RESEARCH NEWS
Washington University in St. Louis

Clinical Studies of Coronavirus: Recommendations and Review Process

The School of Medicine commends its investigator community in continuing to develop high-quality proposals for clinical studies aimed at finding and testing solutions to the COVID-19 pandemic. This intense focus of Washington University investigators bodes well for our ability to discover effective treatments, but also offers challenges that demand increased coordination of our efforts.

In particular, the COVID-19 pandemic has caused major changes to the conduct of patient care and research at Washington University (WashU) and the Barnes-Jewish Corporation (BJC) hospitals. In this environment, we must ensure that key resources, including COVID-19 patients, biospecimens, personal protective equipment (PPE), and research staff, are expended only on studies with the highest projected clinical impact, clear real-world feasibility, and maximum respect for on-the-ground clinical providers. Study design and conduct must comply with WashU/BJC policies on COVID-19 infection prevention, and should reflect federal, state, local, and University recommendations on avoiding unnecessary in-person contact. Demands on participants and providers must be commensurate with projected study benefits.

Investigators are strongly encouraged to carefully consider the above issues in designing their study protocols. In addition, institutional leadership has invested ICTS COVID-19 Research Governance with the additional responsibility and authority to determine which COVID-19 studies may go forward, and which merit prioritized support. These determinations will be made after a detailed review of each study that incorporates scientific, feasibility, policy compliance, and resource use considerations.

Studies should first be submitted to the ICTS for review - please visit icts.wustl.edu for information, and to access the study submission portal. Because the availability of staffing and other resources is likely to be constrained during the pandemic, studies that lack adequate extramural funding support will require a letter from the applicable Department Chair that attests to his/her commitment to devoting the needed resources to enable the conduct of the study. We encourage investigators to respond rapidly to ICTS requests for further information, or to respond to reviewer questions/concerns. Ideally, this will occur prior to IRB submission. Investigators may choose to submit concurrently to the ICTS and to the IRB, but prospective interventional clinical studies above minimal risk will require an approval letter from the ICTS COVID Clinical Studies Committee before they will be advanced to full board IRB review.

We appreciate that this policy reflects a departure from the University's customary practices, but we hope you will appreciate its rationale in light of the ongoing evolution of our research environment.

Sincerely,

Jennifer Lodge, PhD
Vice Chancellor for Research

William Powderly, MD
Director, Institute for Clinical and Translational Sciences

Amanda Cashen, MD
Executive Chair, Institutional Review Board