Research Considerations and Huron's Perspective During COVID-19
The Triage Period

Huron's research enterprise solutions team remains committed to keeping you apprised of best practices, regulatory changes to federal guidelines, and other useful information as you work to manage your research programs while responding to COVID-19. To that end, we have prepared the following information. Many institutions are currently in the "triage" period of COVID-19 response. In this period all institutions are absorbing and reacting to a rapidly changing landscape to ensure the safety of their research participants (human and animal), faculty, and staff, and the integrity of what is deemed "essential" research. The framework below describes issues and considerations during this triage period as well as Huron's perspective. In the coming days and weeks, we will update and provide additional information as we all move toward stabilization and transformation after COVID-19. Given the variability of impact to date on the research community, some of the material below may already be covered in your institutional response or be inapplicable. Please use what you can and share with your colleagues anything they may find useful. And please, continue to share your experiences with us — we intend to gather your experiences and learnings to share best and useful practices as they develop. This community is innovative and will remain strong through this pandemic.

Impact Area	Issue/Considerations	Facts/Guidance to Consider	Huron Perspective
General Research	How do institutions decide what is essential versus nonessential clinical, animal and bench research? And who should ultimately decide? How do institutions enhance their current communications and governance/decision-making capabilities to adapt to the rapidly changing environment? How do institutions manage research staff deemed to be conducting nonessential research?	Federal agencies such as the Food and Drug Administration (FDA) and National Institutes of Health (NIH) have issued guidance to assist in ensuring the safety of trial participants, maintaining compliance with good clinical practice (GCP) guidelines, and minimizing risks to trial integrity during the COVID-19 pandemic: The FDA's Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic, released March 18, 2020, provides guidance specific to investigational drug and device research. The NIH's Guidance for NIH-Funded Clinical Trials and Human Subjects Studies Affected by COVID-19, released March 16, 2020, outlines the flexibilities available to recipients conducting NIH-funded clinical trials and human subjects studies.	We have seen variation regarding research and personnel that institutions deem "essential." Within the broad guidance published, there is no one size fits all. Huron recommends that you develop/review/refine your institutional practices, taking into consideration the health and safety of your patients, participants and personnel; your research mission; and your obligation to your community. Ensure that you have appropriate governance in place to promote timely, efficient and institutionally aligned decision making at a detailed level. In the clinical research realm, some institutions are pausing on noninterventional studies, such as tissue banking and correlative sample studies, that require close contact with research participants, and also interventional studies for which there are other standard-of-care (SOC) options for the research participants on those trials. But they are maintaining studies for which there are no SOC options available. Others are continuing all interventional studies and conducting SOC visits (where appropriate) via telehealth. Most changes to active research will require principal investigator (PI), sponsor and institutional review board (IRB) approval. Ensure that your study teams are working closely with all relevant parties. Institutions that are considering COVID-19-related bench, translational and/or clinical research should begin to think about a process to prioritize such studies, factoring in scarce clinical and research personnel, equipment, and other resources. Develop work-from-home (WFH) guidance for all researchers, factoring technology limitations, to keep administrative work up to date and to ensure continued compliance with sponsor, local and federal guidelines. Develop continuity plans for research administration, including the potential for staff absence and dealing with operations that cannot be conducted remotely. These might include managing paper processes where absolutely necessary, depositing checks, etc. Consider research resources that could be shifted to clinical needs, including allowing clinical research nurses to receive necessary

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			institutional training and signoff to be included in the nurse labor pool available to provide support during COVID-19. Develop business continuity plans to ensure "essential" research continues and regular operations can be reconstituted when the crisis subsides. Documentation of all such decisions is important.
Human Research Protections/ Institutional Review Boards (IRB)	How will investigators and IRB leadership determine whether study-specific COVID-19 risk mitigation plans are needed for human research and whether certain research studies should proceed or be temporarily placed on voluntary hold? Where study-specific COVID-19 risk mitigation plans are needed, what content should they include, and how should they be implemented? Are there special regulatory processes for investigational treatments for COVID-19?	The FDA's "Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic," released March 18, 2020, provides guidance specific to investigational drug and device research. **Emergency Investigational New Drug Applications:** On March 24, 2020, the FDA announced that it will facilitate access to COVID-19 convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of single patient emergency Investigational New Drug Applications (eINDs) for individual patients. The announcement can be found here: COVID-19 Emergency INDs for convalescent plasma	Huron has released a series of Human Research Protections Program (HRPP) toolkit supplement documents (typically available only to toolkit subscribers but being made available to all institutions) to provide HRPPs additional resources and tools to manage their research during the COVID-19 pandemic. These materials are aimed primarily at investigators/study teams. They are intended to provide guidance for determining whether study-specific COVID-19 risk mitigation plans are needed for certain studies and, if yes, to provide considerations for the kinds of modifications that may be needed and how the mitigation plans should be documented and communicated to the IRB and others. The HRPP toolkit supplemental documents include the following: ○ Flowchart: Study-Specific COVID-19 Risk Mitigation Planning ○ HRP-092 - SOP - COVID-19 Risk Mitigation Planning ○ COVID-19 Considerations for Investigators Conducting Human Research (can be used as "Appendix 12" to HRP-103 - INVESTIGATOR MANUAL) ○ HRP-350 - Worksheet - Research-Specific COVID-19 Risk Mitigation Plan ○ HRP-219 - Form - COVID-19 Modification
Clinical Research Pre-Award	Should institutions continue to process studies in their clinical trials pipeline?	Once clinical care and essential research studies are prioritized, assess your available workforce to process the clinical trial pipeline.	Continue to develop coverage analyses, study budgets and contracts for clinical trials in the pipeline, in anticipation of opening new studies post-COVID-19. Processing these studies while prioritizing COVID-19 needs will help ensure a strong portfolio of research options in the near future. Remember that certain study team members will not be considered "essential," are working from home, and are likely anxious about their jobs without enough work to perform. Maintaining pre-award activities helps mitigate this concern.

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Pre-Award Grants Management	If electronic signature technology is not currently in place to enable proposal and contract execution across the institution, how do institutions manage the triaging and receipt of all signatures while working remote? How are institutions managing shifting proposal deadlines? Some sponsors are changing deadlines, some are extending and some are canceling entirely. Do PIs and pre-award offices have the resources to track new funding announcements? It is likely that new grants will be part of the government stimulus package. Are there any special considerations to account for proposing research that requires engagement with foreign counterparts where COVID-19 has been prevalent? If a PI has an upcoming submission (e.g., over the next six months) for a travel or conference grant and the location is undetermined, how should the PI proceed while taking into account COVID-19? Specifically, as it relates to any travel arrangements and site selection.	Some proposals and contracts require multiple institutional signatures. As individuals do not have printers or scanners at home and FedEx, etc. are not options, technology that can interface with work or personal computers and phones is necessary. If an institution has a pre-award electronic management system, due dates on all pending proposals must be updated. If an institution is manually tracking this effort, the consolidation of information and dissemination to staff and PIs can be a challenge. Specific guidance regarding proposal deadlines and new COVID-19 proposal opportunities can be found here: COVID-19: Information for NIH Applicants and Recipients of NIH Funding NIH Provides Administrative Flexibility in COVID-19-Affected Projects NSF Coronavirus Information Website DOD — Frequently Asked Questions Consider how the research will be conducted and completed (e.g., labs, patient enrollment, surveys, etc.) and whether it is feasible given current global constraints. Sponsors will likely be issuing guidance over the course of the year but likely not in the immediate near term.	E-signature technology should be deployed to ensure continuity of proposal submissions, with supporting policy changes as necessary to allow for its use. Revise/enhance WFH research administration policies to support the preparation and submission of proposals and contracts in the future. A centralized, transparent means for tracking proposals in the pipeline (from ideation through submission) is necessary to ensure adequate support to PIs and the ability to quickly shift pre-award staff workload. This includes technology enablers (e.g., enterprise research applications) and personnel dedicated to monitoring proposal deadlines and updates, and who serve as a communication conduit between sponsors and PIs. As workload shifts, pre-award offices should consider dedicating a part-time resource to reviewing stimulus packages and federal/sponsor websites to identify funding opportunities. Using practices similar to determining “essential” research and managing overall risk, institutions should assess the benefits and risks related to foreign collaborations at this time with consideration given to the recent spate of enforcement activity related to foreign influence in research. Engage with sponsors to determine if an award requiring travel can be deferred or extended until travel is feasible or other measures are introduced.
Post-Award Grants Management	If research operations are delayed and additional costs are incurred, will institutions be able to recoup these costs? How should these costs be monitored, tracked and reported? What supporting documentation and communication will be needed to notify	The United States Office of Management and Budget (OMB) authorized flexibilities in response to COVD-19 in OMB Memorandum M-20-17. In addition, specific federal agencies such as NIH, the National Science Foundation (NSF), the Department of Energy (DOE), NASA, the United States Army Medical Research	Awarding agencies may allow recipients to continue to charge salaries and benefits to currently active federal awards consistent with the recipient organization's policy. Based on sponsoring agency policies, issue institutionwide guidance with specific examples of what are allowable salary and nonsalary costs incurred to provide internal staff additional guidance. Additionally, institutions should maintain appropriate records and cost documentation to substantiate costs related to project activities, as well as

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	sponsors regarding delays in research that may cause late financial and programmatic reporting? If research is delayed and cannot be completed within the awarded timeframe, will sponsors provide extensions, and what documentation is needed for approval?	Acquisition Activity (USAMRAA), and the Department of Defense (DOD) have also released their own clarifications and guidance. Per OMB M-20-17, awarding agencies may allow up to three months of financial, performance and other reporting deadline extensions, and one year of closeout reporting deadline extensions. Agencies may waive the requirement to provide prior notice of delays related to COVID-19 on a grant-by-grant basis. Per OMB M-20-17, awarding agencies may grant an automatic no-cost extension for a period of up to 12 months for awards that were active as of March 31, 2020, and with an end date prior to December 31, 2020.	travel/conference cancellation or other fees related to interruption of operations or services. Some awarding agencies have published reporting extensions related to COVID-19. In cases where guidelines are unavailable, institutions should promptly notify the award's program officer of expected reporting delays. Institutions should document the impacts of COVID-19, including details and timeline of disruptions to research operations, and references should be made to institutionwide policy or state/federal regulations where possible (as this may be requested by sponsors). Agencies may have published guidelines on award extensions related to COVID-19; institutions should refer to and check these websites for updates. Although OMB guidance allows for 12-month automatic extensions, institutions should note that agencies may adhere to their standard no-cost extension practice. For example, NSF's guidance, released March 23, 2020, in response to COVID-19, is to follow its standard policies related to no-cost extensions. Institutions should assess and triage which award extensions are due in the next four to six weeks, which awards may be ready for closeout, and which awards might need extensions.
Clinical Research Post-Award	What is the specific guidance provided by Centers for Medicare & Medicaid Services (CMS)? Will Medicare cover testing and treatment for its beneficiaries enrolled in COVID-19 clinical trials?	CMS announced it was approving Medicaid Section 1135 waivers to 13 states (and counting) in response to COVID-19. Examples of waivers under 1135 include temporarily suspending prior authorization requirements and extending existing authorizations for services. CMS issued a 10-page FAQ for healthcare providers regarding Medicare payment for laboratory tests and other services related to COVID-19. CMS clarifies topics such as the following: There is no special diagnosis-related group (DRG) for COVID-19, payment will be made for medically necessary extensions due to COVID-19, coverage will be allowed once a COVID-19 vaccine is available, etc. This fact sheet states Medicare Advantage is required to cover all Part A and B services related to COVID-19.	If a clinical trial or clinical research study has been placed on hold, communicate this decision to the project sponsor and document that communication in the study file. In circumstances where remote work to keep studies active and patients enrolled in a study results in additional administrative burden, submit an amendment to industry sponsors requesting reimbursement for the additional time and effort. Where possible, conduct study visits by telehealth in lieu of in-person visits. If the study visit is considered otherwise standard of care and thus a billable service, and is conducted via telehealth, Medicare considers the service to be the same as an in-person visit and is reimbursing at the same rate as regular, in-person visits starting March 6, 2020, and for the duration of COVID-19.

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		CMS issued two Healthcare Common Procedure Coding System (HCPCS) codes for certain COVID-19 laboratory tests in response to an urgent need to bill for these services. Both codes are effective Feb. 4, 2020, and will be available in the Medicare claims processing system April 1, 2020. Local Medicare Administrative Contractors (MACs) are responsible for developing the payment amount for claims they receive until Medicare has established national rates. Starting March 6, 2020, and for the duration of COVID-19, Medicare will provide payments for telehealth services. These visits are considered the same as in-person visits and are paid at the same rate as regular in-person visits. Specific guidance can be found here: Medicare and telehealth visits Congress passed a bill eliminating the need for Medicare beneficiaries to pay their Part B deductible or coinsurance associated with COVID-19 testing and treatments. The Internal Revenue Service (IRS) issued a notice related to high-deductible health insurance plans and expenses related to COVID-19.	For institutions participating in a COVID-19 clinical trial from a post-award/financial perspective: ○ Design the financial component of the informed consent form (ICF) to be specific to how Medicare and Medicaid are managing COVID-19. For instance, Medicare will waive Part B deductible and coinsurance associated with COVID-19 testing and treatments. This ICF amendment will likely require approval by the IRB. ○ If your institution is one of the 13 states approved by CMS, ensure the prior authorization team is aware that the Medicaid Section 1135 waiver temporarily suspends prior authorization requirements and other components to provide relief to Medicaid beneficiaries during this period. ○ Add HCPCS U0001 and U0002 and AMC CPT 87635 to the charge description master and physician order set to receive expedited payment processing by Medicare and Medicaid. These codes are effective Feb. 4, 2020, and will be available in the Medicare claims processing April 1, 2020. All Medicare rules and regulations still apply.
Institutional Animal Care and Use Committee (IACUC)	How do institutions maintain program compliance for animal care and use during COVID-19?	Many IACUCs are operating under long-standing guidance on how to conduct remote meetings. IACUCs are charged with performing semiannual facility inspections and program reviews; large portions of these activities are typically performed in person. The Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture (USDA) conducted a joint webinar, "Pandemic Contingency Planning and Its Impact on Animal Care," on March 19, 2020, to provide guidance on many topics, including facility inspection and program review. Both agencies indicated that additional guidance is forthcoming.	Institutions should determine how to perform a semiannual program review remotely via teleconference or videoconference. Program review could be conducted as a series of meetings to allow schedule flexibility for IACUC members and other program review participants who currently have other competing COVID-19-related priorities. Program review should include a detailed analysis of the institution's current disaster plan. Institutions should determine whether they can complete facility inspections on their current schedule or whether a waiver from OLAW is needed. For inspections that proceed, institutions should consider changing the inspection process to allow the inspectors to maintain physical distancing, for example: ○ For areas with non-USDA-regulated species, institutions may use one qualified individual to conduct an inspection.

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		OLAW released notice NOT-OD-20-088 to address IACUC flexibilities during COVID-19.	○ For areas with USDA-regulated species, institutions must involve two IACUC members in the inspection; however, members do not need to perform the inspection together in a side-by-side manner and could instead inspect different facilities or inspect the same facility at different times.
Animal Care and Use	What steps can institutions take to maintain the level of care for animal populations due to increased resource demands, while also protecting staff?	Careful planning will be essential for maintaining the necessary level of care for animals and for protecting the welfare of both staff and animals. As a primary step, many institutions have already designated animal care staff as essential personnel for on-site presence and are staggering or separating groups of staff to allow for social distancing. Actions for further protecting animal populations across institutions include population control and limiting nonessential research requests. Measures across institutions have been collectively escalating in just the past week and show the need for potentially significant impacts to research to protect both colonies and research. The following articles highlight the difference in response between March 18 and March 23, where institutions have increasingly transitioned from elective reductions in animal populations to more directed or even mandated reductions. The cases outlined in these articles are consistent with reports from many other institutions with which Huron has been in contact. *Science*, March 18, 2020 *Science*, March 23, 2020 Overall, these cases underscore the need for a defined escalation plan for animal operations planning in order to give researchers time to respond, to best enable care for animals and to consider the welfare of animal care staff in the upcoming weeks.	Institutions should develop defined, stage-based plans to address and further prepare for animal support needs during COVID-19. Plans should address management of staffing, animal populations and inventory: **Animal care staffing:** Stagger staffing support, emphasizing that investigators should provide trained staff for animal monitoring, escalating to reduction in services unrelated to direct care. Institutions should also consider measures to manage the human component to address an increasingly stressful environment, and to protect against work-related staff departures. Examples include encouraging staff to seek counseling support and employee assistance program (EAP) resources if responsible for mass euthanasia of animal species, cross-training in different services areas, and retention compensation packages for staff who commit to providing support throughout the disruption. **Colony population management:** Plan to limit new studies, breeding and elective reductions of nonessential animals, escalating to requirements for population reduction for non-genetically-significant animals. **Personal protective equipment (PPE) and supplies:** Increase PPE for employees around potentially COVID-19-susceptible animal populations and inventory management of animal supplies and staff PPE, escalating security measures to prevent loss of PPE.