Considerations for Evaluating Participation in COVID-19 Human Subjects Research

Establishing a COVID-19 Research Review Committee

April 3, 2020

With the COVID-19 global pandemic underway, many institutions have begun conducting human subjects research related to SARS-CoV-2/COVID-19, and many will be contemplating doing so soon. This document has been created to assist institutions with strategically evaluating engagement in research specific to SARS-CoV-2/COVID-19; to ensure alignment with organizational priorities; and to ensure that finite personnel, equipment and supplies are reasonably allocated.

The Huron Point of View

Huron typically encourages the establishment of a structured research feasibility review process within any enterprise engaged in human subjects research. Such processes provide structure within which individual research efforts can be aligned with an organization's mission, vision and available resources, and wherein resources are prioritized. Research related to SARS-CoV-2/COVID-19 is no exception. During a global pandemic when resources are highly constrained, a systematic review of such research is ever more critical. Types of research to be included would be research on the SARS-CoV-2/COVID-19 patient population, or a SARS-CoV-2- and COVID-19-related hypothesis, including but not limited to:

Interventional	Noninterventional/Observational
Drug	Data use/registry
Device	Retrospective chart review
Diagnostic/procedural	Lifestyle management or quality of life
Specimen collection and/or banking	

For organizations *with an existing research feasibility review process*:

- Consider supplementing an existing committee with subject matter experts who can evaluate SARS-CoV-2/COVID-19 research priorities, or consider establishing an ad hoc committee to specifically evaluate COVID-19 research.

For organizations *without an existing feasibility review process*:

- Consider establishing a feasibility review committee.

The following outlines key considerations when establishing a SARS-CoV-2- and COVID-19-specific research review committee:

COVID-19 Research Feasibility Review Committee Representation	• Clinical leaders from emergency medicine, pulmonary medicine and infectious diseases should be included to assist with evaluating scientific merit and alignment with organizational priorities and capabilities. • Infection control and risk management representatives can be included to evaluate the overall impact to the institution.

Research Prioritization	• Organizational prioritization will vary, but the following topics should be considered:
	  ○ Alignment with national and global priorities for combating the COVID-19 outbreak
	  ○ Alignment with organizational strategy and mission
	  ○ Scientific impact
	  ○ Availability of resources (staff, facilities, equipment, supplies), particularly if reallocation is required for clinical care purposes
	  ○ Ability to recruit study participants
	  ○ Level of risk

Scientific Merit	• Consider the degree of alignment with the World Health Organization's 2019 novel coronavirus blueprint. • Evaluate ongoing research that may compete with or be complementary to the proposed research. • Assess investigator experience in the field of study. • Evaluate the robustness of the proposal/protocol with respect to the objectives, safety and efficacy endpoints, etc.
Resources and Facilities	• Review proposed measures for minimizing risk to the research team and existing risk to the clinical care team. • Review methodology for ensuring COVID-19-specific personal protective equipment (PPE) is available for staff involved in research, or that any research-specific tests/procedures can be handled by clinical personnel already interacting with study participants. • Assess the methodology for handling, storing and shipping research specimens. • Ensure processes for disinfecting workspaces and equipment.
Participant Recruitment	• Confirm the ability to screen, recruit and consent patients that are infected. ○ Assess proposed recruitment strategy and safety measures. • If necessary, consider the ability to recruit to healthy volunteers.
Risk Management	• Calculate the risk of exposure for research staff, investigators, clinical care staff, and healthy or recovering volunteers. ○ Consider the involvement of ancillary departments (e.g., pathology, laboratory medicine, radiology, etc.) in measuring the risk of exposure. • Ensure appropriate processes for managing exposure.