Navigating Sponsored Research Impacts During COVID-19

Huron Perspective for the Stabilization Period

Huron's research enterprise solutions team remains committed to keeping you apprised of best practices, regulatory changes and other useful information as you manage your research programs while responding to COVID-19. The research industry is shifting toward the stabilization period of the pandemic. Stabilization is about creating a sustainable paradigm for the various administrative, regulatory, financial and scientific support activities necessary to maintain an institution's research mission — often while observing varying degrees of social distancing mandated by campus and local officials. Common elements of stabilization include guidelines for working from home, clinical trial participant screenings, updated schedules and protocols for social distancing among those employees who need to work on-site, provisions for managing or adapting paper-based processes, and enhanced communication pathways. Operations may be tested as infection rates vary locally and individual personnel may be unable to work due to personal or family illness. As the contours of the pandemic continue to evolve, the environment in which institutions operate is also likely to continue to change over coming months.

Federal sponsors of research are providing additional flexibility around funding and reporting, but institutions will need to remain focused on financial compliance, especially with respect to documentation and any funding specifically for pandemic-related efforts. Institutions should also begin evaluating and updating their financial models for the research enterprise to account for short- and longer-term effects of the crisis.

Impact Area	Issue/Considerations	Facts/Guidance to Consider	Huron Perspective
General Research	How should institutions stay apprised of changes to federal guidance related to SARS-CoV-2/COVID-19? How should institutions consider and prioritize SARS-CoV-2/COVID-19 research? How should institutions prepare for a possible "all hands on deck for COVID-19 patient care" need? What are the implications for research? For institutions not severely impacted by COVID-19 (e.g., pediatric institutions or institutions not in	Continue to reference the flexibilities authorized by the United States Office of Management and Budget (OMB) in response to COVD-19 in OMB Memorandum M-20-17, as well as guidance and clarification issued by other federal agencies such as the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Energy (DOE), NASA, the United States Army Medical Research Acquisition Activity (USAMRAA) and the Department of Defense (DOD). Huron is also monitoring these agencies and publishing highlights of those changes. The FDA Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency, released on March 18, 2020, and periodically updated, provides guidance specific to investigational drug and device research.	For those institutions that already have an established research feasibility review committee, Huron recommends establishing a SARS-CoV-2/COVID-19 ad hoc research review committee, comprising subject matter experts who can evaluate such research priorities on behalf of the institution. For those institutions that do not have an existing research feasibility review committee, Huron recommends establishing one. We have published a framework to assist institutions with thinking through this process. Please visit our COVID-19 resource page, and scroll down to the hyperlink titled "Considerations for Evaluating Participation in COVID-19 Human Subjects Research" within the Research Enterprise Impacts and Opportunities section of our resource page.

	COVID-19 hot spots, etc.), how can they begin to slowly ramp up research activities while still respecting social distancing guidelines, limited supplies and equipment, etc.?	As institutions shift research resources toward efforts that are directly related to COVID-19, even that limited subset of work still requires close monitoring. "Several countries are already recommending chemoprevention or treatments for which there is no convincing evidence of benefit and banning export of these medicines, thereby compromising the trials needed to establish the evidence. It is possible that none of the current therapeutic interventions being trialed or recommended will prove beneficial. Large, well conducted clinical trials are needed urgently to support guidelines on prevention and clinical management. These trials must not detract from already overstretched health services and, with travel bans in many places, they must be designed to accommodate remote initiation and monitoring."[1] Establishing daily communication between clinical operations teams and research operations teams is ever more critical. Many insights will be gleaned from sharing information across these groups to make informed staffing and other operational decisions. This is an excellent opportunity to bridge the traditional divide that exists in these areas and create an important partnership during such unprecedented times. Pausing nonessential research was a necessary first step for many in the early stages of this pandemic. As COVID-19 becomes the "new norm," thought should be given to reestablishing clinical research portfolios that were paused in the initial triage period of the pandemic. Research offers many advantages that should not be forgotten: innovative and lifesaving treatment options to patients that would otherwise not be available; diversification of service offerings and revenue streams; and regional, national and international recognition.	We recommend creating a SARS-CoV-2/COVID-19 taskforce/team with representatives from each research administration department (e.g., Office of Sponsored Projects, institutional review board (IRB), institutional animal care and use committee (IACUC), etc.) that is responsible for elements of compliance. These individuals would be responsible for staying current with regulatory changes related to SARS-CoV-2/COVID-19 and would inform updates to related institutional guidelines. Examples include: • The policy regarding cutoff dates of SARS-CoV-2/COVID-19-related travel bookings to be covered by institutional funds, if deemed unallowable by the sponsor. • Revised forms that require additional SARS-CoV-2/COVID-19-related supporting documentation. • IRB review of emergency use authorizations (EUA) and emergency investigational new drug (eIND) applications related to SARS-CoV-2/COVID-19 treatments. Updates to institutional guidance should be communicated via a COVID-19 comprehensive website or regular institutional/campuswide email updates. Consider hosting webinars or office hours to allow employees to ask questions. Consider establishing a daily management huddle between key clinical operations leaders and research operations leaders at a hospital. The purpose would be to discuss the daily hospital COVID-19 census, studies deemed essential and the number of patients on such studies, and how to share valuable clinical resources among these key priority areas.

[1] "Global Coalition to Accelerate COVID-19 Clinical Research in Resource-Limited Settings." The Lancet, April 25, 2020. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30798-4/fulltext

			The institutions that are not severely impacted by COVID-19 can consider ramping some clinical research studies back up, keeping in mind the need to offer treatment options to patients, but also the reality of scarce resources and social distancing precautions. To that end, the study feasibility review committee concept noted above can be extended to encompass review of existing research protocols to confirm alignment with institutional priorities and available supplies and equipment. Huron encourages such a review only after departmental/divisional review to confirm the benefit of the treatment or intervention to the specific patient population, against available conventional care options. Studies that were deemed "nonessential" due to being noninterventional studies could also ramp back up in a remote capacity and via telehealth visits with patients, as long as technology is not a limitation for research personnel or current and potential research participants.
Human Research Protections/ Institutional Review Boards (IRB)	Develop a strategy for opening and prioritizing SARS-CoV-2/COVID-19-related research studies. Identify a process for staying current with regulatory changes related to SARS-CoV-2/COVID-19, including changes in FDA emergency use authorizations (EUA) and emergency investigational new drug (eIND) guidance. Plan to address any backlog of submissions resulting from the SARS-CoV-2/COVID-19 pandemic. Develop plans and criteria to lift current restrictions or holds when activating new research projects or allowing previously approved projects to continue.	Prioritizing SARS-CoV-2/COVID-19 research studies and opening treatment protocols as quickly as possible is critical during the pandemic. The FDA continues to issue at least daily guidance, including expanded access uses of investigational articles. Institutions should have a process in place to review FDA guidance as it is released to determine applicability and the approach for implementing, where appropriate. Since research requiring in-person interaction without the prospect of direct benefit to research participants has generally been put on hold, and many other protocols are being modified, organizations need to consider the process of managing submission review backlogs for both the modifications and restarts. Organizations should consider if plans are necessary to lift restrictions or holds, as there may be additional regulatory criteria considerations (e.g., new information about a test article) that may impact reopening projects.	The FDA has been working closely with medical product developers to clarify regulatory and data requirements necessary to move products forward in development as quickly as possible. Organizations should respond quickly to provide treatment options to patients, including assessing guidance in real time and utilizing available resources, such as client alerts and the weekly Clinical Research Management Briefing issued by Huron. Other organizations are issuing similar supportive resources. Information contained in Huron's Human Research Protection Program (HRPP) toolkit supplement provides additional guidance institutions can use to help them continue to keep research moving forward in an environment where social distancing will be required for the foreseeable future. Institutions should consider the impacts of voluntary holds on certain research studies, and what the process will be to review these accumulating submissions once research can continue.

			Additionally, as financial and operational pressures mount, institutions may also consider the following: • Review research utilizing the least-restrictive review category. • Apply flexibility in the regulations where allowed. • Take advantage of burden-reducing aspects of the Revised Common Rule, including not requiring continuing review for minimal risk research.
Clinical Research Pre-Award	To what extent should institutions continue to process studies in their clinical trials pipeline, and how do they do so with the knowledge that resource constraints exist in some areas where there are inherent dependencies?	The prioritization of resources for clinical care needs and studies deemed as "essential" continues to be of paramount importance. Once these needs are prioritized, the available workforce should continue to process the clinical trial pipeline at a reasonable pace, with an understanding that regulatory personnel and IRB committees may not have the immediate bandwidth to process nonessential studies in the pipeline.	While continuing to develop coverage analyses, study budgets and contracts for clinical trials in the pipeline, this period of slower activity is an ideal time to cross-train these pre-award personnel to assist with study startup or study maintenance efforts related to regulatory affairs management (e.g., processing of essential regulatory documents, preparation of documents for submission to sponsors and IRBs, etc.). This approach would prove beneficial in terms of building a capable cross-functional workforce to assist with non-patient-facing responsibilities, to ensure the continuity of research.
Pre-Award Grants Management	Pre-award proposal and award management systems do not have an identifier to track COVID-19. As internal reporting to track COVID-19 research will be important and sponsors will expect that institutions are managing awards impacted by COVID-19 differently than those that are not, systematic, on-demand reporting will be key over the next two to five years. Sponsors issuing COVID-19 proposals are expecting quick turnaround times. As these proposals may have unique requirements and	While sponsors have allowed flexibility in managing awards, it will be critical that institutions track which awards are allowed this flexibility and which directly support COVID-19 research in order to ensure the institution is following the correct set of guidelines. Applicants and proposal stakeholders should remember that proposal development is collaborative and complex, especially during the time of COVID-19. Additionally, the proposal review and submission process will likely require additional time as staff are working remotely. Home internet speeds, email file storage capabilities or other institutionally acceptable file-sharing technologies, etc., may all impact the timeframe for receipt and review of proposal applications.	Create a COVID-19 identifier in the pre-award proposal and award management system to flag COVID-19-impacted proposals and specific COVID-19 proposals. Ensure this information is maintained and reviewed on a recurring basis (monthly at a minimum) to facilitate on-demand internal reporting and external communications to sponsors, including anticipated after-the-fact reporting from sponsors. This will enable the institution to manage workload and proposal complexity as COVID-19 proposals may have unique requirements that require more experienced personnel to handle. Consider the development of standard institutional memos for principal investigators (PIs) to include in their COVID-19-related grant proposals. This may include external documents, such as cover letters, that include

	exceptions that allow for one-time waivers, such as an indirect cost waiver, institutions should ensure proposals provide information in a consistent and agreed-upon manner. For active research that is continuing during this period, including proposed COVD-19 research, institutional leaders, deans, chairs, etc. should pay close attention to how the principal investigator's proposed scope of work will be achieved, and if it can be achieved given distancing.	With work-from-home requirements resulting in lab closures, etc., the ability to achieve research aims may be limited or halted entirely. Reducing costs where possible is more important now than ever. Evaluating research to ensure the proposed scope of work is achievable is a strong step toward stewardship of institutional and grantor resources.	specific language on the institution's ability to conduct COVID-19 research or required internal components such as indirect cost waivers. Consider shifting policies temporarily to allow more time for the central pre-award office to conduct a thorough review of the proposal, e.g., "OSP requires 5 business days to review proposals. However, for all proposals due between April thru May, OSP requires 7 business days." Institutional leaders should charge deans or department chairs with reviewing and directing research activities as follows: • In the near term, the scope of work of sponsored projects that have been (or may be) awarded should be reviewed against forthcoming university decisions about in-person, on-campus courses, formal summer programming and on-campus research activity. • PIs should review project plans for the feasibility of achieving their scope of work, assuming institutional policy will most likely require a shift to off-campus activities for a large portion of performance periods in 2020. • In cases where scope cannot be achieved as proposed, PIs should work with pre-award offices on whether to formally request approval for any of the following: scope adjustments, delayed project starts and extensions. Pre-award offices should track this information and communicate back to institutional leaders.
Post-Award Grants Management	How can the institution best monitor and track COVID-19-related charges?	Creating a COVID-19 general ledger (GL) expense account or expense tag may be difficult for some institutions. However, it may be possible to create child project accounts to capture COVID-19-associated costs for further review as guidance is updated by sponsor agencies.	Segregate COVID-19-related costs by creating new GL expense accounts for these costs to be charged to, or if available, utilizing financial system functionality to flag these costs. Doing so will make it easier to identify, review, report and clean up COVID-19 costs as

	How can the institution provide good customer service to PIs while dealing with challenges of remote work?	In cases where staff does not have access to technology needed for virtual meetings, at minimum, monthly phone calls with departments or PIs should be encouraged. Institutions should consider providing trainings for staff on how to utilize Zoom, Skype or other virtual meeting technologies to continue to keep lines and modes of communication open to PIs.	guidance evolves. Monitoring COVID-19 charges will allow the institution to gauge potential financial impact to the institution if deemed unallowable by the sponsor. Keep central administration engaged with departments and the research community via virtual meetings. Maintaining communication channels with PIs will be crucial in helping the institution identify research delays and their effect on funding, salary reallocations and other issues while also providing a forum for PIs to ask questions and receive guidance.
Clinical Research Post-Award	What can institutions do to take advantage of the new rules and waivers announced by the Centers for Medicare & Medicaid Services (CMS)? How can institutions adapt to shifts in the scope and conduct of research while still maintaining compliance and managing financial performance?	On March 30, CMS announced an array of new rules and waivers of federal requirements to allow hospitals and healthcare systems to effectively manage potential surges of COVID-19 cases. Key takeaways that can apply to clinical research from a post-award perspective, and which will last the length of the pandemic, include the following: • **Hospital Without Walls:** This program allows hospitals to transfer patients to outside facilities, such as ambulatory surgery centers, hotels and dormitories, while still receiving hospital payments under Medicare during COVID-19. For example, a hospital can use a hotel to take care of patients needing less intensive care while using its inpatient beds for COVID-19 patients. CMS clarified that providers will need to ensure this is in accordance with the state's pandemic plan. • **Patients Over Paperwork:** CMS is temporarily eliminating paperwork requirements to allow physicians to spend more time with their patients. Hospitals will not be required to have written policies on processes and visitation of patients who are in COVID-19 isolation. Medicare is also allowing payment coverage for respiratory devices and equipment for any medical reason determined by physicians. • **Telehealth Coverage Expansion:** CMS will now pay for more than 80 additional services when furnished via	Though CMS is offering regulatory and financial flexibilities, the longer-term impact of clinical research is difficult to anticipate from a financial and compliance perspective. Hospitals, healthcare systems and academic health centers with substantial clinical research activity will face financial uncertainty with reduced research patient billable services to payors and invoices to sponsors, as well as increased labor costs attributed to the study team's quarantine and illness. Those who do not have as much financial flexibility (through reserves and charitable donations) will likely need to examine and innovate their clinical research operations in order to remain viable. As institutions step into this stabilization period, clinical research offices and study teams should consider: • Developing cash flow projections related to essential clinical trials. Incorporate the reimbursement received by Medicare and most insurance payors for telemedicine visits that can be leveraged for research-related visits. • Identifying alternative locations for protocol-driven assessments, such as local labs or imaging centers, for visits where telemedicine is not an option. Ensure sponsors will accept this option and reimburse for those services that are invoiceable.

		telehealth, which includes emergency department visits and discharge visits. CMS is also now allowing for visits to be done via telephone only and will cover these types of visits as they typically would for an in-person visit.	• Amending research protocols or obtaining written waivers from sponsors to allow telemedicine and alternative location visits to be compliant to reduce the administrative burdens on researchers and their study teams. • Ensuring clinical research staff continue to keep track of research patient data in a compliant manner to prevent future issues, and ensuring claims related to COVID-19 clinical trials are flagged as high priority to receive quick reimbursements from Medicare and sponsors.
Animal Care and Use [Operations and Institutional Animal Care and Use Committee (IACUC)]	How will institutions prioritize allocation of limited resources as research resumes? What funding will be required for stabilization? To what extent will institutional animal care and use committee (IACUC) workload increase as research resumes? What steps can we take to anticipate appropriate staffing levels?	The Office of Laboratory Animal Welfare (OLAW) has published a set of FAQs that provide authoritative guidance for several of these key questions. The Guide for the Care and Use of Laboratory Animals (Guide) requires institutions to have “a disaster plan that takes into account both personnel and animals.” (OLAW COVID-19 FAQ VI.1) OLAW has noted that institutions may contact the NIH awarding institute for administrative supplements for unanticipated costs resulting from the COVID-19 crisis. (OLAW COVID-19 FAQ VI.6) The IACUC must adhere to the expectation for review of existing protocols and plan for modifications where necessary. (OLAW COVID-19 FAQs VI.6 and VI.14) IACUCs that received waivers to postpone semiannual facility inspections must conduct the inspections as soon as it is safe to do so. (OLAW COVID-19 FAQs VI.11) Additionally, AAALAC International is allowing flexibility in scheduling site visits for the remainder of 2020.	COVID-19 has immediately impacted animal research and will have longer-term impacts on resources as research resumes. Institutions should begin to plan now for the recovery period to identify necessary funding, ready specialized facilities, prioritize the future allocation of resources and resume research in a coordinated way. Institutions should develop stabilization road maps that consider the needs and timeline of individual teams and the capacity of the institution. Understanding the needs at a researcher level will allow labs to make important research decisions in the near term regarding pacing and prioritization, and to identify financial impact. Additionally, institutions should determine the capacity of facilities to resume to normal levels but should also evaluate whether facilities can and should be adapted to higher biosafety-level standards to allow for expanded COVID-19 and SARS-CoV-2 research. Institutions should consider creation of a scientific merit committee to guide allocation of new research, especially COVID-19 and SARS-CoV-2 research. The committee should be composed of a cross-sectional stakeholder team to inform operational needs and provide authoritative oversight, including representatives from research leadership, compliance and operations. The committee would ideally function as a subcommittee

			of the IACUC or in close conjunction with the IACUC to determine which studies should be prioritized for scientific merit. Processes should also be adapted to guide the administration of research while resources are not at full capacity. Facilities should move to more central allocation of resources, such as animal purchasing and personal protective equipment (PPE) distribution, if not already in place. Facilities should also establish review processes to ensure that breeding and space usage are aligned with institutional directions. These processes may need to have the collaboration of deans and department chairs to fully enforce. IACUCs should continue to monitor protocol expiration dates to ensure protocols for existing research projects do not lapse. IACUCs should also prepare for an increase in significant changes to current protocols, including changes in research plans and/or an increase in COVID-19 and SARS-CoV-2 research to be reviewed. IACUCs that postponed semiannual facility inspections should plan for resuming facility inspections and update inspection procedures if needed. Animal care and use programs scheduled for a summer or fall 2020 AAALAC site visit should also consider AAALAC International's flexibility when scheduling a site visit.
Institutional Biosafety Committee (IBC)	How should Institutional Biosafety Committees (IBCs) evaluate the potential risks and requirements of conducting COVID-19 research, including but not limited to clinical, animal, recombinant, synthetic nucleic acid research, etc.? How are IBCs coping with the flood of requests for new SARS CoV-2/COVID-19 projects?	Multiple agencies have published guidance on assessing the risks and managing safety/compliance for institutions considering SARS-CoV-2/COVID-19 research. The World Health Organization (WHO) has published this biosafety guidance, which provides a broad range of guidance on risk and safety. The Centers for Disease Control and Prevention (CDC) has also published this FAQ document on laboratory biosafety related to COVID-19.	Of all the research and healthcare communities impacted by COVID-19, the biosafety community is arguably the best suited to cope with this type of crisis. Risk assessments and guidelines for working with agents like SARS-CoV-2/COVID-19 are well documented and a required component of any institution with an IBC. Some institutions have had to convene more frequent meetings of their IBC to manage the flood of requests for new SARS CoV-2/COVID-19 projects.

	How are institutions coping with high demand and limited supply of personal protective equipment (PPE)?	While not COVID-19-specific, this document, published by the Association of Public Health Laboratories (APHL), focuses on risk management and includes several examples of biosafety risk assessments that are applicable to the current situation. The CDC has published information on strategies to optimize the use of PPE. In biosafety labs, N95 respirator masks in particular are in short supply. • The CDC has also published this guidance pertaining specifically to N95 masks. • Additionally, this article from the Journal of ABSA International includes detailed information on decontamination and reuse of N95 respirators.	Most of the work now being done on SARS-CoV-2 is being done in Biosafety Level 3 labs. For institutions with limited or no capacity at that level, the established risk assessments and requirements for facilities, PPE, decontamination equipment, and personnel should be assessed and weighed against short- and long-term needs and the institution's ability to mitigate risks and maintain standards.