joined by Andrew Chase, vice president of research management and research finance for Partners HealthCare.

Before delving into individual institutions' plans, Tahmassian gave an overview of "the most common planning principles that we are seeing," which he said are also in place at Harvard:

- Timing implementation to lifting of stay-at-home orders on the state level.
 - Ensuring availability of personal protective equipment (PPE).
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- Preparing buildings for return and controlling access to buildings.
- Developing low-density work plans.
- Allowing those who can work remotely to continue to do so.
- Testing employees and providing notification of symptoms.
- Instituting “contingency plans for rapid lab closure if team member(s) test positive.”

Harvard: Lab Research Might be ‘Easiest’

Tahmassian said institutions should be realistic and honest, and acknowledge the “inevitability” of COVID-19 infections despite all efforts.

Asked for a “date when research would reopen,” Tahmassian said Harvard has “aspirational dates,” or “roughly two to three weeks after the governor declares the state is reopening.”

From Tahmassian’s perspective, “lab research can be the easiest to start in part because labs...tend to be relatively self-contained. You do have a PI, you have students, graduate students, post-docs and staff researchers. So that’s a fairly well-defined population. It’s relatively easy to continue to manage,” perhaps also using shifts. “I think that more challenging [will be] behavioral sciences, psychology” and other studies that have “human subjects who are coming in from a variety of different locations,” he said.

The size of the research team will also factor into how members can operate safely. Tahmassian said the average research team is “six to 10 people,” with the range being from two people to 100 in a team. The smaller the team, the easier to maintain safe spacing and work shifts, Tahmassian noted, but figuring this out will still pose a challenge. “I think inevitably there’s going to be a gap, in most institutions, between the time the research starts and the time that the undergraduates come in,” he added.

Harvard’s institutional review board is working with a group of researchers, Tahmassian said, to “walk through the life cycle of the research” to determine how subjects will be handled, from asking screening questions to providing PPE to “what to do...once the subject leaves.”

“It’s a little different from when they were just walking in [and] sitting in a waiting room. Now they have to be scheduled,” Tahmassian said. “My guidance to you is...walk through your processes one by one” and use a committee approach. He added that this group has been expanded to “include people from some of the affiliated hospitals and some of the other institutions in the Boston area to make sure that there is some consistency amongst what they are doing.”

Tahmassian said Massachusetts General Hospital has “converted the lab-safety people to COVID-safety people, which we think is a brilliant idea. And we are doing a similar thing where these individuals are going to receive a little bit of additional training and guidance. They will act as the local...advisors to the returning researchers and also to keep an eye [on] and monitor adherence to PPE, social distancing and communicate” when they see issues or procedures that need to be modified.

UNH: ‘Research Resumption Team’

On May 8, James W. Dean Jr., UNH president, announced that in-person and on-campus instruction would begin for the fall semester. The announcement, however, noted that students will have “options and flexibility,” as courses “will be offered in a blended format to ensure access for everyone. Students can choose to stay home, be on campus and go to class, or be on campus but only attend some classes in person.” Griffin said “lots of teams

on campus” are working on implementation of undergraduate research. “I don’t expect that we will return to normal in the fall, but I expect we will be closer to normal than we certainly are today,” she said.

Noting that “research is woven into the curriculum for our undergraduates” at UNH, Griffin said there is a “desire to have them return to campus” quickly. Griffin added that research administrators also “have an obligation to manage faculty expectations. In some ways, we’re gatekeepers to protect not only our students, but our faculty, our staff and everyone else.”

A campus-wide “research resumption team” is developing UNH’s plans, with a restart also proposed as a phased approach, Griffin said, based on a model developed by the University of California, Berkeley. At the time of the webinar, UNH “critical research” was permitted, which included time-sensitive studies that “would result in loss of data or loss of animal life [and] anything that would have a significant financial impact,” Griffin said.

Griffin noted that UNH, as a land-grant university, offers seasonal research involving mostly undergraduates that would normally begin now; this is being factored into plans. “Faculty are really concerned about how do we get [and] keep our undergraduate students engaged, and if we are going to let them be engaged, how do you do it safely and appropriately? That’s what we’ve been working on,” she said, adding that it has been important to include a lot of “constituents” in the planning process.

At UNH, there is “not going to be an institutional policy...they’re not all coming back in September. There’s going to be a blended learning environment,” Griffin said, adding, “we’re trying to think about contingencies.”

UNH is also developing an employee health attestation, as it is required by the governor, which will be accompanied by a “tracing component,” she said.

Providence College: ‘Responsible Restart’

For Providence College, the issue is similar, said Monahan. Undergraduates are “all we have...we have no graduate programs in the sciences. Our faculty can’t do their scholarship without the undergrads.” She echoed Griffin’s remarks that “student health and safety is at the forefront,” but also noted that “we can’t wait until there’s absolutely no risk, because we don’t know when that will be.”

Providence College hopes to accommodate students who were “depending on summer research,” Monahan said. Plans are being developed by a group but are subject to change, she added. As of May 9, Rhode Island’s governor had moved the state into phase one of a reopening plan.

As of the time of the webinar, Providence College had set a date of June 29 for the resumption of “a limited amount of undergraduate research,” a date Monahan said is linked to the possible start of phase two or three in Rhode Island. The date also coincides with the start of a summer session.

Monahan agreed that labs “already have a good handle on how to manage their labs, how to interact so they can develop individual plans that come together with institutional guidance.” Providence College intends to test out plans before implementing something campus-wide, she added.

Providence College, Monahan said, “was actually in a better place than maybe some smaller institutions” when the pandemic occurred because it already had an institutional business continuity plan as well as plans for departments. But “what wasn’t there was coordination of those business continuity plans across the respective areas,” she said.

To address this, Providence College established a “100-plus-person” group serving on 12 subcommittees that reports to a COVID-19 academic continuity committee, as well as a “separate committee at the cabinet level

related to some of the financial issues.” Additionally, a “responsible restart” working group is addressing summer-related issues, Monahan said, adding that Providence College’s general counsel is “very much front and center” on several of these committees, and is weighing in on the resumption of research.

Partners: Twice-a-Day Attestation

Chase noted that Partners has had “a lot of research activity actually that didn’t stop,” such as therapeutic trials in oncology, and there has been an increase related to COVID-19-focused research as well. As a result, in Partners’ research community, “we have a lot of people who are ready to open up immediately and pointing to [the] other groups that have already been actively engaged in research for the last two months.”

Chase noted that “we have included different research groups within the overall reopening structure to ensure that there is continuity and coordination between research and the other clinical activities.”

How research is treated is “dependent on the overall approach for clinical care,” Andrew said. “Anyone who is entering the hospital is administered a face mask, period. And then additionally, if you’re an employee, you have to fill out essentially a survey before you arrive at the hospital.” Twice during the workday “you attest to your symptoms and that you’re...asymptomatic, you don’t have a fever or cough” or other health concerns.

Partners has a three-phased approach, said Chase, with phase one being “what’s your plan.”

Each PI “is going to come up with a plan based on their individual circumstances and lab,” with options potentially “being able to continue remote [operations] in a full-time capacity,” said Chase. After an approved plan, the PI would go to the lab and “actually start preparing,” which could include placing orders for equipment and supplies and creating schedules for employees, college graduates and student interns. He noted that the “routine research hiring” cycles have been disrupted, and no longer are PIs thinking about “bringing [these individuals] into the labs for summer.”

PIs, Chase said, are feeling a “lot of anxiety” and are wondering, “How am I going to be able to deliver in the new environment if I don’t actually have access to all these different resources that I used to have?” Phase three would occur “at some point in the future—whether that’s near or far,” when there is “more containment and an actual vaccine,” and then approaches could be revised, Chase said.

Looking Back, With Hindsight

At the conclusion of the webinar, the speakers were asked to comment on what activities they would have engaged in prior to the pandemic, if they knew what was to come.

Tahmassian noted that, in his career, planning for disruptions has always been based on events that are of limited duration, such as hurricanes or earthquakes, although he praised Harvard for acting quickly to shut down its operations during the pandemic.

Griffin noted the limits of UNH’s planning as well, saying it has a crisis management plan and has conducted tabletop exercises, “but we ran them on active shooter plans. We didn’t do anything around a pandemic,” she said.

“There’s two things that I’ve learned. One, you have to make sure you have a solid crisis management communication strategy,” Griffin said, adding that “in this situation, you can’t over communicate.” The anxiety individuals are feeling about their jobs and at home—where many are “taking over teaching roles”—feeds their need for information, said Griffin. Additionally, going forward, she “would make sure that we review our emergency plans on a more regular basis than we have.”

For her part, Monahan said Providence College is “a traditional institution [that] did not have remote, work-from-home policies” prior to the pandemic. Better planning and support for remote work would have been beneficial, she said, although Providence College “certainly pivoted quickly.”

Still she added that “as research administrators, we are always nimble, and we are quick to respond to things. And I think we have, as a community, in the face of uncertainty, really made a lot happen.”

1 Theresa Defino, “Restarting Studies After COVID-19 Will Require Adaptations, Scrutiny of Study Site Capacities,” *Report on Research Compliance* 17, no. 5 (May 2020), <https://bit.ly/2Th1XKO>.

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