

Getting Back to Work: Ramping Up Your Research Programs During a Pandemic

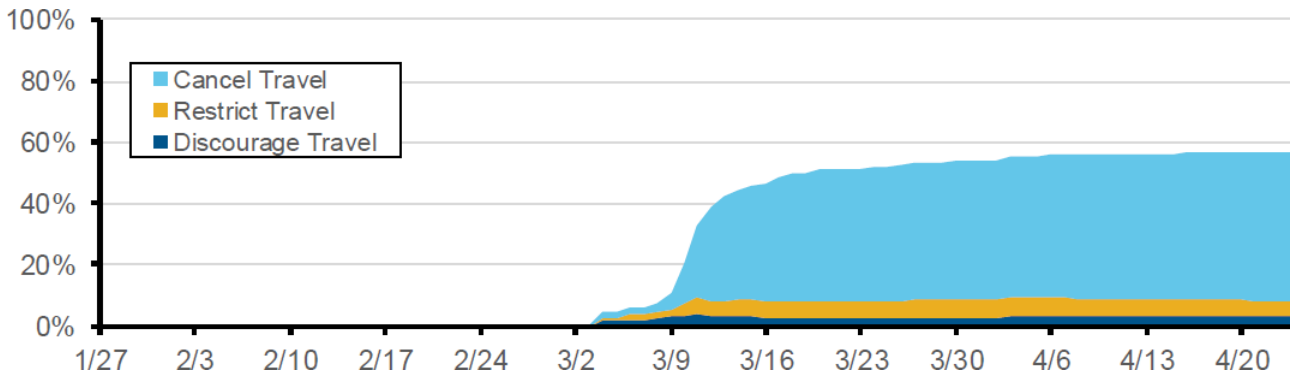
As universities and health systems across the United States slowly begin to ramp up their research activities, we thought it would be useful to share how several institutions are managing that process. Members of Huron’s research enterprise solutions team facilitated discussions with research leaders at more than 25 institutions between April 24 and May 5, 2020. While many were still developing their plans, we identified several themes and innovative ideas during these discussions. This paper provides a summary of our findings. It is not intended to be a how-to guide but rather should be considered a helpful resource as you begin ramping up research at your institution.

Background¹

On January 30, 2020, the World Health Organization declared COVID-19 a global health emergency. The pandemic’s spread has radically challenged higher education in unprecedented ways. As early as January 15, U.S. institutions began responding to the COVID-19 pandemic by:

- Establishing dedicated websites to update their communities on the pandemic.
- Announcing actions through internal emails, public memos, social media and multimedia channels.

By early March, most institutions began restricting travel for all faculty, staff and students.



And by mid-March, many institutions had suspended or greatly curtailed all “nonessential” research. While the definitions varied from institution to institution, in general, essential research was priority research, such as COVID-19 (bench or human subjects) research, as well as research that provided therapeutic benefit to participants where standard-of-care options could not. Many institutions formed multidisciplinary committees or task forces, comprised of leaders and/or their representatives

¹ Adapted from *Going Viral — Responses to the COVID-19 Pandemic in the American Higher Education Industry*, Huron Education, May 1, 2020. <https://www.huronconsultinggroup.com/-/media/Resource-Media-Content/Education/COVID-19/Going-Viral-COVID-Tracking-Initiative.pdf?la=en>.

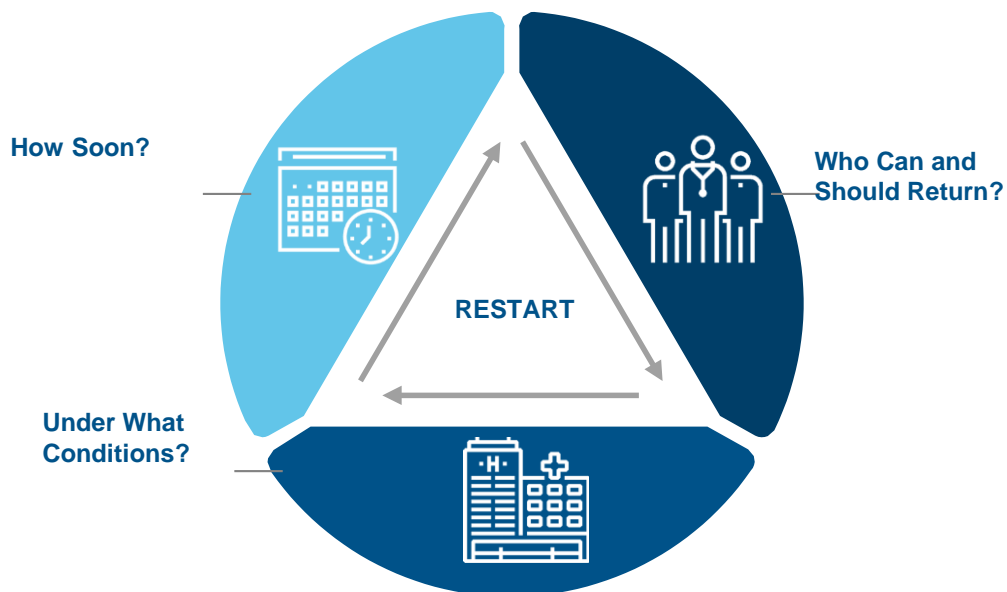
from all research and clinical areas of the enterprise, to decide which research would be placed on hold (nonessential), which research would resume, and which new research studies would be allowed to open despite the pandemic. The makeup of these committees or task forces varied by institution but essentially comprised the following stakeholder groups:

- Executive leadership
- Bench, animal and human subjects research operational leaders
- Biosafety
- Infection control
- Infectious disease
- Pulmonary
- Emergency medicine





Once the decision of essential versus nonessential research was made, these same COVID-19 committees/task forces stayed intact to develop new policies and procedures governing everything from maintaining research laboratories under modified operations to COVID-19 screening, testing and social distancing requirements. Communications increased dramatically with some institutions issuing multiple updates in a single day. Institutions further embraced technologies such as video conferencing and software that facilitates collaboration. There were calls to support one another and to do your part to help those on the front lines, including limiting the use of and even donating personal protective equipment (PPE). The words “flatten the curve” became our new normal. And all of this happened over the span of one or two weeks. The thoughtful, organized and graceful way this was handled is nothing short of remarkable.

Starting to Restart





Now that the number of new COVID-19 cases has begun to decline and more information about progression of the disease and treatment options has become available, individual states are beginning to relax stay-at-home restrictions. In anticipation of this, universities and health systems have been planning to restart their research operations. At the core, leaders focused on three key questions:







And aligned on a few key principles:

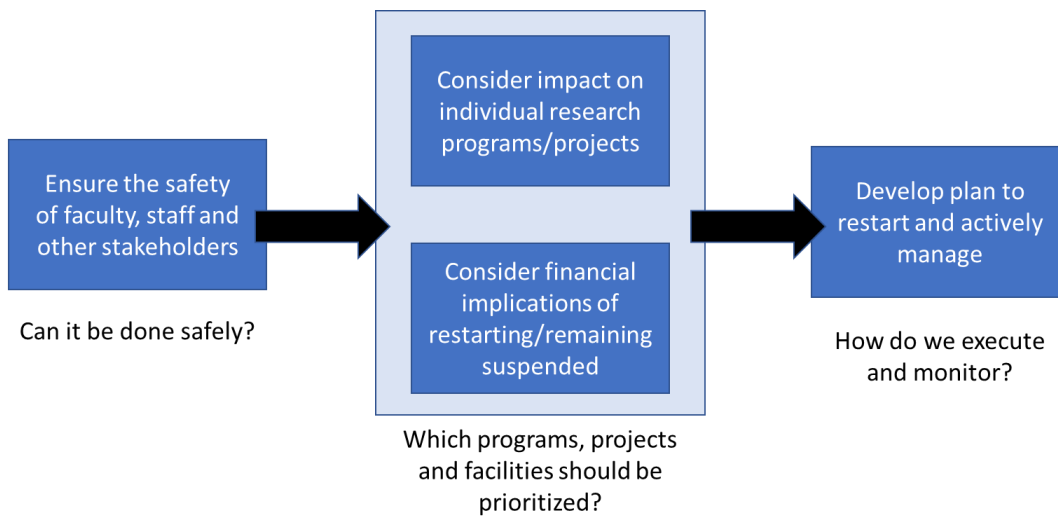
	Safety, security and well-being of researchers, staff, students and subjects (animal and human)
	Adherence to state and local government restrictions
	Slow and deliberate ramp-up
	Evidence- and metrics-based decision making

Our informal survey of more than 25 leading research institutions conducted between April 24 and May 5, 2020, revealed all had started developing plans. As the table below suggests, there was quite a bit of similarity among the institutions.

Key Considerations for Reentry		Key Features	 ← Most/All → Few
Reentry Planning	A plan for re-initiating research activities	<ul style="list-style-type: none"> Central coordinating committee Standard guidelines Distributed planning process 	
Safety Considerations	Availability of PPE	<ul style="list-style-type: none"> Ability to procure or develop Ability to disinfect Screening of employees daily 	
	Social distancing/density control	<ul style="list-style-type: none"> Shift work Social distance spacing in work areas Density control for common spaces (e.g., bathrooms, break rooms) 	
	Nonessential staff continue to work from home	<ul style="list-style-type: none"> Essential versus nonessential and at-risk staff designations used to stagger return to campus "Essential" refers to on-campus presence, rather than essential to research generally 	
	Research participant/subject screening	<ul style="list-style-type: none"> Develop methodology to screen and triage research participants and patients 	
	Testing	<ul style="list-style-type: none"> Screen employees (temperature checks) Some are evaluating developing their own testing 	

Key Considerations for Reentry		Key Features	
		<ul style="list-style-type: none"> Few are considering antibody testing 	
Research Considerations	Prioritization of research	<ul style="list-style-type: none"> Established tiers/levels to designate which research returns to campus first 	
	Participation in COVID-19 research	<ul style="list-style-type: none"> Seeking bench and clinical research focused on COVID-19 	
	Use of technology	<ul style="list-style-type: none"> Use of existing systems to track staff entry/exit Use of telehealth for research visits Use of eConsent 	
Financial Considerations	Financial impact on research	<ul style="list-style-type: none"> Seeking supplemental relief funding Less than 5% furloughed staff to date. Some are not ruling this out in the future 	

In addition, a review of the responses also revealed an overarching framework for how institutions were approaching the process for restarting their research programs: ensuring the safety of everyone, then weighing the relative cost/risk of restarting (or not restarting) certain research programs, and finally developing a plan specific to that program, facility or team. In the subsequent sections, we explore each of these elements and summarize the actions taken and plans developed among the institutions we surveyed.



Safety. First.

Not surprisingly, the cardinal planning principle we heard related to safety. Every leader we interviewed expressed understandable concern about the faculty, staff, research subjects and other stakeholders who would be impacted by a decision to restart a program or continue the suspension. At the time of our interviews, the information about how to safely get back to work — the need for and nature of testing, social distancing rules, facility sanitizing procedures and many other issues — was evolving. Therefore, while there was general consensus regarding the issues to be considered, there was some variability regarding how and the extent to which each should be addressed.

- **Following state guidelines:** Just under half (45%) of the institutions we spoke with cited a phased approach to reopening based on guidelines issued by their states. Some specific examples of publicly available information include:
 - [University of Washington](#)
 - [University of Michigan](#)
- **Screenings and testing:** All institutions are prioritizing methods to screen and triage patients and research participants before they return for in-person visits. Decision trees, checklists and apps have been developed to assist patients and research participants with evaluating their health prior to attending an in-person visit. Some institutions spoke about screening employees daily, via structured interviews and temperature checks, and potentially testing staff who are symptomatic. Some institutions are even considering developing their own testing.
 - The research community at an institution on the West Coast came together to launch an in-house COVID-19 testing lab on March 24. The lab is an example of the many collaborations that have been happening at that institution and in the healthcare community. In this case, members of the research community rallied to support the clinical community and testing in a drive to combat COVID-19.
- **Social distancing:** Reentry plans at all institutions involve a variety of tactics and methods that may become the new norm:
 - Reconfigure workspaces and common areas to allow for 6-foot distances. At the outset of COVID-19, one institution only allowed one person to occupy every other research bay, which was the equivalent of 15-foot spacing. As the number of cases in that state continue to decline, the institution will loosen restrictions and move to 6-foot spacing per commonly accepted COVID-19 standards.
 - Shift work to minimize the number of people in a building and a given space. Clinical research personnel are aligning their work schedules with clinical hours, while basic and bench researchers are working a second, and sometimes a third, shift.
 - Maintain working from home for employees who can do so, to reduce campus crowding. This may also mean that some employees will be on campus for a portion of the normal workweek, working remotely the rest of the week.
- **Personal protective equipment (PPE):** Masks and commonly accepted sanitary techniques such as frequent hand-washing and use of hand sanitizer were common themes for all institutions. Many spoke of not ramping up research programs until the supply chain for PPE is strong, and noted that research will adjust if the clinical side of the enterprise begins having trouble with PPE access. Some have a strong supply chain, and others started grassroots efforts early in the pandemic to make their own masks and face shields, or procure them from local sources. Some institutions even partnered with local distilleries to procure supplies of ethanol-based hand sanitizer. One institution in particular spoke about collaboration with their university engineering department to design and manufacture new dispensers using 3D printers, and to make their own disinfectant wipes.
- **Shared spaces:** Ongoing cleaning and sanitation of all workspaces and shared spaces, including bathrooms, conference rooms, break rooms and elevators, is a significant concern to all institutions. Due to a limited number of environmental services personnel, limiting access and limiting the number of buildings that can be reopened at any given time are strong considerations.
- **Incident management:** Institutions are charging their infection control and occupational health departments with managing contact tracing and reporting.

Several leading research institutions published online guides to assist their research communities with the ramp-up process. The following are several examples:

- [The University of Washington](#)
- [Duke University](#)
- [Yale University](#)
- [Emory University](#)
- [University of California, San Diego](#)

Impact on Research Programs

In addition to safety, institutions are also forced to consider how their decisions to restart or further the suspension of work will have both short- and longer-term impacts on a project or program. Key questions to consider include:

- Will further delay disrupt a project to the point where all or a part of the effort will need to be re-performed? What would be the impact if another shutdown becomes necessary?
- What is the risk that key personnel will leave the institution for other opportunities? Might heavily funded researchers be recruited to other institutions that have fewer restrictions?
- Will expensive supplies expire? Will additional animals need to be euthanized or re-derived?
- Are there externalities (e.g., supply chain issues) that might restrict the institution's ability to restart a project?
- What is the impact of COVID-19 on the conduct of research not performed in on-campus labs? Can researchers performing research off campus (fieldwork, international, etc.) still do so? Can social scientists still interact with people?

Financial Considerations

Given the nature of this crisis, discussing financial implications requires sensitivity. Understanding and considering the financial implications of various courses of action are critical to the long-term health of the institution. Most of the institutions surveyed as part of this effort acknowledged this was an important dimension for decision making and expressed some level of concern regarding the "cost" of COVID-19. The formal actions underway or planned were mixed.

- **Seeking COVID-19-specific research opportunities:** All institutions surveyed were seeking bench and clinical research opportunities focused on COVID-19. Principal investigators across these organizations are working alongside grants administration and clinical research administration offices to meet fast deadlines for COVID-19-specific federal research funding opportunities, and to expedite study startup processes in order to secure COVID-19-specific clinical trials or approvals for unapproved therapies to treat the disease caused by the novel coronavirus. To that end, local institutional review boards (IRBs) have processed approvals for emergency-use authorizations and emergency investigational new drug (eIND) approvals in record time — less than 48 hours in some instances.
- **Preparing for potential relief funding:** The federal government has put forth several stimulus relief acts from the CARES Act (Coronavirus Aid, Relief and Economic Security) to the HEROES Act (Health and Economic Recovery Omnibus Emergency Solutions). The most recent, the HEROES Act, passed by the House of Representatives on May 15, is a \$3 trillion follow-on relief package to the \$2.2 trillion CARES Act package signed into law in March. Some funding, albeit limited, has been earmarked to help mitigate the impact on research institutions, including:
 - National Science Foundation (NSF) research and related activities: \$125 million to prevent, prepare for and respond to the coronavirus
 - National Institutes of Health (NIH): \$4.74 billion to expand COVID-19-related research on the NIH's campus and at academic institutions across the country to support the shutdown and startup costs of biomedical research laboratories across the nation

Several additional steps are required before this bill gets signed into law.

Research grants and contracts offices at the institutions we spoke with are updating policies to manage stimulus grants as they get awarded, and are seeking guidance from their peers and external firms to ensure they manage and track spending of these funds in an appropriate manner.

Huron, along with several other firms and organizations across the research industry, has created guides to assist institutions with navigating the key federal initiatives, policies and funding opportunities available due to COVID-19. One such resource is [Huron's Stimulus Relief Gateway](#).

- **Furloughs:** Unfortunately, several institutions we met with had already furloughed segments of their workforce or were considering it as a necessary step to mitigate long-term financial damage.
- **Calls for Donations:** Some institutions have launched fundraising efforts tied to COVID-19 research as well as donations of face masks and other PPE. The following are some examples:
 - [Oregon Health Sciences University](#)

- [Johns Hopkins Medicine](#)
- [Fred Hutchinson Cancer Research Center](#)
- University of Pennsylvania:
 - [For face masks and other PPE](#)
 - [For coronavirus research](#)

Recommendations

Preparing a plan for reentry should not be a one-size-fits-all set of uniform rules. Rather, the planning process should be like assembling a puzzle where the overall plan for your institution is a series of individual pieces, each piece its own carefully considered plan. Since the uncertainty that has challenged institutions in the early phases of the pandemic is likely to linger in the near to intermediate term, plans will need to be flexible and take into consideration a range of potential scenarios. As you finalize and begin executing your plans, we recommend the following:

- 1. Build capability for managing ongoing change.**
 - a. Improve communications and response capabilities by investing in technologies that facilitate two-way communication (e.g., apps for self-reporting health screening and contact tracing).
 - b. Strengthen decision-making processes by refining committee structures, meeting frequency and reporting tools to allow for more nimble responses when needed.
- 2. Develop tools and guidelines to facilitate planning at the local level.**
 - a. Establish clear parameters for developing ramp-up/restart plans and tools to document and communicate those plans to leadership for approval.
 - b. Develop a process for ongoing monitoring and reporting related to each plan.
 - c. Consider approaches to rolling up plans to understand aggregate impacts.
- 3. Optimize research administration to accommodate a work-from-home model.**
 - a. Assess the impact of work-from-home limitations on compliance, quality and turnaround times. Identify gaps and opportunities for improvement.
 - i. Can processes and roles be modified?
 - ii. Can technology be better leveraged?
 - iii. Would outsourcing certain functions make sense and/or provide additional leverage?
 - b. Consider long-term options and benefits of working from home.
- 4. Evaluate the [financial health of your research programs](#).**
 - a. Estimate the impact of COVID-19 on your research programs, including actual losses, potential gaps in funding to continue existing projects, and future costs to address safety requirements.
 - b. Evaluate the potential impact of COVID-19 on other sources of financial support, including clinical revenues and philanthropy.
- 5. Measure gaps and develop plans to identify new funding sources or re-prioritize investment of more limited resources. **Document, document, document!****
 - a. As is true for any situation with government money, audits should be anticipated, even expected. The middle of a crisis may not be the most likely time to consider audits, but documenting now will most assuredly pay off down the road.
 - b. If necessary, have administrative personnel attend meetings to capture key considerations and the resulting decisions if questioned or challenged at a later date.
 - c. Plan internal audits (formal or informal) or monitoring activities in the near term to ensure that the documentation is complete while the information and decisions are fresh and recollections are easy.

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